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Patents vs Public Health: The Case of Pharma Companies

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ABSTRACT
How do copyright laws and digital media patents intersect and interact in the protection of intellectual property in the modern age, and what are the implications for innovators, and consumers?
Keywords: *Patent, Roche vs. Cipla, Bayer Corporation vs. Natco Pharma, Moderna vs. Pfizer Biontech*

I. INTRODUCTION

This research paper will explore the meanings and details of terms like copyrights, patents, laws created based on them and dive into further detail based on the same topics. These components will be discussed based on detailed and varying patent-infringement and copyright-infringement cases typically in the field of pharmaceutical companies.

ADDRESSING THE KEY TERMS

How do copyright laws and digital media patents intersect and interact in the protection of intellectual property in the modern age, and what are the implications for innovators, and consumers?

Copyright- In simple terms, a copyright is the right to copy that protects originally created works. It ensures that the original creators of any work, along with others, those who are given the license to, are permitted to reproduce it.

Copyright laws- A copyright law is a legal charter that protects the legal owner of an intellectual property, i.e., authors, artists, and publishers. It is a legal means for people to protect their work in areas such as film, literature, music, and theatre.

Patent- A patent is a right allocated for an invention, design, or idea. It prevents others from copying and using the invention without the permission of the patent holder.

Digital Media Patents- This refers to a patent granted for an invention in the domain of digital media and technology such as applications, programmes, computer software, hardware, video games and other components of digital media.

Protection of Intellectual Property- This refers to the protection of intellectual works, which are created and produced solely with the imagination and creativity of an individual such as literature, art, theatre, and inventions. This property is protected by a law (copyright law, patent law, trademark law, etc), to maintain the originality of the work and give the owner complete rights for the usage, sharing, and modification of an intellectual property.

Modern Age- The digital age simply refers to the epoch where technology and digital products have formed an important and integral part of the human race's everyday life.

II. IMPLICATIONS

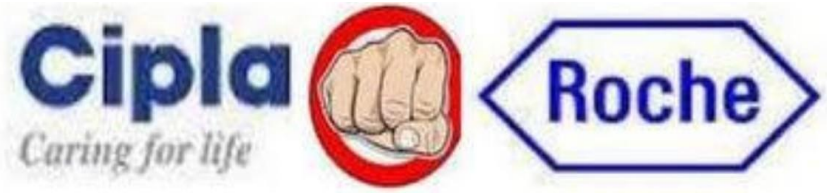
This refers to the crucial role all these components play in the life of different people.

Innovators-For innovators, knowing that their innovations will be protected through licenses and other laws, they will begin to increase the investment in the development and formation of modern technologies and other digital media inventions.

Consumers- For consumers, the protection of property, products and inventions in today's day and age is the most beneficial. The copyrighting and patenting, etc of such things can lead to mass development of technologies and products that benefit not only consumers directly, but society. But at the same time, this can also limit the availability of technology and creative works present for the public.

III. ROCHE VS CIPLA

In February 2007, Rocha, and Pfitzer had claimed that they had been granted a patent for a medical drug 'erlotinib. At the time, this drug was being marketed in India under the brand name of TARCEVA. In December 2007 and until January 2008, news about Cipla's plan to launch a generic version of erlotinib was being reported in Indian newspapers. This caused Roche to commence patent infringement proceedings.



IV. CIPLA'S DEFENCE AND COUNTER CLAIM

Since December 2007, Cipla had already been selling its drug, which was under the brand name ERLOCIP.
Since erlotinib was acquired from Quinazoline and a derivative of it, Roche's patent was invalid.
In the way that Roche's invention was published in the complete specification and claims did not entail any inventive step.
The complete specification was not sufficient in terms of describing the invention or how it was to be performed(method).
There was a significant difference in the cost of Roche ($100) and Cipla's ($33) drugs which should have been considered.
Cipla also argued that because the drug was a lifesaving drug, the principal factor of public interest issue should also be considered account.

ROCHE'S SUBMISSION

Erlotinib was not a salt, ester, polymorph, mixture of isomers of any particular 'known substance. Hence Section 3(d) of the PATENTS ACT was NOT applicable since it prohibits derivatives only of a 'known substance'.
Erlotinib's properties differed from those of Astra Zeneca's Gefatinib (prior art citation). Hence it was an entirely different compound. It is important to consider the question of 'accessibility' to, and usage of, the invention in the territory when establishing where the balance of convenience falls. However, it is not necessary that the drug be produced in India.
After considering both ROCHE's and CIPLA's cases, the Single Ruling announced by the judge was:

PUBLIC INTEREST

Cipla was manufacturing and marketing its generic drug version of erlotinib which was available at around 1/3rd the price of Roches drug, Tarceva. Tarceva was imported, and in fact not manufactured in India. The need for secure long-term supplies, along with the right to access of life-saving drugs was a significant issue in India. In such a situation, the potential injury caused to the public if the generic version of the drug was available is a remarkably critical point favouring a refusal to grant an injunction.

VALIDITY OF THE PATENT

The doubts that Cipla raised about the validity of the patent were dismissed by the judge, stating that the Patent Office had appropriately addressed them during the opposition phase. Overall, the judge believed that a persuasive case had been established by Roche in support of its patent infringement claim but the lower pricing and 'public interest' of Cipla's drug tilted the balance in favour of Cipla. Roche was not satisfied with the single ruling; hence an appeal was filed by Roche against the order of the single judge. He argued that it failed to protect the rights of the patentee, which proved contrary to future research in the field of pharmaceuticals.

OBSERVATION OF THE BENCH FOR THE RULING

Non-infringement- The bench believed that the patent that was in question for them was related to a mixture of polymorphs A and B, whereas Roche's Tarceva drug consisted only the B polymorph, a patent for which had not yet been granted. Roche was

criticized for not disclosing this fact, during the proceedings in front of the single judge as well as during the time of examination. The bench paid attention to the fact that the B polymorph of erlotinib hydrochloride' was not considered by the single judge because it was solely the subject of a later patent application. Roche was condemned for failing to provide a sufficient and fair description of its invented drug and not earlier filing an X-ray diffraction data for Tarceva and Erlocip (erlotinib) that would have proved useful in showing whether the crystalline structure of Cipla's Erlocip tablets correlated to Roche's patented version. Roche's appeal was dismissed by the court and the original order of the single judge was upheld. Apart from the fact that Cipla had put forward a credible and fair challenge to the validity of the patent, the judgement was based majorly on the fact that it did not fully elaborate the public interest point relating to the pricing of the drugs. Finally, in September 2012, Cipla Ltd. won a landmark patent case against Roche Ltd after it has been proved that it did not infringe any patent in India. This was because it had been scientifically proven that Cipla's version of the drug was a variant of polymorph B of Roche's patented drug instead.

HYPOTHESIS

The judgement of the court in this patent case was extremely fair and on-point. Because it had been scientifically proven that Cipla's version of the drug was a completely different version(variant) of Roche's originally acclaimed drug, this information could not be dismissed and Cipla therefore, had a fair claim to openly market and promote the sale of its drug. Another important piece of information that cannot be ignored while examining Cipla's win is that Roche failed to provide an exact description of its drug which caused their appeal to be dismissed by the court. This was also a major component in the non-success of Roche's patent case.

BAYER CORPORATION VS NATCO PHARMA

THE BAYER CORPORATION

The Bayer Corporation is a subdivision of Bayer AG which is a German multinational pharmaceutical company. In 1990, they invented 'SORAFENIB', a drug which was used in the treatment of liver and kidney cancer at an advanced stage. A few years later in 1999, a patent application was filed by them for sorafenib in the US.

NATCO PHARMA LTD.

Natco Pharma Ltd. is a major drug manufacturer in India. It is a generic pharmaceutical establishment based in Hyderabad. Natco Pharma filed an application for a to get a license to create a drug, one that would be a generic version of the drug 'NEXAVAR.' This application was filed under section 84 of the Patent (Amendment) Act of 2005.

COMMENCEMENT OF THE PATENT CASE

The Bayer Corporation patented their drug sorafenib in the US and later also filed a patent application for the drug in India in 2000. In 2005, sorafenib was launched in India by Bayer under the trade name 'NEXAVAR'. The sale and import of nexavar in India started after The Bayer Corporation were granted the patent in March 2008.

The drug was found to be being sold at an eminently high price and was overpriced for 2.85 lakh rupees for a month time. Considering this the Bayer Corporation was approached by Natco to be given a license for the production and sale of nexavar at

a much lower price (8800 rupees a month).

CIPLA'S ENTRY INTO THE SITUATION

While this request for a license had been declined by The Bayer Corporation, Cipla (the pharmaceutical company that has already been discussed in earlier parts of the research paper) had already formulated a generic version of the drug and began its sale without a license.

NATCO SUCCESSFUL IN RECIEVING COMPULSORY LICENSE

Seeing this situation, Natco Pharma approached the Control of Patents to obtain a legal compulsory license for its drug, nexavar. The Bayer Corporation then, in return stated that developing a drug like nexavar would require investing time, money and efforts into development and research for the creation and production of the drug. They appealed the Bombay High Court with this disputation and believed that they must be given the complete rights to exercise their monopoly. Also, they put forward the fact that Cipla had made the same drug available in the Indian market, that too at an affordable price (5400 rupees per month), hence granting a compulsory license to Natco Pharma was highly unnecessary.

ADDITIONAL HIGHLIGHTS

After all these raised objections, the first ever company to be granted a compulsory license in India was Natco Pharma in March 2012. The 3 primary reasons for this were:

The Bayer Corporation was not being able to produce enough of the drug in terms of quantity and as a result only 2% of all patients were being sold the drug.

The drug was not affordable by the public in India because it was sold a rate which was too expensive.

The drug manufactured by The Bayer Corporation was solely imported into India, and not manufactured in the territory of the country. This was a feature that stopped them being granted a compulsory license in the Patent Act 1970.

Due to the last reason, India amended its section 83 a and b to state that "the patentee shall be working in India and the patent cannot be granted for merely importing the product."

FINAL VERDICT

It was in favour of Natco Pharma and needed the following conditions to be fulfilled:

The drug, nexavar was to be produced and sold at 8800 rupees per month.

Natco Pharma had to pay a royalty of 7% on The Bayer Corporation's total shares.

The drug was meant to be sole solely for the treatment of kidney and liver cancer.

The license for nexavar was non-transferable and the right to sublicense the drug only belonged to the government.

The drug could not be imported by Natco Pharma.

It was compulsory for Natco Pharma to supply the drug to at least 600 patients annually, which is what they had committed earlier.

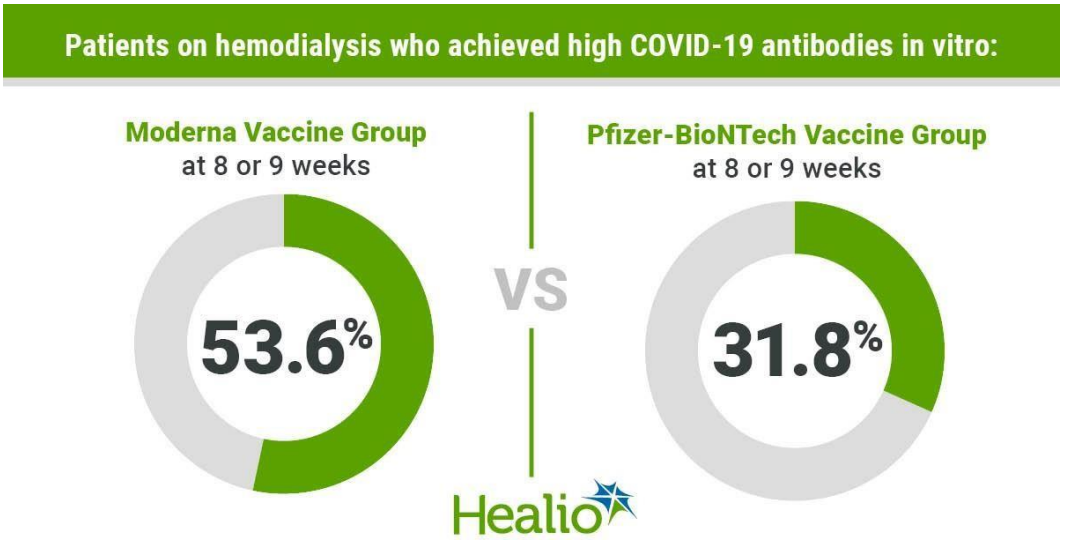
HYPOTHESIS

I believe this case could have been concluded differently. The unoriginal drug was being marketed cheaply and was more easily available and accessible to the common public. Overall, this resulted in the benefit of the people of the country. This drug helped people suffering from an ailment for which the medication was developed originally by the Bayer Corporation and at a much higher price. Hence, while the patent had been infringed, it conclusively resulted in the public's welfare. This case could have gone differently, in the aspect that the terms of the verdict could have given permission for the drug to be imported by Natco Pharma since the priority while marketing a drug or medicine should be the well-being of the people.

MODERNA VS PFIZER BIONTECH

Moderna filed 2 patent infringement cases against Pfizer BioNTech claiming that they infringed on its patents in developing the Covid-19 vaccine which was disbursed to hundreds of thousands of people during the pandemic. Moderna filed these lawsuits in the US district court of Massachusetts as well as in the regional court in Germany. Along with this Moderna has accused the pharmaceutical company Pfizer BioNTech (Germany based) for violating their rights of intellectual property on key elements of its MRNA technology in developing the Covid-19 vaccine. Moderna claimed that they had patents for the MRNA technology possible for the creation of their vaccine from 2010 to 1016. Moderna stated that the companies, Pfizer BioNTech had copied this MRNA technology without their permission. This technology differs from the general pattern of giving vaccination shots. Most vaccines contain dead of weakened forms of viruses which are then injected into our body for the purpose of the immune system being able to recognise it and creating antibodies against it. But in the MRNA technology, only the pathogens genetic code is used, and the vaccines are produces very quickly. In a statement Moderna stated, 'Moderna expected companies such as Pfizer BioNTech to respect its intellectual property rights and would consider a commercially reasonable license should they

request one for other markets, but Pfizer BioNTech have failed to do so.' Whereas Pfizer and Biotech mentioned that MRNA technology had been discovered by scientists and was even used in the production of vaccines as early as in 1990. They also declared Moderna's patents invalid, as they were based on separate patent applications, that too from as early as the year 2004. Moderna had pledged, In October 2020, to not enforce any of its patents relating to Covid-19 while the pandemic continued. Hence Moderna lost this patent case and Pfizer BioNTech vaccine was authorised for use. Their vaccine also proved to have a 95% success rate against the Covid-19 virus. Afterwards, less than 2 years later, such that patents can be worth even millions and billions of dollars, such lawsuits were not remained unheard of in the pharmaceutical industry.



HYPOTHESIS

In my opinion, the sale of both Moderna's and Pfizer BioNTech's vaccines should have been licensed, since during the Covid-19 epoch, the issue of the availability of vaccines was a major one. The ruling of the patent infringement case was as clear-cut and contained all that was imperative for this case. In conclusion, Pfizer BioNTech's vaccines turned out to be more effective than Moderna's for treating people suffering from COVID-19 while the pandemic flourished. This could not have been possible if Pfizer BioNTech was not granted authorisation to market their vaccines.

V. CONCLUSION

The purpose of this research paper was to identify the distinct kinds of cases of patent-infringement and copyright-infringement that occur in the pharmaceutical companies, including both national and international scenarios.

Based on the cases contained in this research paper, it can be concluded that patent and copyrights play a fundamental part in the pharmaceutical industry in the invention of new drugs and the sale of previously made drugs in a different area. Patents and copyrights and their respective laws paved way for major changes in the way people originality was treated.

In conclusion, I would like to share my opinion on all these cases and their verdict.

ROCHE VS CIPLA

The judgement of the court in this patent case was extremely fair and on-point. Because it had been scientifically proven that Cipla's version of the drug was a completely different version(variant) of Roche's originally acclaimed drug, this information could not be dismissed and Cipla therefore, had a fair claim to openly market and promote the sale of its drug. Another important piece of information that cannot be ignored while examining Cipla's win is that Roche failed to provide an exact description of its drug which caused their appeal to be dismissed by the court. This was also a major component in the non-success of Roche's patent case.

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