F. HOFFMANN-LA ROCHE LTD. AND ANR. V. CIPLA LIMITED

[RFA(OS) 92/2012 AND RFA(OS) 103/2012]

COURT: Delhi High Court

DECIDED ON: 27th November, 2015

BENCH: Justice Pradeep Nandrajog & Justice Mukta Gupta

INTRODUCTION

A Patent is a statutory right granted by the Government to the patentee for an invention for a limited period, in exchange of full disclosure of their invention and for excluding others from making, using, selling, and/or importing the patented product or the process for producing that product without their consent. The most important thing relating to a patent is the fact that the information about the product or the process must not be in public knowledge. The main objective of introducing the concept of patent was to promote scientific invention and ensure that the inventor gains monetary benefits.

Throughout the years our nation has seen many patent disputes between foreign multinational pharmaceutical companies and Indian generic drug companies. Regardless, the suit between Roche and Cipla has surely set the principles with respect to any patent infringement suit.

The landmark case took place between Roche, a Swiss Multinational Health-Care Company having its operations throughout the world & another Pfizer incorporated in the U.S. on one hand and Cipla, an Indian Multinational Pharmaceutical and Biotechnology Company on the other. The second plaintiff, along with M/s. Pfizer Products, Inc. as joint applicants, had been granted a certificate bearing Patent No.196774 by the Controller General of Patents, Trademarks and Designs, New Delhi on 23rd February, 2007 for a small drug molecule medically termed as a "Human Epidermal Growth Factor Type-1/Epidermal Growth Factor Receptor" (HER/EGFR) inhibitor, commonly known as Erlotinib. The said drug was claimed to be a breakthrough for the treatment of cancer. The drug was in a tablet form and was sold under the trademark name 'Tarceva'. The said drug was approved as US6900221 by the U.S Food & Drug Administration in the year 2004 and thereafter by the European Union in the year

2005. On record as per the Amendments of 2005 in the Patents Act, 1970, Erlotinib stood patented. The patented item, which Roche introduced into the Indian market in 2006, was advertised under the brand name 'TARCEVA'. Meanwhile, Cipla Limited, second biggest pharmaceutical company in India was reported in an English daily "Mint" dated 11.1.2008 to launch a generic version of Erlotinib in India and that it plans to export it to various countries as well. It is also claimed that Cipla have been marketing and selling the product since December, 2007 under the brand "Erlocip".

The plaintiff alleged that the drug Erlotinib had been developed after long years of research and that enormous expenditure had been incurred. The innovation was duly protected by law and hence Cipla had no right to opt to manufacture, sell or offer to sell any version of the drug Tarceva (Erlotinib) and that such action of the defendant, as announced and acted upon by it, would be in blatant violation of the legal rights of the plaintiffs.

FACTS

The dispute that emerged between the parties are based on the compound which is commonly known as "Erlotinib Hydrochloride". In February 2007, Roche after claiming that it had been awarded a patent for 'Erlotinib' began selling the drug under the brand name TARCEVA. In January 2008, it was reported that Cipla is intending to dispatch a generic version of 'Erlotinib'. This made Roche initiate infringement proceedings against Cipla. Roche asserted that Cipla had encroached its Patent No. 196774 otherwise called 'Erlotinib Hydrochloride' which is certified to Roche.

Roche's plea for grant of ad-interim injunction was rejected[1] by Single Bench, Delhi High Court as it felt that halting Cipla's production would be against public interest and inferred that the balance of convenience lies in favour of Cipla. On appeal[2], the Bench upheld the decision but centered more on the failure of Roche to build up a prima facie case of infringement.

The SLP[3] filed by Roche against the decision was also dismissed.

[1] F. Hoffman-La Roche Ltd & OSI Pharmaceuticals, Inc. v. Cipla Ltd., I.A 642/2008 in CS (OS) 89/2008, (Delhi High Court, 2008) (S. Ravindra Bhat, J.)
[2] F. Hoffman-La Roche Ltd & OSI Pharmaceuticals, Inc. v. Cipla Ltd., FAO (OS) 188/2008, (Delhi High Court, 2009) (Dr. S. Muralidhar, J.)
[3] F. Hoffman-La Roche Ltd & OSI Pharmaceuticals, Inc. v. Cipla Ltd., SLP (Civil) No. 20111/2009, (Supreme Court of India, 2009) (Dalveer Bhandari, J. and Dr. Mukundakam Sharma, J.)

Then, the parties returned to the trial before Single Judge, Delhi High Court, where the Judge delivered the final decision[4] that Roche could not adequately prove that Cipla's manufacture of Erlocip infringed its Patent No. 196774. On appeal[5], the Division Bench decided in the favour of Roche.

Roche from the earliest starting point of the suit claimed that Erlocip is Erlotinib Hydrochloride and claimed that manufacture of Polymorph B of the compound Erlotinib Hydrochloride was sufficient to trigger infringement of Patent No. 196774. On this, the Judge stated that- "*Any process engaged with making Polymorph B of Erlotinib Hydrochloride would include the preparation of Erlotinib Hydrochloride itself; actually, scrutiny of US6900221 uncovers that it is clearly expressed that Erlotinib Hydrochloride in Polymorph B structure results from re-crystallization of Erlotinib Hydrochloride utilizing various solvents and temperature conditions."* Thus if the suit were found to reveal Erlotinib Hydrochloride, any polymorphic form of the same would encroach the suit patent as Erlotinib Hydrochloride itself would be underlying every such polymorphic version. *"This compound may exist in several polymorphic forms, but any and all such forms will be subsumed within this patent. Therefore, as Cipla's Erlocip is admittedly one particular polymorphic form of the Erlotinib Hydrochloride compound (Polymorph B), it will clearly infringe the IN `774 patent."* Therefore, with this argument, the case went in favour of Roche.[6]

ISSUES

1) Whether Roche's compound patent, i.e. Patent No. 196774, is valid?
2) Whether Cipla's product, Erlocip which is Polymorph B of the compound Erlotinib, infringes Roche's patent for the compound Erlotinib?

[4] F. Hoffman-La Roche Ltd & OSI Pharmaceuticals, Inc. v. Cipla Ltd., CS (OS) No.89/2008 and C.C. 52/2008, (Delhi High Court, 2012) (Manmohan Singh, J.)
[5] F. Hoffman-La Roche Ltd & OSI Pharmaceuticals, Inc. v. Cipla Ltd., RFA(OS) 92/2012 and RFA(OS) 103/2012, (Delhi High Court, 2015) (Pradeep Nandrajog, J. and Mukta Gupta, J.)
[6] Amala Haldar, An Overview On The Roche Vs. Cipla Dispute, iPleaders, (Sept. 22, 2013) https://blog.ipleaders.in/overview-roche-vs-cipla-dispute/#:~:text=Facts%20Of%20The%20Case,sold%20by%20Roche%20as%20TARCEVA.&text='%20This%20made%20Roche%20initiate%20infringement,which%20is%20licensed%20to%20Roche

RULE APPLIED

The Division Bench held that Cipla's product Erlocip, which is claimed to be a Polymorph B form of the compound Erlotinib, infringes the Patent No. 196774 and affirmed its validity as well. The Division Bench set the correct legal principles for establishing infringement i.e. mapping the infringer product with the patented claims.

The Bench cited *Hind Mosaic and Cement Works & Anr. vs. Shree Shahjanand Trading Corporation & Anr.* [7] in the following words, "*an infringement analysis involves comparison of each and every limitation of the claim with the allegedly infringing device. The analysis cannot be performed by comparing the product manufactured by the patentee with the allegedly infringing product*."

The Defendant alleged that their product Erlocip is a Polymorph B form of the compound Erlotinib Hydrochloride and since the patent application for the Polymorph B of Erlotinib Hydrochloride is rejected, Cipla is free to make polymorph B form.

The Division Bench of the Delhi High Court held that Patent No. 196774 claim, *the compound of formula A, a novel [6,7-bis (2-methoxy ethoxy) quinazolin-4-yl] -(3-ethynyl phenyl) amine hydrochloride], is clearly not limited to any polymorphic form of Erlotinib Hydrochloride, but to Erlotinib Hydrochloride itself*. The bench further stated that *"this compound may exist in various polymorphic structures; however, any such structures will be subsumed within this patent. Along these lines, as Cipla's Erlocip is certainly one specific polymorphic form of the Erlotinib Hydrochloride compound (Polymorph B), it will infringe the Patent No. 196774"*.

The Division Bench also summarized the principles of claim construction as follows: -

1) Claims define the territory or scope of protection.

2) There is no limit to the number of claims except that after ten claims there is an additional fee per claim.

[7] 2008 (37) PTC 128 (Guj)

3) The broad structure of a set of claims is an inverted pyramid with the broadest at the top and the narrowest at the bottom (Manual of Patents Office – Practice and procedure).

4) An independent Claim can be the most extensive sphere claim. It has lesser limitations than any dependent claim which is reliant upon it.

5) Where claims are 'dependent', they are incorporated by reference 'everything in the parent claim, and adds some further statement, limitations or restrictions'. (Landis on Mechanics of Patent Claim Drafting)

6) Where claims are 'independent' although relating to the same inventive concept this implies that the 'independent claim stands alone, includes all its necessary limitations, and is not dependent upon and doesn't involve limitations from another claim to make it complete… An independent Claim can be the broadest scope claim. It has fewer limitations than any dependent claim which is dependent upon it. (Landis on Mechanics of Patent Claim Drafting)

7) Different claims define different embodiments of the same inventive concept.

8) If subsidiary claims contain an independent inventive concept different from the main claim, then the Patent Office will insist on the filing of a divisional application.

9) The subject matter of claims can be product, substances, apparatus or articles; alternatively, methods or processes for producing said products, etc. They may be formulations, blends of different substance including recipes. Dosage regimes or in some countries' methods of use or treatment may also be claimed.

10) To invalidate a patent, the challenger must invalidate each claim separately and independently as it is quite likely that some claims may be valid even while some are invalid.

11) In an infringement action, first, define the scope and meaning of the claims including its terms. In the case of *Herbert Markman vs. Westview*[8] the Court held that an infringement analysis entails two steps:

- To decide the significance and extent of the patent claims asserted to be infringed.
- To compare the appropriately interpreted claim with the device blamed for infringing.

12) Each claim has a priority date and hence a group of claims in a specification may have multiple priority dates. This possibly implies that if a patent application with certain priority date and claims was trailed by another application with different claims and different priority dates, at that point if they were combined or related with another application, each claim would hold the original priority date

On the question of obviousness, the Division Bench held that "*to test obviousness the first test required to be applied is to see who is a Person of Ordinary Skilled in the Art (POSA) and its characteristics. The features of a person skilled in the art are that of a person, who practices in the field of endeavour, belongs to the same industry as the invention, possesses average knowledge and ability, and is aware of what was common general knowledge at the relevant date.*"

The Division Bench crafted "*the steps to determine obviousness/lack of inventive step in the light of the following inquiries are required to be conducted: -*

Step No.1 To identify an ordinary person skilled in the art,

Step No.2 To identify the inventive concept embodied in the patent,

Step No.3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date.

Step No.4 To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,

[8] 517 U.S. 370 (1996)

Step No.5 To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hide side approach."

The Division Bench held that the teaching of the prior art document should be considered as a whole and that similarity of structure alone was insufficient for prima facie unpatentability. To show conspicuousness other than structural similarity, there ought to be an explanation or inspiration that appeared in the earlier art to cause the specific structural change to accomplish the properties that the candidate was looking for. Cipla's expert witness, who was presented as a Person Skilled in the Arts (POSA), was not a medicinal Chemist and could not be considered as a POSA and the Court held that Cipla has been unsuccessful in satisfying the tests laid down above to establish prima facie that the patent was obvious.

Cipla also sought revocation of the suit patent for violation of Section 8 of the Patents Act and contented that if Polymorph B of Erlotinib Hydrochloride is presumed to have been covered in the suit patent, this would imply Polymorph B of Erlotinib Hydrochloride to be same and substantially the same as the suit patent. Roche was then under an obligation to have disclosed before the patent office while prosecuting its application resulting in Patent No. 196774 that it had applied for grant of the patent for Polymorph B of Erlotinib Hydrochloride resulting in US6900221 which fact was not disclosed.

The Division Bench rejected this ground as well as it held that Cipla did not prove that inventions IN `774 and US `221 are same or substantially same.

Further, the Bench held that when Roche was prosecuting its application for grant of Suit Patent IN `774 separate application for grant of the patent for Polymorph B form of Erlotinib Hydrochloride was filed on February 06, 2002. The Suit Patent was a product patent relating to the new molecule Erlotinib Hydrochloride whereas US `221 was an improvement patent application relating to certain polymorphic structures. The Court attributed the non-filling of the details of the application resulting in grant of patent US `221 by Roche to the bona fide belief of Roche that the application resulting in patent US `221 is not the same or substantially the same compound.

To conclude, the Division Bench affirmed the validity of Roche patent, IN `774, and set aside the Single Judge decision dismissing the suit for injunction filed by Roche. However, keeping

in view the fact that the IN `774 patent would expire in March 2016, the Bench did not grant an injunction against Cipla. Subsequently, the Division Bench of the Delhi High Court directed Cipla to render accounts concerning the manufacture and sale of Erlocip for the calculation of damages.

ANALYSIS OF JUDGEMENT

The main question was whether denying infringement to the drug of Roche was correct or not, as it highlighted evergreening of the patent which has been expressly denied under section 3(d) of the Indian Patent Act, 1970.

Section 3(d) of the Patents Act provides for "What are not inventions". The sheer disclosure of another type of a known substance which doesn't bring about the upgrade of the known adequacy of that substance or the mere discovery of any new property or new use for a known substance or of the simple utilization of a known procedure, machine or mechanical assembly except if such known process brings about a fresh product or engages at least one new reactant.

If we carefully analyse section 3(d) of the Indian Patent Act, 1970. we can see that it lays down denial of the patent in three circumstances:[9]

1) Mere discovery: Mere discovery as per the Webster's Third International Dictionary of the English Language, articulation "discovery" alludes to "the act, process or a case of gaining knowledge of or ascertaining the existence of something previously unknown or unrecognized." Therefore, discovery would mean simply finding out something which is known in the world whereas innovation involves an inventive step.

2) A new form of a known substance: This would mean that the existing substance is being presented in a different manner or in other words new derivatives of a known substance. This would not be patentable unless it is proved that they differ significantly about efficacy.

3) It does not increase efficiency: This means that a new form of a known substance will be allowable only when it is shown that they differ in properties and that this difference

[9] Swarup Kumar, Inside Views: Scope, Implications Of Section 3(d) Of The Indian Patents Act, 1970 (As Amended), International IP Policy News, (June 1, 2007), http://www.ip-watch.org/2007/06/01/scope-implications-of-section-3d-of-the-indian-patents-act-1970-as-amended/

has led to enhanced efficacy. The efficacy can be in the form of enhanced stability or freedom from specific disadvantages or even perhaps increase in bioavailability but it should not be an eye-wash increment in efficacy but a significant increment.

A patent is a monopoly right which is given to the inventor as a reward for his hard work and years of research. It is given only when there is an inventor who has invented something useful and non-obvious. A patent in India is allotted for 20 years after which it is in the public domain to be used. The concept of non-obviousness means that it should not seem obvious to a person who is an expert in that field.

In the case of *Dhanpath Seth & Others v. Nil Kumal Plastic Crates Ltd*[10], a patent was claimed on the mere fact that the device was made of polymeric material instead of the traditional bamboo material. The Court held that there was nothing new in manufacturing a traditional Kilta made of natural material from synthetic material.

Similarly, in the present case, the fact that Roche had derived Polymorph B out of the combination of Polymorph A and B was not an inventive step as Polymorph B was a more stable form of Erlotinib Hydrochloride was a well-known fact to anyone in the same field.

In the present case, the application to the Controller General of Patents, Trademarks and Designs for a patent on Polymorph B was rejected because it did not show enhanced therapeutic efficacy over the closest prior art. Prior art would mean the knowledge existing in the public domain. The existing technologies can be understood to mean prior art.

In the present case, the Court quoted that *"A mere difference in physical property is a well-known conventional variation of the same pure substance not showing unobvious properties."* Therefore, the charges alleged by the applicant are in the physical properties and not in the therapeutic efficacy. This amounts to evergreening tendency which has been denied by Section 3(d).

Section 3(d) keeps a check on over evergreening as it, in turn, affects the public health of a country, the manufactures may charge heavy prices which are not affordable by the public at large and while they continue to enjoy their monopoly which is completely against the concept of patents. It is quite evident that the drug which was being made available by Roche was three

[10] AIR 2008 HP 23

times more expensive than the drug which was available by Cipla. While granting patent and passing injunction orders what is more important to see is the public benefit at large. In the present case the drug was a life-saving drug that was being manufactured in India, at a comparatively lower price and hence the claim of infringement was rejected.

It is not that a newer version of an already patented drug is not patentable in India, it's just the fact that if the newly developed drug gives better performance to the existing one then it is patentable. But, this enhanced efficacy has to be proved experimentally only then will the patent application be eligible for its acceptance. Section 3(d) promotes the subsequent expansion of existing chemical substances, compounds, technologies that help fulfil the health requirement of the public, and balance public goods.[11]

In the case of *Novartis Ag v. Union of India & Ors*[12], it was seen that Section 3(d) was interpreted as therapeutic efficacy of the drug and not just the improvements in the physical characteristics or stability of the product. Similarly, in the present case also there were signs of only improvement in the stability and the physical composition of the drug. However, there were no statistics which were presented before the Court to show that there is any improvement in efficacy in drug usage.

The main contention which was raised in the case of *Novartis Ag v. Union of India & Ors* was that Section 3(d) ought to be removed as it was against the TRIPS agreement. But what the Court instead said was the main aim of the patent system is not only to provide benefit to the inventor for 20 years but also restrict the expansions of such term once the term has expired. The Court said that the Amendment was intended to:

1) Preventing ever-greening;

2) To provide easy access to the denizens of this country for life-saving drugs; and

3) To discharge their constitutional obligation of providing health care to its citizens.

What is to be noted in the present case and in cases involving drug is that Right to Health is a cause of concern in major parts of the world especially African and Asian countries and in such

[11] Kant A, Section 3(d): 'New' Indian Perspective, Journal of Intellectual Property Rights, 14 (9) (2009) 385-396
[12] Novartis Ag v. Union of India & Ors., Civil Appeal No. 2706-2716 of 2013 with Civil Appeal No. 2728 OF 2013 with Civil Appeal No. 2717-2727 of 2013, (Supreme Court of India, 2013), (Aftab Alam, J.)

situations, price plays a major role. If the price of these life-saving drugs is allowed to be fixed at a higher rate by allowing monopoly and not restricting evergreening, then companies like Roche will keep on creating drugs that are thrice as expensive as that which were created by Cipla. In such cases, the most important aspect is public concern which are to be given an upper hand.

CONCLUSION

The Patent (Amendment) Act of 2005 showed that India has adopted an IP regime that showcased the spirit of WTO, but at the same time keeps a provision for prohibiting 'evergreening' by making available expensive medicines available at nominal rates by encouraging market competition. What has been shown by the Indian judiciary through cases like Novartis and Cipla is that Section 3(d) is acting as a guard against evergreening of patents as the pharmaceutical companies have a habit of simply changing just one component which does not in any manner change the efficacy of the product and re-apply for a product, this restricts the research and development pace and leads to the downfall of the country. Also, what has been made clear through these cases is that while granting and considering patent applications what will be of at most importance is the public benefit at large.

Patent laws in India encourage inventions but are against providing absolute rights, they provide a restrictive right whereby encouraging more research and development and development of better medicine in the market.