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Doctrine of Equivalents in India: Beyond the "Essential Elements"

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To conform to the TRIPS Agreement, The Indian Patents Act 1975 has been amended several times to comply with the global requirements. However, there is no clear directive in the statutes of the law as well as in the subsequent Court opinions regarding the analysis of the infringement by equivalence factor. In *Raj Parkash* v *Mangat Ram Chowdhry, 1977* the Court provided the analysis of "Pith and Marrow" in line of the British analysis. Thereafter in the new regime of the patent law provides in *Sotefin SA* v *Indraprastha Cancer Society, 2022* case the analysis of essential elements again. Now the Court has come across the question of equivalence in case of the chemical invention, i.e., in the alleged infringement by Natco, India for the preparation of the agrochemical Chlorantraniliprole or CTPR and thereby infringing the Indian Patent 298645 owned by FMC Corporation, Singapore. The Court applies the doctrine of equivalents to ascertain if there is an act of infringement to FMC's patent by analyzing the case beyond the essential elements of a claim and set forth a new method of determination where the previous cases had fallen short of.

Keywords: Doctrine of Equivalents, Infringement by Equivalence, Indian Patenst Act, Chlorantraniliprole, CTPR, Rynaxypyr, CORAGEN, Pith and Marrow, Function-Way-Result, Essential Elements, Evergreening of Patent, Chemical Invention, FMC Corporation, Natco, Chemical Process, Reaction Mechanism, Order of Reaction, Reaction Kinetics, Rate of Reaction

The Doctrine of Equivalents

Doctrine of Equivalents or simply DoE is the most well recognized tool to bar attempts to avoid a patent right by means of insubstantial changes to the claimed parameters. However, although in the US and Europe the tool has been practiced rigorously to sufficiently enforce the patent rights, India has been lagging behind since the inception of its patent act and the situation is yet to improve even after the product patent regime was implemented in 2005. There is no clear directive in the statutes of the law as well as in the subsequent court opinions regarding the analysis of the infringement by equivalence factors.

The US Position

In the US, the Court relies the *"Function-way-result Test"* to determine the act of infringement under equivalence. That is to say, whether the alleged device/method performs "substantially the same function in substantially the same way to obtain the same result." Substantially does not mean working identically, but whether a specific set of parameters can actually be replaced/ substituted by another set that acts exactly as an equivalent is to be determined. In the field of chemical substances and their manufacturing methods, *Warner-Jenkinson Co.* v *Hilton Davis Chemical Company*, 1997[1] case is the landmark decision set forth by the US Supreme Court wherein the determination of equivalence has been applied as an objective inquiry on an element-by-element basis.

Analysis in the UK

In the Europe, the approach to the test of equivalence is somewhat a similar one and is widely known as the *"Pith and Marrow"* analysis that is determining the scope of the claims by the essential part or substance of invention. In 1980, the House of Lords adopted the *"Catnic test"* wherein the determination of infringement was taken as a matter of construction rather than as a matter of reality. In 2017, the UK Supreme Court sets a question in *Actavis* v *Eli Lilly* that whether it would be obvious to the person skilled in the art, reading the patent at the priority date that the variant works substantially the same way the claimed invention does, knowing that the variant achieves substantially the same result as the invention.

Indian Patents Act and the Doctrine of Equivalents

Point to be noted that Indian patent act of 1975 and the amendments till 2005, although provides in

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Section 48 the rights of the patentee in cases of product patents as well as method patents and in Section 104-115 clarifies the matters associated with the act of infringement, *per se* does not define what constitutes the act of "infringement", let alone defining the matter of infringement by equivalence. Under the circumstances it is important that the subsequent Court opinions define the latent terms of the act.

Equivalents in Pre-CTPR Cases

Indian courts for decades had been relying upon the "Pith and Marrow" analysis although no opinion *per se* defined the Doctrine of Equivalents. That is to say, DoE in India has never been expressly dealt with by the Court of Law.

Raj Parkash v Mangat Ram Chowdhry, 1977[2] was the case of "Pith and Marrow" analysis. Relying upon the Australian case *Beecham V. Bristol Laboratories* [1968], Delhi High Court discouraged the insignificant variations in the patented product or process and opined that infringement would indeed occur if the substance of the patented article is copied. The "Pith and Marrow" of the invention is the most important thing and rather than the elaborated specifications.

In Ravi Kamal Bali v Kala Tech, 2008[3], the demand to apply the doctrine of equivalence has been sought by the plaintiff. The Court found that the infringing product and the patented invention had the same 'usage/purpose', the same 'nature of material', and functions on the 'same principle'. In the event of a substantial difference in the constructional and functional aspect of the product, the main structural body of the locking device alone could not be held responsible for the claimed invention. The Court considered what the term "invention" means, and also what the terms "improvement" and "modification" involve. However, the Court did not set forth a practice to determine the equivalence factors.

The CTPR Case: *FMC Corporation & Ors.* v *Natco Pharma Ltd*[4]

Chlorantraniliprole (CTPR) – marketed as the brand Rynaxypyr® is a human made insecticide and an original invention of E. I. du Pont de Nemours and Company (DuPont). FMC Corporation, Singapore in 2017 acquired certain assets relating to DuPont's Crop Protection business and research and development organization including CTPR. Branded as CORAGEN®, Chlorantraniliprole does more to optimize the yields and quality of the crops by achieving consistent and long-lasting control of key pests.

CTPR lost the patent protection in India on 13 August 2022. The specific molecule Pat No. 201307 and a series of its family members 213332, 215218, 205622 and 213177 all expired in India on the same day. CTPR's next series of patent protection in India was thus depending upon a few process patents of which Pat No. 298645 (The '645 Patent) is very important because it claims the key step of the chemistry utilized in the manufacturing process of the molecule, i.e., the condensation between two key intermediates - anthranilic acid amide intermediate and pyrazole carboxylic acid intermediate to form the core moiety of CTPR. The '645 Patent is set to expire on 6 December 2025.

Natco Pharma Ltd. of Hyderabad is the generic manufacturer of CTPR after the expiry of the molecule patent in August 2022 and the defender of the present case. FMC alleges that Natco infringes the '645 Patent by using directly or indirectly any process(s) covered by the said patent and hence seeks a decree of permanent injunction against the Defendant. FMC's contention was that although Natco may not infringe the '645 Patent literally, the generic company's process involves insubstantial modifications of the patented invention and thus forms an equivalent.

After a meticulous study of the factual basis of the case as well as the scientific advisors' opinion, Honourable High Court of Delhi on 19 September 2022 said that Natco's process cannot be termed as *"an insignificant or trivial or insubstantial change and thus the process prima facie does not come under the rigors of Doctrine of Equivalents."*

Analysis

The '645 Patent, in particular the claim 1 of the patent, covers a process for preparation of CTPR (Fig. 1).

The claimed process involves combining a carboxylic acid compound of formula (2), an aniline compound of formula (3) and a sulfonyl chloride, to prepare or manufacture Chlorantraniliprole or CTPR of formula (1).

It was revealed that the alleged process of the defendant uses thionyl chloride – chemically represented as SOCl2) – instead of a sulfonyl chloride. Thus the process of the defendant was distinguished from that of the patented invention.

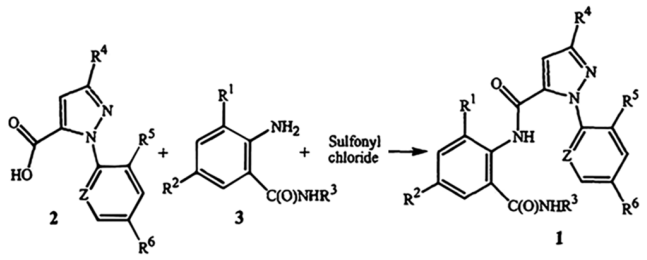

Fig. 1 — Process for preparation of CTPR

The fact finding process states that there is no methane sulfonic acid impurity in the Natco process, meaning thereby the defendant does not use sulfonyl chlorides as claimed in the '645 patent.

FMC's argument was that, both the patented invention and defendant's method thus rely on activation of 3-Bromo-1-(3-Chloro-2-pyridinyl)-1H-pyrazole-5-carboxylic acid into an activated intermediate, which reacts with 2-Amino-5-chloro-3, N-dimethylbenzamide to produce CTPR and are 'equivalent'. That means, the carboxylic acid group –COOH of the pyrazole carboxylic acid (Formula 2) is first converted to activated –COCl group and then condenses with the amino group –NH2 of the anthranilic acid amide intermediate (Formula 3). Since both the reagents – sulfonyl chloride in the patented invention and thionyl chloride of the defendant's variant – activates the –COOH group in the same way, does the same function of condensation to achieve the same resultant compound CTPR; the defendant's variant is thus an equivalent of the claimed invention and amounts to the act of infringement by Doctrine of Equivalents.

Now the question before the court is, *"Whether Defendant's process (hereinafter referred to as 'Natco process') performs substantially the same function, i.e., activation of carboxylic acid moiety, in substantially the same way, i.e., coupling of carboxylic acid (Formula 2) with aniline (Formula 3), to achieve the same result, i.e., yield CTPR."*

Court considered that in previous such analyses, foreign countries have developed five legal standards: (a) all elements rule; (b) Tri-partite test; (c) insubstantial differences test; (d) obviousness test and (e) known interchangeability. The court then unfolds these methods one-by-one and goes beyond the given tests to decide the present case.

The "Essential Element" under the *Pith and Marrow Doctrine*

Court also relied on the *"Pith and Marrow"* doctrine in a similar manner of the case *Raj Parkash* v *Mangat Ram Chowdhry,* 1977, however, since this case *was under the 1911 Indian Patents and Designs Act, which did not have any provision pari materia to Section 10(4) of the Act*, this does not support the Plaintiffs' case.

While applying the all elements rule, it has been found that 17 out of the 19 elements were common in the alleged chemical process and the remaining 2 'non-essential' elements was insubstantial. Both the Scientific Advisors opined that use of sulfonyl chloride is 'essential' to the process claimed in IN'645 and the reagent used in defendant's process differs considerably in most properties.

The US Doctrine: *Function-Way-Result* test

The court thereafter unfolds the *modus operandi* or *functioning* of the defendant's process vis-à-vis the patented method, that is if the processes of the claimed invention and the defendant function in the same way or not. It was seen that the claim language of the '645 patent involves the term "combining" and the patent description explains the meaning of the term 'Combining' as 'contacting the chemicals with each other'. Therefore, this is *not an open ended term*.

Also, the description revealed that the patented process involves a specific sequence of addition of the reagents – (1) combining a carboxylic acid of Formula 2 and aniline of Formula 3 to form a mixture, and (2) then combining the mixture with a sulfonyl chloride.

On the other hand, Natco's process is a two-step one. In the first step pyrazole carboxylic acid (Formula 2) is reacted with thionyl chloride and reaction mass is directly taken to the next step without isolation of the intermediate. In another reactor the amino compound of Formula 3, acetonitrile and 3-picoline are taken and reaction mass from the first reactor is reacted into it.

Court found these two processes different and went on commenting that when the same product is manufactured through a different process the patentee cannot extend their patent monopoly to the variant.

To understand whether the reagents used in the suit patent and in the Natco process are the equivalent, the court appointed two scientific advisors. The two eminent personalities found that the use of sulfonyl chloride in the patented invention and that of thionyl chloride in the defendant's process *"has different and distinct role in achieving the same task and accomplishing substantially, the same result"* so as to

the defendant's process cannot be termed as a minor or insubstantial variation."

Doctrine of Purposive Construction: Constituting the Essential Features of the Claim

> *"Non-essential or trifling variations or additions in the product would not be germane, so long as substance of the invention is found to be copied"* – Sotefin SA v Indraprastha Cancer Society, 2022[5]

The claim language when construed in the given context of the specific purpose it serves, reveals few elements as *essential* and others as *non-essential*. This is determined taken into account the status of common knowledge of an ordinary skill that a variant of a particular element would not make a difference to the way in which the invention works and whether according to the intent of the inventor that element was essential.

Thus when the purposive construction shows that the sulfonyl chloride according to the intent of the inventor is an essential element and the defendant with his ordinary skill in the art replaces it with a variant, such omission of essential element is no infringement.

The Warner-Jenkinson Analysis

> *"Doctrine of Equivalents must be applied to individual elements of the claim and an analysis of the role played by each element in the context of the specific patent claim will thus inform the enquiry as to whether a substitute element matches the function, way and result of the claimed element or whether the substitute element plays a role substantially different from the claimed element. The determination of equivalents should be applied as an objective inquiry on an element-by-element basis."- US Supreme Court in* Warner- Jenkinson Co., Inc. v Hilton Davis Chemical Co., 520 U.S. 17 (1997)

The Court found in the present case*, prima facie*, sulfonyl chloride more particularly methane sulfonyl chloride is the "essential and integral part" of the patented invention while combining the compounds of formulae 2 and 3.

The Court further went on to find whether defendant's use of thionyl chloride in place of methane sulfonyl chloride is a merely minor/trivial change to ascertain the DoE. In other words, whether the replacement of the essential/integral part of the patent invention is insubstantial in the context of the chemistry practiced to manufacture CTPR – is the question before the court.

Both the scientific advisors found that the two reagents are not the same – as long as the physical and chemical properties are concerned. The by-products yielded upon reacting them also are different. Also, they found that the mechanisms of the reagents are different. In Natco process, thionyl chloride is used as a chlorinating agent to react with carboxylic acid to displace the –OH group present in the acid and replace it with the chlorine atom to form an acid chloride. But in the patented invention sulfonyl chloride is added to the mixture of a carboxylic acid to *activate the process* and thus *acts as a coupling agent to control the rate of reaction* as well as the yield produced by it.

The essence of the HC judgement actually resides here.

If we schematically write the two processes, the difference is clear and convincing:

(i) Patented process

Compound of Formula (2) + Compound of Formula (3) + Methane sulfonyl chloride

↓

CTPR + Methane sulfonic acid

Methane sulfonyl chloride takes part with the reactants as a "coupling agent", activates Compound of Formula (2) and thus impacts on the rate of the reaction. This is a second-order reaction rate kinetics.

Court said, *"Coupling Agent is a compound which provides a chemical bond between two dissimilar materials."*

(ii) Defendant's process

Compound of Formula (2) + Thionyl Chloride

↓ 1st step: Chlorination

Chlorinated Compound of Formula (2)

↓ 2nd Step: Reacted with Compound of Formula (3)

CTPR + SO2 and HCL gases

This is a two-step process. The 1st step, chlorination, is a separate reaction and the chlorinated compound is then subjected to the rate limiting step. The 2nd step is the substitution reaction. Clearly the reagent in question – thionyl chloride – does not take part in the rate limiting step, i.e., the second step.

Court found, *"Chlorination' is a process in which chlorine is introduced into a molecule while 'coupling*

reaction' refers to class of organic reactions that involve joining of two chemical species."

Thus it has been established before the court that the role of the two reagents are entirely different, that is, the way they function are different. When we consider the *function-way-result* test, the "function" and the "way" of the reagents are different by virtue of their physicochemical properties and their role in the reaction mechanism. The *"result"* is also different considering the by-products of the two reactions. While the patented invention yields methane sulfonic acid, the Natco reaction releases SO2 and HCl gases. *"They are different compound with different reactivity and physical properties."*

Therefore, the use of thionyl chloride in the defendant's process in place of sulfonyl chloride not only replaces the essential element required for the reaction of the patented invention, but also mechanistically is not a trivial or insubstantial change.

In comparing the CTPR case against the *Raj Parkash* v *Mangat Ram Chowdhry,* 1977 – which was the classical case of *Pith and Marrow* analysis in India – the court commented, *"Defendants had made variations which were unessential and were marketing a product which was substantially the same as the one conceived by the Plaintiff, which is diametrically opposite to the facts of the present case."*

So, in the final opinion of the court, defendant is allowed to launch their product generic CTPR and any requirement of injunction sought by the plaintiff was nulled.

Conclusion

The previous analysis in the *Raj Prakash* case has fallen short when Court attempted to apply in case of chemical inventions. When the invention is a chemical process, it is required to meticulously analyze the reaction mechanism to ascertain the infringement by equivalences.

The present case thus establishes the following guideline to determine whether the alleged element is unambiguously the equivalent to the element recited in the claim language by following these critical steps:

(i) Step-1: To analyze all the elements of the claim in question
(ii) Step-2: To find out the essential elements and to determine which of these elements is replaced in the alleged infringing device/method
(iii) Step-3: To determine whether the variant used in the process is a true equivalent of the claimed essential element or not. Take a deep look in the reaction mechanism, find out the reagents' physicochemical properties, their roles in the reaction kinetics and the by-products they yield.

This is, therefore, an opinion of substance that looks beyond the essential elements of a claim.

The Road Ahead

> *"In a process claim, the monopoly is restricted to the method by which the product is manufactured and if the same product is manufactured through a different process/ method, the patentee cannot extend its monopoly to the different process"* – In the CTPR Case, *FMC* v *Natco,* Delhi High Court, 2022

Indian Patents Act of 1957, after subsequent amendments and conforming to the TRIPS Agreement has come across the first time the question of infringement by equivalence.

In absentia of the appropriate statute on what constitutes the act of infringement or a preceding legal opinion, it is the court who establishes the point of law. Honourable Delhi High Court has mastered in this case to do the job to provide a guideline how to determine the equivalence factor. The opinion is not only a precedent case but also an opinion of substance when taken into account the essence of the elemental organic chemistry.

The act of ever-greening the patent monopoly beyond the full term of a molecule patent has always been the center of discussion. This judgement clearly shows that the strength of the subsequent patent resides in the inventive elements only. To understand whether truly the invention extends beyond that term, one must analyze the root cause of the chemical reaction in question – the reaction mechanism.

There might be some contra-opinions concerning whether or not the court has taken considerably into the account of the question of patentee's contention to cover the variant at the time of the patent-filing. A meticulous study of the specification of the '645 Patent as well the PCT application publication WO2006062978A1 that has been nationalized in India as a precursor of the '645 Patent, reveals that the patentee never mentioned the use of thionyl chloride in place of sulfonyl chloride. Rather, these specifications clearly mentions, "*Sulfonyl chlorides are generally of the formula* $R^8S(O)_2Cl$ *(*Formula 4*) wherein* R^8 *is a carbon-based radical……..Sulfonyl chloride compounds preferred for the present method*

because of their commercial availability include methane sulfonyl chloride (R^8 is CH_3), propane sulfonyl chloride (R^8 is $(CH_2)_2CH_3$), benzene sulfonyl chloride (R^8 is Ph), and p-toluene sulfonyl chloride (R^8 is 4-CH_3-Ph). Methane sulfonyl chloride is more preferred for reasons of lower cost, ease of addition and/or less waste."

Honourable High Court, *albeit* captured this point in the opinion, however could have further emphasized that the patentee meant the reagent for the given reaction is "Sulfonyl chloride" and did not envision the use of thionyl chloride in the place of it at the time of conceiving the invention in question. The claims are drafted specifically to Sulfonyl chlorides and nothing else. The specifications – both PCT as well as the Indian one – in their entirety along with the prosecution history that is available in public never reveal an idea of replacing the "Sulfonyl chloride" with thionyl chloride. Under the circumstances, the patent right could not be extended beyond the term that has been drafted and meant by the patentee.

Nonetheless, this opinion has established the way of analyzing the equivalence factors in case of chemical inventions. This would undoubtedly set forth an instance to treat the question of infringement by equivalence in India specifically when the invention is a chemical reaction.

References

1 *Warner-Jenkinson Co., Inc*. v *Hilton Davis Chemical Co.,* 520 U.S. 17 (1997).
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3 Bombay High Court opinion on *Ravi Kamal Bali* v *Kala Tech And Ors*., 12 February 2008.
4 Delhi High Court opinion on *FMC Corporation & Ors*. v *Natco Pharma Limited*, 19 September 2022.
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