2022/DHC/0053

IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment delivered on: 05.12.2022

\+ **FAO(OS) (COMM) 301/2022**

FMC CORPORATION & ORS. ..... Appellants

versus

NATCO PHARMA LIMITED ..... Respondent

Advocates who appeared in this case:

For the Appellants : Mr Ramesh Singh, Senior Advocate with Dr Sanjay Kumar, Ms Arpita Sawhney, Mr Arun Kumar Jana, Ms Meenal Khurana, Mr Harshit Dixit and Mr Priyansh Sharma, Advocates.

For the Respondents : Mr J. Sai Deepak, Mr G. Nataraj, Mr Avinash K. Sharma, Mr Ankur Vyas, Mr Shashikant Yadav and Ms Harshita Agarwal, Advocates.

CORAM
HON'BLE MR JUSTICE VIBHU BAKHRU
HON'BLE MR JUSTICE AMIT MAHAJAN

JUDGMENT

VIBHU BAKHRU, J

1. The appellants have filed the present intra-court appeal impugning an order dated 19.09.2022 (hereafter '**the impugned order**'), passed by the learned Single Judge, rejecting the appellant's application under Order XXXIX Rules 1 and 2 being [IA No. 8130/2022 in CS(COMM) 349/2022 captioned '***FMC Corporation and Ors. v. Natco Pharma Limited***'].

2. The appellants have filed the aforementioned suit seeking a decree, restraining the respondent from infringing a patented process/method for the manufacturing/preparation of Chlorantraniliprole (hereafter '**CTPR**'). The patent is in respect of the process or method, as claimed in Indian Patent no.298645 (hereafter referred to as '**the suit patent**' or '**IN'645**').

Factual Context

3. FMC Corporation (hereafter '**appellant no.1**') is a company incorporated in the United States of America, engaged in the production and sale of agrochemicals, and providing consumers with cost-effective solutions for enhancement of crop yield and quality by controlling a broad spectrum of insects, diseases etc. as well as in non-agricultural markets for pest control.

4. FMC Agro Singapore Private Limited (hereafter '**appellant no. 2**') is appellant no.1's subsidiary, registered under the laws of Singapore. FMC India Private Limited (hereafter '**appellant no. 3**') is appellant no.1's subsidiary, established in India since 1973. Appellant nos. 1 and 2 are joint patentees of the suit patent (hereafter collectively referred to as '**FMC**'). The appellants claim that appellant no.1 carries on the business of manufacturing and selling agrochemicals in India, *inter alia*, through appellant no.3. Appellant no. 3 also holds the license to import and market appellant no.1's final product CTPR.

5. Natco Pharma Limited (hereafter '**NATCO**') states that it is a vertically integrated and R&D focused pharmaceutical company,

engaged in developing, manufacturing and marketing of finished dosage formulations (FDF) and active pharmaceutical ingredients (API).

6. The suit patent was granted in favour of E.I. Du Pont De Nemours and Company on 09.07.2018, under Section 43 of the Patents Act, 1970 (hereafter '**the Patents Act**') titled "*METHOD FOR PREPARING N-PHENYLPYRAZOLE-1-CARBOXAMIDES*". By a Confirmatory Assignment Agreement dated 01.05.2018, E.I. Du Pont De Nemours and Company assigned the suit patent in favour of the patentees (FMC) with effect from 01.11.2017.

7. The bibliographic details of the suit patent, as set out in the appeal, are reproduced as under:

Indian Patent No.	IN 298645
Patent Application No.	3548/DELNP/2007
Title	METHOD FOR PREPARING N-PHENYLPYRAZOLE-1-CARBOXAMIDES
Applicant	E.I. Du Pont De Nemours and Company
Date of filing in India	11.05.2007
International Application No.	06.12.2005
Priority Dates	07.12.2004

W.O. Publication No.	WO 2006/062978 Al published on 15.06.2006
Section 11A Publication	31.03.2007 - The application was published in the official gazette issued by the Patent Office thereby being open the public to file pre-grant opposition.
Date Of Grant	09.07.2018
Grantee	E.I. Du Pont De Nemours and Company
Date of expiry of patent	06.12.2025
Patentee/ Assignee	FMC Corporation, FMC Agro Singapore Pte. Ltd.

8. The suit patent is in respect of 12 claims that have been granted in respect of the preparation of anthranilic diamide insecticide. The aforementioned method involves combining (l) a carboxylic acid compound, (2) an aniline compound and (3) a sulfonyl chloride to prepare or manufacture CTPR. By the patented method, a pyrazole carboxylic acid of Formula 2, and aniline of Formula 3 and a sulfonyl chloride are combined (contacted) to prepare CTPR.

9. The appellants state that they were able to procure a document titled 'Environmental Management Plan for obtaining consent for establishment (CEF) – Expansion' submitted by NATCO to the Andhra Pradesh State Pollution Control Board. According to the appellants, NATCO has disclosed synthesis of CTPR in the said document, and it

was evident that NATCO was employing the patented method, as claimed by Claim nos.1, 5 to 8 and 11 of the suit patent, to prepare an identical product – CTPR. NATCO has also filed a patent application (PCT International Application No.PCT/IN2019/050321) claiming priority from Indian Application No. 201841015241, which disclosed the preparation of CTPR.

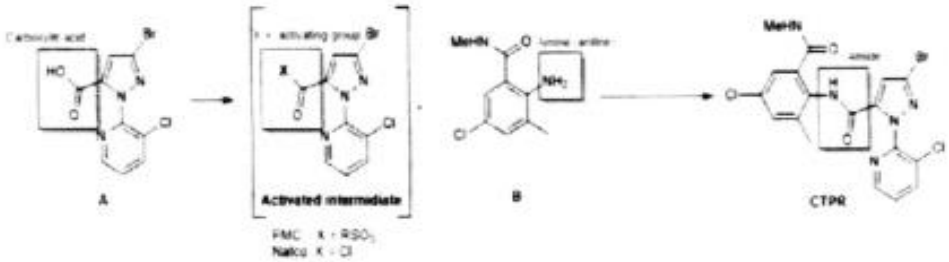
The Dispute

10. The appellants allege that the process, as disclosed by NATCO in its aforementioned application, is equivalent to the process claimed in the suit patent IN'645. They claim that since both the methods, as claimed in the suit patent and in NATCO's application, describe an amide bond formation reaction to yield CTPR, the manufacturing processes, as claimed in the suit patent and NATCO's application, are equivalent processes. On the basis of equivalence, the appellants claim that NATCO's process infringes the suit patent.

11. Paragraphs nos. 35 and 36 of the plaint, which articulate the reasons for alleging that NACTO's process infringes the suit patent, are set out below:

> "35. The manufacturing process disclosed in IN'645 and the alleged manufacturing process disclosed by the Defendant both rely on activation of a pyrazole carboxylic acid (A) tin this case, 3-Bromo-I-(3-chloro-3-pyridinyl)-1H-pyrazole-5-carboxylic acid; Natco ref: A/BPC) into an activated intermediate, which reacts with an aniline compound (B) (in this

case, 2-Amino-5-chloro-N,3-dimethylbenzamide; Natco ref: AC/ADB), to produce chlorantraniliprole (CTPR). Thus, as shown in the following scheme the process disclosed in [N'645 and the alleged process disclosed by Natco are equivalent:



36. In view of the foregoing, it is clear that the process of IN'645 and the alleged process of the Defendant are equivalent and effect the same transformation between the same reactants (A and B, see Scheme 1) to derive the same product (CTPR). Therefore, the Defendant's alleged process falls within the scope of claim I of IN'645."

12. It is relevant to mention that FMC had also filed prior suits in relation to patents relating to CTPR. NATCO states that FMC had filed the first suit – CS(COMM) No.611/2019 – alleging that NATCO had infringed the patent IN'207307/IN'307 and IN'213332 (Process Patent IN'332). According to NATCO, FMC had claimed a product patent in respect of CTPR as part of its Markush claim in patent IN'204978, which expired on 21.03.2021. FMC had also filed another suit [being CS(COMM) No.167/2021] alleging infringement of the product patent IN'307 as well as IN'215218.

13. NATCO states that, in view of the history of litigation instituted by FMC in respect of its four patents (IN'978, IN'307, IN'332 and

IN'218) in relation to CTPR and / or intermediates / processes leading to CTPR, NATCO sent a notice dated 27.04.2022, under Section 105 of the Patents Act, asserting that the process to be employed by NATCO for manufacture of CTPR (hereafter referred to as '**the NATCO Process**') did not infringe FMC's patent IN'645 (suit patent). FMC responded to the notice dated 02.05.2022 seeking certain further information regarding the NATCO Process and immediately thereafter, within a period of less than an hour, served a copy of the plaint alleging infringement of IN'645. NATCO claims that, in view of FMC's intent to initiate the action for infringement of IN'645, NATCO filed a suit [being CS(COMM) No.295/2022] seeking a declaration of non-infringement under Section 105 of the Patents Act. Notice of the said suit was issued on 06.05.2022. On 03.05.2022, FMC instituted a suit [being CS(COMM) No.349/2022] claiming infringement of IN'645. The said suit was listed in this Court on 23.05.2022, when the learned counsel appearing on behalf of NATCO made a statement on behalf of NATCO that it would not launch the product CTPR until expiry of the two patents IN'307 and IN'332, which were due to expire on 13.08.2022. He stated that NATCO would launch the product after expiry of the said patents by using a process that did not infringe the suit patent IN'645.

14. As is apparent from the above, the principal controversy involved in the present case is whether the process employed by NATCO for manufacturing CTPR infringes the suit patent.

Appointment of Scientific Experts

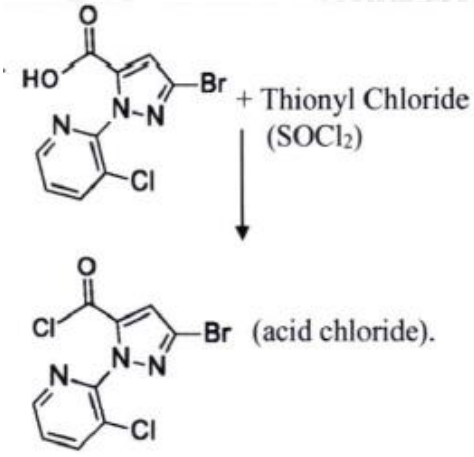
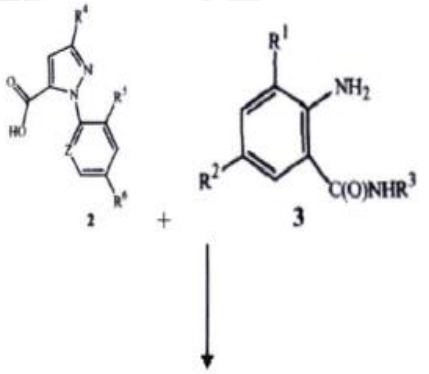
15. By an order dated 29.07.2022, with the consent of the parties, the learned Single Judge appointed two scientific advisers, namely, Dr. Gopakumar Nair and Dr. Raghavan Soman for examination of the issues relevant to the controversy in the case. Since Dr. Raghavan Soman expressed his inability to accept the assignment, the learned Single Judge, by an order dated 08.08.2022, appointed Prof. Bhalchandra Mahadeo Bhanage in place of Dr. Raghavan Soman. The terms of reference, as framed by NATCO and FMC for reference to the scientific advisers, as recorded in the order dated 29.07.2022, passed by learned Single Judge, are set out below:

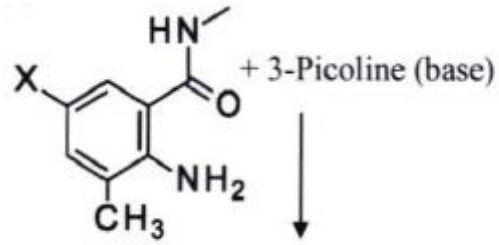
> **"Terms of Reference (I) (NATCO)**
>
> 1. Are 3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxylic acid and 2-Amino-5-chloro-N,3-dimethylbenzamide intermediates used in suit patent IN'645 disclosed in prior art IN 215218 and IN 284017 and also in WO'518?
>
> 2. Are 3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxylic acid and 2-Amino-5-chloro-N,3-dimethylbenzamide intermediates coupling disclosed in prior art WO'518 for example, in the pages and scheme and description reproduced above in Paragraph VI (A)?
>
> 3. Is the reagent thionyl chloride used in the Natco process for converting the pyrazole carboxylic acid to acid chloride the same as the reagent used for coupling the pyrazole carboxylic acid with aniline as set out in Claims 1 to 11 of IN 298645? Do thionyl chloride which is an inorganic chloride, and sulfonyl

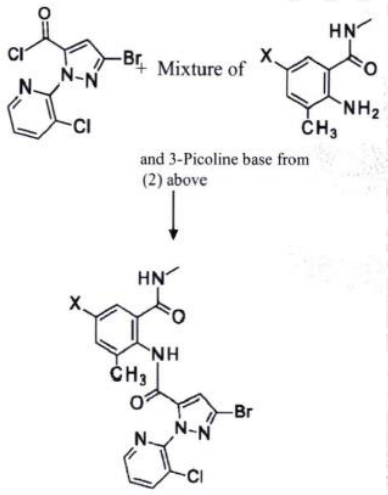
chlorides which are organic chlorides, have different physical and chemical characteristics?

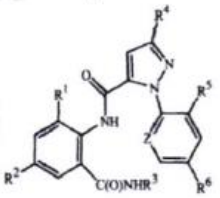
4. Is Methane Sulfonic acid impurity present in Natco product as per data given in CIBRC dossier? 5. Are the following two process distinct or the same?

5. Are the following two process distinct or the same?

NATCO Process	**IN 298645 Process**
(1) 	(1)  Mixture I (2 + 3)

<table>
<tr>
<td>(2)
 

Mixture of benzamide and 3-picoline base</td>
<td>(2)
Mixture I (2+3) + Base
↓
Mixture II (2 + 3 + Base)</td>
</tr>
<tr>
<td>(3)
 

(If X= Cl, Chlorantraniliprole of formula-Ia; and if If X= CN, Cyantraniliprole of formula-Ib)</td>
<td>(3)
Mixture II (2+3+Base) + Sulfonyl chloride ($R^8S(O)_2Cl$)
↓
  </td>
</tr>
</table>

6. In the process of IN'645 when sulfonyl chloride is used the chloride is knocked off and sulfonyl group attached to the pyrazole carboxylic acid to form mixed anhydride. Is this statement correct?

7. In the NATCO Process when thionyl chloride is used the chloride group is attached to the carboxylic acid group in the pyrazole carboxylic acid to form carbonyl chloride which is not a mixed anhydride. Is this correct?

8. Is the NATCO process which requires reacting a pyrazole carboxylic acid with thionyl chloride to obtain an acid chloride and then reacting the acid chloride so

formed with an aniline within the scope of Claims 1 to 5 of IN'645? Is that correct?

Terms of Reference (II) (FMC)

(i) Whether the Defendant's process is disclosed in the complete specification of the suit patent IN'645?;

(ii) What are the essential feature(s) of the process covered and claimed by the suit patent IN'645?

(iii) Whether the Defendant's process for preparing Chlorantraniliprole (CTPR) is covered and claimed by the process claimed by the suit patent IN'645?;

(iv) Whether the Defendant's process for preparing Chlorantraniliprole (CTPR) is equivalent to the process claimed by the suit patent IN'645 ?;

(v) Whether 3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5 carboxylic acid and 2-Amino-5-chloro-N,3-dimethylbenzamide used in the Defendant's process for preparing Chlorantraniliprole (CTPR) are same as claimed by the suit patent IN'645?;

(vi) Whether 3-Bromo-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5 carboxylic acid and 2-Amino-5-chloro-N,3-dimethylbenzamide used in the Defendant's process for preparing Chlorantraniliprole (CTPR) are equivalent as claimed by the suit patent IN'645?;

(vii) Whether the Defendant's process for preparing Chlorantraniliprole (CTPR) as disclosed in the document "Environment Management Plan for obtaining consent for establishment (CFE)- Expansion" submitted to AP State Pollution control Board is same as disclosed by the Defendant at the Central Insecticides Board and Registration Committee (CIB&RC) in light of the documents submitted by the Defendant by virtue of the disclosure/discovery?;

(viii) Whether the impurity profile of the end product, CTPR obtained in the Defendant's process is same as the impurity profile of the product, CTPR, submitted by the Defendant at the Central Insecticides Board and Registration Committee (CIB&RC) in light of the documents submitted by the Defendant by virtue of the disclosure/ discovery?

(ix) Whether Annexure VII shows identical impurity profile to the Plaintiffs' registered CTPR made by patented process IN'645. Attention is drawn to same Annexure VII at page 7, section 15 shows the Defendant's alleged process for manufacture.

(x) Whether Annexure VIII which is an independent analysis of the Defendant's CTPR, shows the same impurity profile as the Plaintiffs' CTPR?

(xi) Whether Annexure IV which is the Defendant's TIM registration certificate shows the exact impurity profile of the Plaintiffs' CTPR.

(xii) On reviewing the documents submitted, as the Defendant has tied its raw materials (including, thionyl chloride) with the Plaintiffs' impurity profile, whether the process of the Defendant can still be considered to be different than the process of the Plaintiff's patented process covered by IN'645."

Impugned Judgement

16. At the outset, the learned Single Judge noted that the product patent IN'307 in respect of CTPR and the process patent IN'332 had expired on 13.08.2022. The examination in the suit was limited to infringement of the suit patent IN'645, which is a process patent. The learned Single Judge examined the patented claims as well as the 'Description of the Invention' and the 'Embodiments of the Claims' as

submitted to the Patent Office, and noted that the process entailed mixing of a carboxylic acid (Formula 2) and an aniline (Formula 3) whether with the base or a solvent and thereafter, adding sulfonyl chloride to the said mixture. It was also noted that the detailed description indicated that reactants could be combined in various orders, however, the method necessarily entailed use of sulfonyl chloride with the mixture. The notes also explained the role of sulfonyl chloride and described it as the preferred compound because of commercial availability and the same included methanesulfonyl chloride and p-toluenesulfonyl chloride. The process used by NATCO (the NATCO Process) did not use sulfonyl chloride; it uses thionyl chloride as a reagent. The court, *prima facie*, accepted that thionyl chloride has a different and a distinct role and that the NATCO Process employed a different sequence of reactions. Accordingly, the Court, *prima facie*, found that the difference between the suit patent and the NATCO Process was not minor or insubstantial.

17. The Court relied extensively on the responses received from the two expert scientific advisers and found that they had clearly opined that the two processes were not similar and that sulfonyl chloride did constitute an essential feature of the suit patent IN'645. Accordingly, the Court permitted NATCO to launch its product – CTPR, albeit subject to a condition that it would remain bound by the undertaking that it will not use the process as claimed in the suit patent IN'645 or any other process that infringed the said patent. In addition, NATCO

was directed to keep accounts of the sales and file the same along with an affidavit on a quarterly basis.

Submissions

18. Mr. Ramesh Singh, learned Senior Counsel appearing on behalf of the appellants, in effect, sought to reagitate the contentions as advanced before the learned Single Judge. He submitted that the NATCO Process for preparing CTPR was not identical to the FMC process (suit patent) but applying the doctrine of equivalents, it infringed the suit patent. He submitted that the NATCO Process and the suit patent entail stoichiometric activation of the carboxylic acid intermediate, leading to a coupling reaction between the activated acid intermediate and the aniline intermediate. He stated that this was the essential feature of the suit patent IN'645. The use of thionyl chloride in the NATCO Process instead of sulfonyl chloride as a reagent is an insubstantial variation as sulfonyl chloride was not essential to the suit patent IN'645. Next, he submitted that the learned Single Judge had grossly erred in not appreciating the response submitted by the expert advisers. He submitted that one of the scientific advisers had clearly opined that the NATCO Process and the suit patent IN'645 were equivalents, however, this was misunderstood and disregarded by the learned Single Judge. He submitted that the physical and chemical properties of the reagents used in the two processes (thionyl chloride and sulfonyl chloride) were not relevant for the purpose of determining whether there was an indirect infringement on the basis of the doctrine of equivalents. He submitted that the NATCO Process was equivalent

to the suit patent IN'645 because it performed substantially the same function – stoichiometric activation of carboxylic acid intermediate in, substantially, the same way [coupling of carboxylic acid intermediate (Formula 2) with aniline intermediate (Formula 3)] to achieve the same result. He has also submitted that the by-products of the NATCO Process are immaterial / inessential / trifling / trivial / minor variation and were required to be disregarded. He, earnestly, contended that what was important was the main product, CTPR, and not the by-products.

19. He relied on the decision of this Court in ***Sotefin SA v. Indraprastha Cancer Society and Research Center & Ors.: 2022 SCC OnLine Del 516***; the decision of the House of Lords in ***Beecham Group Ltd. vs. Bristol Laboratories Ltd. & Ors.: 1978 RPC 153***; and the decision in ***Warner-Jenkinson Co., INC v. Hilton Davis Chemical Co.: 520 US 17***, in support of his contention that the infringing product or process need not be identical to the patent but if it is substantially the same and the variations are insignificant, the patent would be infringed.

20. Mr. J. Sai Deepak, learned counsel appearing for NATCO, opposed the present appeal. He contended that the endeavour of FMC was to evergreen its patent relating to CTPR and continue to prevent use of the patent much after the patent rights have expired. He submitted that FMC had applied for and was granted a Markush claim (IN'978), which expired on 21.03.2021. According to FMC, CTPR was part of the Markush claim covered under the said patent. Notwithstanding the same, FMC had also acquired registration of specific patent in respect of CTPR (IN'307) as well as the process patent

(IN'332). He submitted that both IN'307 and IN'332 were liable to be revoked, as according to FMC, IN'978 had claimed and disclosed CTPR. Notwithstanding the same, FMC had filed suits for enforcement of the said patent and had successfully obtained ad-interim / interim orders, which effectively prevent NATCO from manufacturing the product despite expiry of the said patent. He submitted that claiming patent in the method of CTPR was yet another attempt to evergreen the patent.

21. He countered the submissions that the response of the scientific advisers supported the case of the appellants as contended. He drew the attention of this Court to the responses as well as the analysis of the learned Single Judge in the impugned order and contended that the scientific advisers, appointed by the court, had found that sulfonyl chloride was an essential part of IN'645. He also submitted that the doctrine of equivalents had limited application in a method patent. He submitted that insofar as the product patent is concerned, the same may be relevant but a process patent would be infringed only if the impugned process is identical. He contended that the NATCO process is materially different as it is a two-step process requiring two reactors. In the first step, NATCO uses thionyl chloride to convert pyrazole carboxylic acid to pyrazole acid chloride. In the second step, the acid chloride obtained in the first step is reacted with aniline without using sulfonyl chloride or even thionyl chloride. He submitted that the yield of CTPR by the NATCO Process is lower than the yield of CTPR produced by employing the suit patent IN'645. However, the NATCO

Process, unlike the suit patent IN'645, produces no toxic by-products. He contended that these variations cannot, by any stretch, be considered as insignificant.

22. Mr. J Sai Deepak emphasised that FMC had served the copy of the plaint in less than an hour of receiving NATCO's notice. Although FMC had requested for disclosure of the details of the NATCO Process, it did not wait for the same and proceeded to institute the suit on the belief that NATCO had infringed the suit patent. He stated that they intended to prove the same by establishing the impurity profile by the NATCO Process as similar to that of the suit patent. This would indicate that NATCO was also using Sulfonyl Chloride. He contended that it is established from the dissimilarity in the impurity profile that the NATCO Process is not the same as the suit patent. However, after having realised the same, the appellants have shifted the stance to claim doctrine of equivalents. He contended that the terms of reference framed by FMC, for opinion by the scientific adviser, was also largely designed to establish the similarity in the impurity profile.

Reasons & Conclusions

23. It is apparent from the above that there is no dispute that the NATCO Process is not identical to the claims disclosed in the suit patent. The controversy is confined to examining whether the NATCO Process can be considered as infringing the suit patent, IN'645, by virtue of the doctrine of equivalents.

24. The doctrine of equivalents is applicable where a product or process is not identical to the claim granted in a patent but its essential elements are sufficiently similar to the patented claim, so as to construe the product or process as infringing the patent.

25. In ***Clark v. Adie***: ***(1877) 2 App.Cas. 315,*** the House of Lords considered an appeal where the plaintiff had claimed that horse clippers or horse clipping machines being manufactured by the defendant had violated a patent that related to "*improvement in apparatus for clipping or shearing horses*". The patented invention related to improvement in construction of the apparatus for clipping horses and for shearing and clipping of other animals. The patentee claimed that the use of the patented device had significant advantages in the means of adjusting the cutter to a variety of positions. Several components of the defendant's machine were somewhat similar to those used in the patented device but certain other parts were not. The defendant claimed that there was no infringement, as various parts of clipping machine were already disclosed by the prior art. This was apparent as the patented invention was merely an improvement of known devices. Although the appeal preferred by the patentee was dismissed, Lord Cairns, in his opinion, had referred to the test of 'pith and marrow' as relevant in cases where the infringer had not copied the entire instrument but had made colourable changes. The relevant extract of the said decision referring to such kind of infringement is set out below**: -**

> **"**One mode of infringement would be a very simple and clear one; the infringer would take the whole

> instrument from beginning to end, and would produce a clipper made in every respect like the clipper described in the specifications. About an infringement of that kind no question could arise. The second mode would be one which might occasion more difficulty. The infringer might not take the whole of the instrument here described, but he might take a certain number of parts of the instrument described, he might make an instrument which in many respects would resemble it in all its parts. And there the question which would be either for a jury or for any tribunal which was judging of the facts of the case, whether that which was done by the alleged infringer amounted to a colourable departure from the instrument patented, and whether in what he had done he had not really taken and adopted the substance of the instrument patented. And it might well be, that if the instrument patented consisted of twelve different steps, producing in the result the improved clipper, an infringer who took eight, or nine, or ten of these steps might be held by the tribunal judging of the patent to have taken in substance the pith and marrow of the invention, although there were one, two, three, four, or five steps which he might not actually have taken and represented on his machine."

26. In ***Beecham Group Ltd. vs. Bristol Laboratories Ltd. & Ors.*** (*supra*), Lord Diplock had referred to the decision in the case of ***Clark v. Adie*** (*supra*) and other decisions to explain the import of doctrine of equivalents. The relevant extract of the said decision is set out below:

> "Contemporaneously with the rise of the doctrine of infringing importation there was developing another doctrine known by the phrase adopted by Lord Cairns, L.C. in *Clark v. Adie* (1877) 2 App. Cas. 315 as that of "pith and marrow". It first arose in connection with mechanical patents for machines or processes which made use of novel combinations of

known mechanical principles. Regarded separately each element or integer in the machine or process might not be new; the novelty and accordingly the invention lay in the particular combination of them. When *Clark v. Adie* was in the Court of Appeal (1875) L.R. 10 Ch. 667) James, L.J. was able to say: "In fact, every, or almost every, patent is a patent for anew combination". The doctrine which, in the case of mechanical patents to which it has principally been applied, is also known as the doctrine of "equivalents", which lucidly stated by Lord Parker, then Parker, J., in *Marconi v. British Radio Telegraph* and *Telephone Co. Ltd.* (1911) 28 R.P.C. 181 at 217, where he said: "Where … the combination or process, besides being itself new, produces new and useful results, everyone who produces the same results by using the essential parts of the combination or process is an infringer, even though he has, in fact, altered the combination or process by omitting some unessential part or step and substituting another part or step which is equivalent to the part or step that he has omitted."

The increasing particularity with which the claims are drafted and multiplied in modern specifications may have reduced the scope of application of the doctrine of pith and marrow, but I am unable to accept the argument advanced by Bristol that this has made the doctrine obsolete. It still remains a part of patent law as is acknowledged in speeches delivered in this House as recently as *C. Van der Lely N.V. v. Bamfords Ltd.* [1963] R.P.C. 61: *Rodi & Weinenberger A.G. v. Henry Showell Ltd.* [1969] R.P.C. 367. Directed as it is against colourable evasion of a patent it is not in my view confined to mechanical inventions or to claims for new combinations of integers, but in appropriate cases, though they may be rare, is applicable to claims for new products."

27. In ***Graver Tank & Mfg. Co. v. Linde Air Products Co.: 339 U.S. 605 (1950)***, the Supreme Court of the United States applied the doctrine of equivalents. The following passages from the said judgement, delivered by Justice Jackson, that explain the said doctrine and its applicability, are relevant:

> "4. But courts have also recognized that to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for—indeed encourage—the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law. One who seeks to pirate an invention, like one who seeks to pirate a copyrighted book or play, may be expected to introduce minor variations to conceal and shelter the piracy. Outright and forthright duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and would be subordinating substance to form. It would deprive him of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent system.
>
> 5. The doctrine of equivalents evolved in response to this experience. The essence of the doctrine is that one may not practice a fraud on a patent. Originating almost a century ago in the case of Winans v. Denmead, 15 How. 330, 14 L.Ed. 717, it has been consistently applied by this Court and the lower federal courts, and continues today ready and

available for utilization when the proper circumstances for its application arise. 'To temper unsparing logic and prevent an infringer from stealing the benefit of the invention'1 a patentee may invoke this doctrine to proceed against the producer of a device 'if it performs substantially the same function in substantially the same way to obtain the same result.' Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42, 50 S.Ct. 9, 13, 74 L.Ed. 147. The theory on which it is founded is that 'if two devices do the same work in substantially the same way, and accomplish substantially the same result, they are the same, even though they differ in name, form or shape.' Union Paper-Bag Machine Co. v. Murphy, 97 U.S. 120, 125, 24 L.Ed. 935. The doctrine operates not only in favor of the patentee of a pioneer or primary invention, but also for the patentee of a secondary invention consisting of a combination of old ingredients which produce new and useful results, Imhaeuser v. Buerk, 101 U.S. 647, 655, 25 L.Ed. 945, although the area of equivalence may vary under the circumstances. See Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 414—415, 28 S.Ct. 748, 749, 52 L.Ed. 1122, and cases cited; Seymour v. Osborne, 11 Wall. 516, 556, 20 L.Ed. 33; Gould v. Rees, 15 Wall. 187, 192, 21 L.Ed. 39. The wholesome realism of this doctrine is not always applied in favor of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement. Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 568, 18 S.Ct. 707, 722, 42 L.Ed. 1136. In its early development, the doctrine was usually applied

in cases involving devices where there was equivalence in mechanical components. Subsequently, however, the same principles were also applied to compositions, where there was equivalence between chemical ingredients. Today the doctrine is applied to mechanical or chemical equivalents in compositions or devices. See discussions and cases collected in 3 Walker on Patents (Deller's ed. 1937) §§ 489—492; Ellis, Patent Claims (1949) §§ 59—60.

6. What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. It does not require complete identity for every purpose and in every respect. In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents. Consideration must be given to the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform. An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was.

7. A finding of equivalence is a determination of fact. Proof can be made in any form: through testimony of experts or others versed in the technology; by documents, including texts and treatises; and, of course, by the disclosures of the prior art. Like any other issue of fact, final determination requires a balancing of credibility, persuasiveness and weight

> of evidence. It is to be decided by the trial court and that court's decision, under general principles of appellate review, should not be disturbed unless clearly erroneous. Particularly is this so in a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience."

28. In ***Warner-Jenkinson Co., INC v. Hilton Davis Chemical Co.*** (*supra*), the Supreme Court of the United States expressed the concern that the doctrine of equivalents, as it had come to be applied since the decision of ***Graver Tank & Mfg. Co. v. Linde Air Products Co.*** (*supra*), has "*taken on a life of its own unbounded by patent claims*". The Court also observed that the doctrine of equivalents when applied broadly "*conflicts with the definitional and public-notice functions of the statutory claiming requirement."*

29. The Court also observed that in a case where an invention is expressed as a combination of elements, the doctrine of equivalents would refer to equivalency of each element or part of the invention, which is substituted in the allegedly infringing product or process. The relevant extract from the judgement reads as under:

> "…..Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety……"

30. The Court also discussed whether equivalents are required to be determined by applying the triple test – the function served by a particular element; the manner in which the function is performed; and the results obtained by the element – or by applying the test whether the differences are substantial. In this context, the Court observed as under:

> "All that remains is to address the debate regarding the linguistic framework under which "equivalence" is determined. Both the parties and the Federal Circuit spend considerable time arguing whether the so-called "triple identity" test—focusing on the *function* served by a particular claim element, the *way* that element serves that function, and the *result* thus obtained by that element—is a suitable method for determining equivalence, or whether an "insubstantial differences" approach is better. There seems to be substantial agreement that, while the triple identity test may be suitable for analyzing mechanical devices, it often provides a poor framework for analyzing other products or processes. On the other hand, the insubstantial differences test offers little additional guidance as to what might render any given difference "insubstantial."
>
> In our view, the particular linguistic framework used is less important than whether the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention? Different linguistic frameworks may be more suitable to different cases, depending on their particular facts. A focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements should

> reduce considerably the imprecision of whatever language is used. An analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry 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."

31. The doctrine of equivalents has been accepted in the jurisprudence to protect patent rights from being infringed by infringers using colourable method of making some minor, insubstantial variations to escape the reach of the patent. The doctrine of equivalents, in essence, seeks to address infringers who introduce minor variations as subterfuge to defeat patent rights. The doctrine is applied to ascertain whether there is an infringement by excluding any insubstantial, minor or trivial changes that are designed to deprive the patentee of the benefits of his invention.

32. The doctrine of equivalents is applicable only in cases where the variation or difference between the product or process and the patented claim is insignificant, insubstantial and not essential to the patented claim. In order to determine whether, on the basis of doctrine of equivalents, a product or process infringes the patent, it is essential to determine the essence and scope of the patent. It is important to understand as to what is the invention that is patented. If the invention is infringed by a product or process, the minor differences in the non-essential trappings of the product or process would be irrelevant.

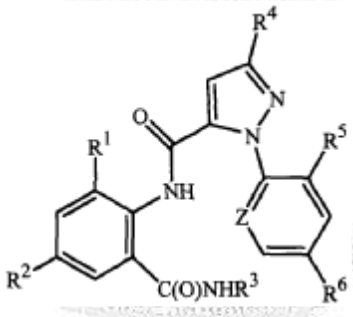
33. This Court is unable to accept the contention that the doctrine of equivalents is only relevant in case of a product patent and not a process patent. If an innovation – whether it is a product or a process – is pirated, an action to prevent such infringement cannot fail solely for the reason that the offending product or the process has certain minor and insubstantial variations or differences as compared to the patent.

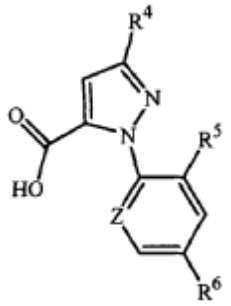
34. The triple test – substantially the same function, in substantially the same way and to yield the same result – is applied primarily to products or devices. A device which substantially performs the same function, in substantially the same way, and accomplishes the same result, may infringe the patent rights. However, when it comes to a process or a method, this test may require to be suitably adapted. In a case where a method of achieving a result is the essence of the patent, achieving substantially the same result would clearly not be relevant. The method with which the result is obtained would be material to determining whether the patent has been infringed. The test of substantial identity of the competing methods must necessarily be viewed by identifying the essential elements and steps of the said process and then examining the manner in which the key elements interact in each essential step that the process/method entails to yield the given result. The essential elements of the given process; the necessary steps of that process; and the manner in which the essential elements interact at each step must be substantially similar to the patented process or method to sustain a claim of infringement. The variations in the competing methods require to be compared to ascertain

whether they are minor/trifling and inessential and have been introduced only to camouflage piracy.

35. In the context of this case, the key question to be considered is whether the sulfonyl chloride is an essential element of the suit patent IN'645.

36. It would be apposite to refer to the relevant claims granted in the suit patent IN'645. The said claims – twelve in number – are set out below:

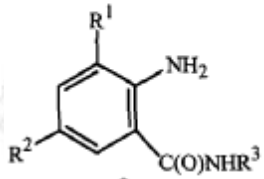
> "1. A method for preparing a compound of Formula 1,
>
> 
>
> wherein
> R^1 is CH_3 or Cl;
> R^2 is Br, Cl, l or CN;
> R^3 is H or C1-C_4 alkyl;
> R^4 is CI, Br, CF_3, OCF_2H or OCH_2CF_3;
> R^5 is F, Cl or Br;
> R^6 is H, F or Cl;
> Z is CR^7 or N; and
> R^7 is H, F, Cl or Br; comprising:
>
> combining (1) a carboxylic acid compound of Formula 2,



2

(2) an aniline compound of Formula 3,

51



3

and (3) a sulfonyl chloride to form the compound of Formula 1.

2. The method as claimed in claim 1 wherein the sulfonyl chloride is of Formula 4

$$R^8S(O)_2Cl$$

4

wherein R^8 is C_1-C_4 alkyl, C_1-C_2 haloalkyl, or phenyl optionally substituted with 1-3 substituents selected from the group consisting of halogen, C_1-C_3 alkyl and nitro.

3. The method as claimed in claim 2 wherein the sulfonyl chloride is methanesulfonyl chloride.

4. The method as claimed in claim 1 wherein the carboxylic acid of Formula 2 is combined with the aniline of Formula 3 to form a mixture, and then the mixture is combined with the sulfonyl chloride.

5. The method as claimed in claim 4 wherein a base is combined with the compounds of Formulae 2 and 3 to form the mixture before combining with the sulfonyl chloride.

6. The method as claimed in claim 5 wherein the base is selected from tertiary amines.

7. The method as claimed in claim 6 wherein the base is selected from optionally substituted pyridines.

8. The method as claimed in claim 7 wherein the base is selected from 2-picoline, 3-picoline, 2,6-lutidine and pyridine.

9. The method as claimed in claim 8 wherein the sulfonyl chloride is of Formula 4

$$R^8S(O)_2Cl$$

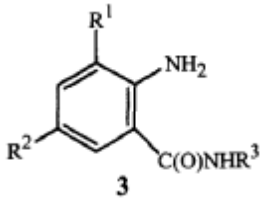
4

wherein R^8 is C_1-C_4 alkyl, C_1-C_2 haloalkyl, or phenyl optionally substituted with 1-3 substituents selected from the group consisting of halogen, C_1-C_3 alkyl and nitro.

10. The method as claimed in claim 1 or claim 4 wherein a solvent is combined with the compounds of Formulae 2 and 3 and the sulfonyl chloride.

11. The method as claimed in claim 10 wherein the solvent is acetonitrile.

12. A compound of Formula 3



3

wherein
R^1 is CH_3 or Cl;
R^2 is Br, Cl, l or CN; and
R^3 is H or C1-C4 alkyl;

provided that

(a) when R^1 and R^2 are Cl, then R^3 is other than H, CH_2CH_3, or $CH(CH_3)CH_2CH_3$;

(b) when R^1 is CH_3 and R^2 is Cl, Br or CN, then R^3 is other than CH_3 or $CH(CH_3)_2$;

(c) when R^1 is Cl and R^2 is Cl or Br, then R^3 is other than CH_3 or $CH(CH_3)_2$; and

(d) when R^1 is CH_3 and R^2 is CN, then R_3 is other than H."

37. The twelfth claim refers to alternative aniline compound and is not relevant for the purpose of the present controversy. As noted above, FMC claims that the method as disclosed in Claim nos.1, 5 to 8 and 11 is infringed.

38. It is apparent from a plain reading that the method disclosed in Claim no.1 is combining a carboxylic compound of Formula 2 with an aniline compound of Formula 3 and a sulfonyl chloride to form compound of Formula 1. The compound sulfonyl chloride has been specifically mentioned and therefore, absent any indication to the contrary, must be accepted as an essential part of the claim. It is also material to note that the sulfonyl chloride or other compounds of sulfonyl chloride have been specifically mentioned in Claim nos.2, 3, 4, 9 and 10. Claim nos.6, 7 and 8 also include use of sulfonyl chloride as they merely substitute compounds other than sulfonyl chloride, as used in other claims, but specifically includes use of sulfonyl chloride.

39. Mr. Ramesh Singh contended that the essential feature of the patent is not sulfonyl chloride, but it is the stoichiometric activation leading to a coupling action. He submitted that there are only three other strategies for activating carboxylic acid; the other two being thermal and catalytic. *Prima facie*, this Court is unable to accept the said contention. The claims or the detailed description of the invention do not specifically indicate that the novel inventive feature of the suit patent is the stoichiometric activation of carboxylic acid intermediate with an aniline intermediate, as opposed to thermal or catalytic.

40. The specifications expressly state that *"this invention relates to a method for preparing compounds of Formula-I by coupling carboxylic acids of Formula-2 with anthranilamides of Formula-3 using a sulfonyl chloride, typically in the presence of a base and a solvent*" (emphasis supplied). A plain reading of the detailed

description of the invention also indicates that sulfonyl chloride compound has been used as an essential part of the invention. The description specifically states that sulfonyl chloride compound is used as a reactant to facilitate coupling of carboxylic acid with anthranilamide to form the N-phenylpyrazole-1-carboxamide. The description also states that the rate of reaction is controlled by controlling the rate of addition of sulfonyl chloride compound. It specifically stated that sulfonyl chloride compounds are preferred for the method because of its commercial availability. Methane sulfonyl chloride is preferred for the reason of lower costs, ease of addition and / or less waste. The following extract from the detailed description of the invention, as disclosed, is relevant:

> "In the present method, the sulfonyl chloride is combined with the pyrazolecarboxylic acid of Formula 2 and the aniline of Formula 3. The reactants can be combined in a variety of orders, such as combining the sulfonyl chloride with the carboxylic acid of Formula 2 to form a mixture and then combining the mixture with the aniline of Formula 3. However, for preparing the particular *N*-phenylpyrazole-I-carboxamides of Formula 1, the most preferable order of combination has been found to comprise combining the carboxylic acid of Formula 2 with the aniline of Formula 3 to form a mixture and then combining the sulfonyl chloride with the mixture (e.g., adding the sulfonyl chloride to the mixture of the compounds of Formulae 2 and 3), because this order of the addition allows convenient control of the coupling process. The rate of reaction is readily controlled by simply controlling the rate of addition of the sulfonyl chloride compound. Therefore an embodiment of note of the present method comprises

> the sequential steps of (l) combining a carboxylic acid of Formula 2 and an aniline of Formula 3 to form a mixture, and (2) then combining the mixture with a sulfonyl chloride. Although addition of the sulfonyl chloride to the mixture containing the aniline of Formula 2 potentially could result in undesirable side reactions, it has been discovered that the particular stereoelectronic profiles of the compounds of Formulae 2 and 3 facilitate obtaining remarkably high yields of compounds of Formula I using the present method."
>
> [emphasis supplied]

41. *Prima facie*, the aforesaid extract also makes it clear that sulfonyl chloride is an integral part of the method as disclosed. The patent applicant had also disclosed that use of sulfonyl chloride results in undesirable side reactions but it is discovered that given the profiles of Formula 2 (compounds of carboxylic acids) and Formula 3 (aniline compounds) results in "*remarkably high yields*" of CTPR.

42. We do not consider it necessary to refer to other passages of "*the detailed description of the invention*" furnished to the Patent Office. Suffice it to state that they also support the aforesaid view that sulfonyl chloride is not reflected as an incidental part of the invention but an integral part. *Prima facie*, it would be erroneous to consider the suit patent IN'645 as an invention that does not involve the use of sulfonyl chloride.

43. The learned Single Judge had, with the consent of the parties, appointed the scientific advisers. Both the parties had referred their queries to the scientific advisers. The learned Single Judge had

examined the same and had found that the response of the scientific advisers fully supported the view that sulfonyl chloride is an essential part of the suit patent IN'645 and the NATCO Process, which used the thionyl chloride, was materially different.

44. The response of Dr. Gopakumar Nair to some of the terms of reference referred to by NATCO and FMC are set out below:

> "Response to NATCO's terms of reference:
>
> ***3. Is the reagent thionyl chloride used in the Natco process for converting the pyrazole carboxylic acid to acid chloride the same as the reagent used for coupling the pyrazole carboxylic acid with aniline as set out in Claims 1 to 11 of IN 298645? Do thionyl chloride which is an inorganic chloride, and sulfonyl chlorides which are organic chlorides, have different physical and chemical characteristics?***
>
> **Reply: The reagents, thionyl chloride and sulfonyl chlorides are different. The said reagents have different physical and chemical characteristics.**
>
> **The reagent thionyl chloride (SOC12) used in Natco's process is different from the reagent sulfonyl chloride of formula 4 i.e. R8S(O)2C1 claimed in claims 1 to 11 of IN298645. The suit patent IN'645 particularly uses methane sulfonyl chloride as claimed in claim 3.**
>
> The inorganic chloride i.e. thionyl chloride (S0C12) has different physical and chemical properties in comparison to the organic chloride

sulfonyl chloride (RSO2C1) **which comprises an alkvl group**.

4. Is Methane Sulfonic acid impurity present in Natco product as per data given in CIBRC dossier?

Reply: No

There is no Methane Sulfonic acid impurity present in the Natco product as per data given in CIBRC dossier.

5. Are the following two process distinct or the same?

Reply: Distinct as explained below.

The processes of Natco (Defendant) and of the suit Patent IN298645 are distinct.

In the Natco's process, 3-Bromo-l -(3-chloro-2-pyridinyl)-l Hpyrazole-5-carboxylic acid is reacted in the first reactor with thionyl chloride (SOC12) to obtain the intermediate acid chloride. In another rector to the acid chloride intermediate is added the mixture of 2-Amino-5-chloro-N,3-dimethylbenzamide in base such as 3-picoline to yield the final product chlorantraniliprole of Formula-Ia wherein X is Cl.

In suit patent IN298645, the carboxylic acid of formula 2 (e.g.3-Bromo-1-(3-chloro-2-pyridinyl)-l H-pyrazole-5-carboxylic acid) and the aniline of formula 3 (e.g. 2-Amino-5-chloro-N,3-dimethylbenzamide) are first mixed in base to obtain the mixture followed by addition of sulfonyl chloride (R8S(0)2C1) to yield the final product of

formula 1, as claimed in claim 1 and claim 4 and described in the specification.

In the suit patent IN'645 all the three reagents are added at one time for the reaction to occur.

It has been noted that the by-products in Natco's (Defendants process are SO2(gas) and HCI (gas), whereas, in the suit patent IN298645 the by-product is solid methane sulphonic acid at the process temperature conducted.

Hence, the process of Natco Pharma is different from IN298645.

7. ***In the NATCO Process when thionyl chloride is used the chloride group is attached to the carboxylic acid group in the pyrazole carboxylic acid to form carbonyl chloride which is not a mixed anhydride. Is this correct?***

Reply: Yes, it is correct.

8. ***Is the NATCO process which requires reacting a pyrazole carboxylic acid with thionyl chloride to obtain an acid chloride and then reacting the acid chloride so formed with an aniline within the scope of Claims 1 to 5 of IN'645? Is that correct?***

Reply: No

Natco's Process **is distinct** from the process claimed in claims 1 to 5 of IN'645. Moreover, in IN'645 sulfonyl chloride is used and also all the three reagents i.e. the acid, the aniline compound and sulfonyl chloride are added at the same time in a single reactor. In Natco's process the carboxylic acid is first converted to its acid chloride using

thionyl chloride in a reactor. The acid chloride so obtained is reacted with 2- Amino-5-chloro-N,3-dimethylbenzamide in another reactor to obtain the product."

Response to some of FMC's terms of reference:

"(i) Whether the Defendant's process is disclosed in the complete specification of the suit patent IN'645?

Reply: No.

(ii) What are the essential feature(s) of the process covered and claimed by the suit patent IN'645?

Reply: The essential features of the process covered in the suit patent IN'645 comprises;(a) the carboxylic compound of Formula 2;(b) the aniline compound of Formula 3; the sulfonyl chloride R8S(O)2C1 of Formula 4.

(iii) Whether the Defendant's process for preparing Chlorantraniliprole (CTPR) is covered and claimed by the process claimed by the suit patent IN'645?

Reply: No

The defendant's process for preparing Chlorantraniliprole (CTPR) **is not covered** by the process claimed by the suit patent IN'645.

(v) Whether 3-Bromo-l-(3-chloro-2-pyridinyl)-lH-pyrazole-5 carboxylic acid and 2-Amino-5-chloro-N,3-dimethylbenzamide used in the Defendant's process for preparing Chlorantraniliprole (CTPR) are same as claimed by the suit patent IN'645?

Reply: No

In Natco's process the *3-Bromo-l-(3-chloro-2-pyridinyl)-lH-pyrazole-5 carboxylic acid* is converted to its acid chloride prior to reaction with *2-Amino-5-chloro-N, 3-dimethylhenzamide.*

(vi) Whether 3-Bromo-l-(3-chIoro-2-pyridinyt)-lH-pyrazole-5 carboxylic acid and 2-Amino-5-chloro-N,3-dimethylbenzamide used in the Defendant's process for preparing Chlorantraniliprole (CTPR) are equivalent as claimed by the suit patent lN'645?

Reply: Yes.

However, in Natco's process the *3-Bromo-l-(3-chloro-2-pvridinvl)- lH-vvrazole-5 carboxylic acid* is converted to its acid chloride prior to reaction with *2-Amino-5-chloro-N,3-dimethvlbenzamide.*"

45. It is clear from the plain responses of Dr. Gopakumar Nair that he found the NATCO Process to be materially different from the suit patent IN'645. Mr. Ramesh Singh had referred to the response of Dr. Nair to FMC's Query no.(iv) and contended that he had accepted the NATCO Process to be equivalent to the suit patent and the learned Single Judge had misinterpreted his opinion.

46. FMC's Query no. (iv) and Dr. Nair's response to the same are reproduced below:

"***(iv) Whether the Defendant's process for preparing Chlorantraniliprole (CTPR) is***

equivalent to the process claimed by the suit patent IN'645?

Reply: Yes, though not literally. The equivalence is distinguished in resultant impurity profile, which differs between the Plaintiffs process and the Defendant's process.

In the suit patent IN'645, the process for preparing Chlorantraniliprole (CTPR) comprises reacting carboxylic acid of Formula 2, the aniline compound of Formula 3 and **the sulfonyl chloride of Formula particularly methane sulfonyl chloride in a single reactor**.

Moreover, in IN'645 process due to the use of methane sulfonyl chloride **there is formation of the solid toxic by-product methane sulfonic acid which is hazardous to the environment**. In Natco's process the use of thionyl chloride results in S02(gas) and HCI (gas) which are released and may be collected and converted to respective acids. **There is no formation of solid by-products that could cause harm to the environment in the Natco's process**. Further, IN'645 employs costly reagent methane sulfonyl chloride, compared to thionyl chloride used by the Defendant.

The results of the reaction using methane sulfonyl chloride compared to the reaction using thionyl chloride does not produce the same result in view of the resultant characteristics of the by-products and impact of the impurity profile of the final product. As such there is no equivalence."

47. There is no ambiguity in the response of Dr. Nair that the NATCO Process is not equivalent to the process disclosed in the suit patent. It would be a complete misreading of the response if the first sentence is read without reading further explanation. Dr. Nair had, in unambiguous terms, stated that the results of the reaction using methane sulfonyl chloride, compared to the reaction using thionyl chloride, does not produce the same result, in view of the resultant characteristics of the by-products. It is also important to note Dr. Nair's response to FMC's Query no. (v) as well. He had explained that the NATCO Process and the process claimed in the suit patent were not the same because in the NATCO Process, the compound of carboxylic acid is converted to its acid chloride prior to reaction with *2-Amino-5-chloro-N, 3-dimethylhenzamide*. Thus, the NATCO Process is a two-step process, with the first reaction yielding an acid chloride and the second reaction involves the acid chloride and base (compounds of Formulae 3) to yield CTPR. On the other hand, the suit patent discloses a single reaction, where sulfonyl chloride is added to the mixture of compounds of Formula 2 and Formula 3.

48. The contention that the response of Dr. Nair supports the view that the NATCO Process is equivalent to the process disclosed in the suit patent and the learned Single Judge had misinterpreted it is, in our view, insubstantial.

49. The responses submitted by Prof. Bhalchandra Mahadeo Bhanage, appointed by the Court, to the terms of reference submitted by the parties, is not materially different. Prof. Bhanage has responded

to FMC's Query no. (iv) – "*whether the Defendant's process for preparing CTPR is equivalent to the process claimed by the suit patent IN'645*" – is in the negative.

50. The doctrine of equivalents must be applied to each element of the process. In the present case, the learned Single Judge had examined the elements of the process and had, *prima facie*, found that the use of thionyl chloride could not be considered as equivalent to the element of sulfonyl chloride in the suit patent. Admittedly, the properties of both the compounds are different. Whilst thionyl chloride is an inorganic compound, sulfonyl chloride is an organic compound. The manner in which the two reagents are used is also different. While in the suit patent, sulfonyl chloride is added to the mixture of carboxylic acid and aniline in one step, the same is not the process used by NATCO.

51. The learned Single Judge, after examining the material facts, concluded as under:

> "17. Case of the Plaintiffs is primarily predicated on the Doctrine of Equivalents and it is sought to be contended that even if the Natco process does not literally infringe the suit patent, it may be found to infringe on the bedrock of 'equivalence'. Contention of the Defendant is that element-to-element test must be applied and tested on that anvil, in the present case there is no infringement since the reagent i.e. sulfonyl chloride is an essential element in Plaintiffs' process and the Natco process admittedly uses thionyl chloride as the reagent, which has different and distinct role in achieving the same task and accomplishing substantially, the same result. Use of a different reagent and a completely different sequence

> of reactions in the Natco process cannot be termed as a minor or insubstantial variation, so as to accuse the Defendant of infringement and piracy."

52. We concur with the aforesaid *prima facie* finding. Accordingly, we find no reason to interfere with the impugned judgment.

53. Both the parties have submitted their Bill of Costs. NATCO's bill indicates that it has incurred litigation cost of ₹30,04,321/-. On examination of the Bill of Costs submitted by NATCO, we find that counsels' fee, aggregating to ₹2,70,000/-, is directly attributable to proceedings relating to this appeal.

54. Accordingly, in view of the above, the appeal is dismissed with costs quantified at ₹2,70,000/-, which shall be paid to NATCO within a period of two weeks from today.

VIBHU BAKHRU, J

AMIT MAHAJAN, J

DECEMBER 05, 2022
RK/GSR