* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% Judgment reserved on 09.03.2026
Judgment delivered on: 04.05.2026

\+ C.A.(COMM.IPD-PAT) 49/2023

SYNGENTA PARTICIPATIONS AG .....Appellant

versus

CONTROLLER OF PATENTS DESIGNS .....Respondent

**Advocates who appeared in this case:**

For the Appellant: Mr. Pravin Anand, Advocate with Ms. Arpita, Advocate.

For the Respondent: Ms. Manisha Agrawal Narain, CGSC with Mr. Navneet Saharan, Mr. Nipun Jain, Advocates.

**CORAM:**
**HON'BLE MR. JUSTICE TUSHAR RAO GEDELA**

**J U D G M E N T**

**TUSHAR RAO GEDELA, J.**

1. Present appeal has been filed under Section 117A of the Patents Act, 1970 (hereinafter referred to as "*the Act*") assailing the order dated 21.07.2023 passed by the respondent-Controller of Patents & Designs (hereinafter referred to as "*learned Controller*") refusing the Indian patent application titled *"POLYMORPHS OF 3-DIFLUOROMETHYL-1 -METHYL-1 H-PYRAZOLE-4-CARBOXYLIC ACID (9-DICHLOROMETHYLENE -1,2,3,4-TETRAHYDRO-1,4-METHANO -NAPHTHALEN-5-YL)-AMIDE*" bearing no.

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201617031900 (hereinafter referred to as "*subject application*"), on the ground of lack of inventive step under Section 2(1)(ja) and Section 3(d) of the Act.

**BRIEF FACTS:-**

2. The subject application was filed on 19.09.2016 before the Indian patent office, and the corresponding PCT application was filed on 24.02.2015 claiming priority from application GB 1403438.3 filed on 27.02.2014.

3. The subject application was published on 13.01.2017. The First Examination Report (hereinafter referred to as "*FER*") was issued on 26.07.2019, and the response thereto was submitted by the appellant on 08.04.2020.

4. Thereafter, the hearing notice was issued on 03.04.2023, scheduling the hearing on 03.05.2023, which was attended by the appellant.

5. Thereafter, the appellant submitted the post hearing written submissions on 29.05.2023 and the impugned order was passed on 21.07.2023. It is this order which is challenged before this Court by way of the present appeal.

**CONTENTIONS OF THE APPELLANT:-**

6. Mr. Pravin Anand, learned counsel appearing for the appellant submits that the impugned order of the respondent is erroneous on the ground that the respondent has erred in rejecting thermal stability data provided in the specification and the affidavit of Dr. John Hone. As per the learned counsel, the respondent has erred in holding that the difference in thermal stability is an inherent property of any monohydrate form as compared to its non-hydrate/ anhydrous form. In support of the above, learned counsel has submitted that

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thermal stability is not an inherent property as polymorphic forms are unpredictable in nature. Further, the learned counsel also submitted that the respondent has failed to cite any reference to demonstrate that thermal stability is an inherent property of monohydrate crystalline polymorph of the compound of formula I. Reliance was placed on paragraph 34 of the judgement in ***AGFA NV & Anr. vs. The Assistant Controller of Patents and Designs & Anr., 2023:DHC:4030***.

7. Another ground raised by Mr. Anand, learned counsel is that the respondent has erred in holding that the monohydrate crystalline polymorph of compound of formula I lacks inventive step without considering the comparative data in terms of "lowering phytotoxicity" furnished by the appellant. He further submitted that the applicant has provided comparative data, and the law on inventive step does not identify that only a particular kind of data can qualify for such a determination.

8. A reliance was placed on the following judgements:

- ***F-Hoffmann-la Roche Ltd. &Anr. vs Cipla Ltd., 2015:DHC:9674-DB***
- ***Agriboard International LLC vs Deputy Controller of Patents & Designs, 2022:DHC:1206***

9. In support of the above, learned counsel further submitted that the applicant has conducted experiments to determine the thermal stability of the hydrate and anhydrous form by using Differential Scanning Calorimetry (DSC).

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10. As per the learned counsel, the applicant prepared slurries of both anhydrous polymorph form 1 as well as the monohydrate crystalline polymorph of compound of formula I in different water/methanol mixtures and at different temperatures. Reliance was placed on Example 3 and Table 3 of the complete specification (hereinafter referred to as "*CS*") of the subject application.

11. It was argued that the phase diagram shown in Table 3 indicates that temperatures more than of 60°C would be required to dehydrate the hydrate of compound (I) at normal ambient relative humidities, and this indicates that the hydrate of IN`1900 would be the stable form of compound (I) in suspension concentrate (hereinafter referred to as "*SC*") formulations. In addition, would also be more stable in other, non-aqueous, formulations after their dilution with water in the spray tank.

12. While referring to the said Example 5 of the CS of the subject application the learned counsel submitted that the two standard SC formulations were separately prepared using the anhydrous Form 1 polymorph and the hydrated polymorph. The SC of the anhydrous Form 1 was contaminated with 5% of the hydrated form and was placed in a temperature cycling oven varying from 0°C to 40°C over 12 hours. Thereafter, two weeks later, the sample was inspected and the microscopy showed that the size of the crystals had increased substantially. Some crystals were removed from the formulation and dried and thereafter, the powder X-ray diffraction pattern was collected and in the outcome, all of the anhydrous polymorph Form 1 were fully converted to the hydrated form. The comparative powder X-ray diffraction trace is shown in FIG. 7.

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13. Regarding the objection on the ground of Section 3(d) of the Act, the learned counsel for the appellant submitted that the respondent has erred in holding that the monohydrate crystalline polymorph of compound of formula I falls under Section 3(d) of the Act in the absence of non-consideration of the enhanced efficacy data in terms of "lowering phytotoxicity" over the anhydrous form of cited art.

14. Learned counsel further submits that the thermal stability data qualifies as enhanced efficacy data. The present invention pertains to the field of agrochemicals and Section 3(d) of the Act does not define efficacy for inventions in the field of agrochemicals unlike pharmaceuticals where the efficacy is defined as being therapeutic efficacy. Reliance was placed on the decision of the Supreme Court in ***Novartis vs. Union of India & Others: (2013) 6 SCC,*** only to submit that the test of therapeutic efficacy under Section 3(d) of the Act is limited only to medicines/pharmaceuticals preparation and not agrochemicals.

15. He also cited the judgment in ***Novozymes vs. Assistant Controller of Patent: (T) CMA (PT) No.33 of 2023*** delivered by the High Court of Madras. He submitted that thermal stability of the crystalline polymorph of the present invention results in lowering of phytotoxicity. It was submitted that a specific polymorph may have properties which make it more advantageous in a particular use compared to another polymorph of the same compound and the physical, chemical and biological properties can have a significant effect on the development of production methods and formulations and the quality as well as efficacy of plant treatment agents like fungicides.

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16. Thus, according to Mr. Anand, the impugned order needs to be set aside and matter remanded for *de novo* consideration.

**CONTENTIONS OF THE RESPONDENT:-**

17. *Per contra*, Ms. Manisha Agrawal Narain, learned CGSC for the respondent no.3, opposed the arguments addressed on behalf of the appellant.

18. She submitted that all the prior art documents D1 to D4 were considered as the closest prior art and the cited D1 discloses the crystalline form of the compound of present formula I (3- difluoromethyl-1 -methyl- 1 H-pyrazole-4-carboxylic acid (9- dichloromethylene-1, 2, 3, 4-tetrahydro-1, 4-methano- naphthalen-5-yl)- amide) and intermediates along with their preparation process. The following compounds from the cited prior arts were submitted by the learned CGSC:

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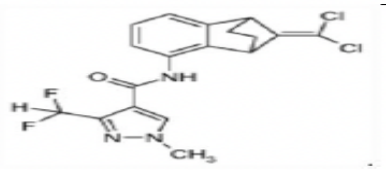
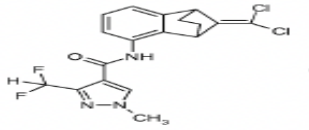
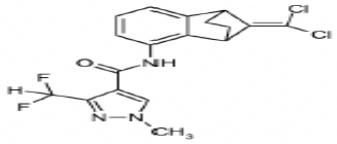
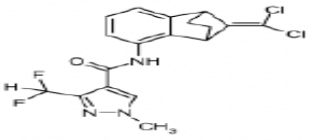
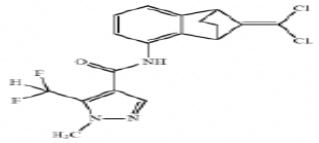
| Compound of present application | Compound of Prior art document |
|---|---|
|  |  (I).<br>Page 3, line 10 of D1 *(@pg. 311 of the Appeal Paperbook)*<br>  (I).<br>Page 21, line 9 of D2 *(@pg. 357 of the Appeal Paperbook)*<br>  (I).<br>Page 16, Line 19 of D3 *(@pg. 383 of the Appeal Paperbook)* |
| |  <br>Page 8, Paragraph [0080] of D4 *(@pg. 399 of the Appeal Paperbook)* |

19. She further submitted that D2 to D4 also disclose the same compound of formula I as well as its process for preparation. As per the learned CGSC, the compound of formula I prepared in the cited literature D1 to D4 generally involved in the crystallisation and/or recrystallisation process in non-aqueous medium that led to the formation of final crystalline product.

20. She submitted that the distinguishing feature of the present application compared to the cited prior arts is the "monohydrate" form of compound of formula I instead of "nonhydrate" form of compound of formula I. She further

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submitted that it is acknowledged that none of the cited documents discloses the "monohydrate" form of compound of formula I and therefore, the technical problem underlying the subject application has to be seen as the provision of further alternate "polymorph" form of compound of formula I having an unexpected effect with regard to the cited prior arts D1 to D4.

21. Learned CGSC for the respondent no. 3 further submitted that the present application does not contain any evidence for such surprising effect over the cited documents D1 to D4 and in the absence of such credible evidence of surprising effect over D1 to D4, the mandate of the inventive step under Section 2(1)(ja) of the Act cannot be considered to be satisfied.

22. She submitted that the X-ray diffraction pattern in claim 1 provided by the appellant is only characterisation data, and it cannot be considered as a technical feature of the presently claimed compound.

23. The learned CGSC submitted that regarding claim no 3, it is found that any agro-chemically active compound should only be applied in form composition and therefore, as discussed in the preceding para, claim no.3 does not meet the requirements of Section 2(1)(ja) of the Act.

24. Regarding the objection under Section 3(d) of the Act, it was submitted that as the compound in its "nonhydrate/anhydrous" form is already known from cited prior arts, the claimed crystalline "monohydrate polymorph" of the subject application is considered as "new form of known substance which does not result in the enhancement of known efficacy". Therefore, the subject matter as claimed in claim nos.1 and 2 is not allowable under Section 3(d) of the Act.

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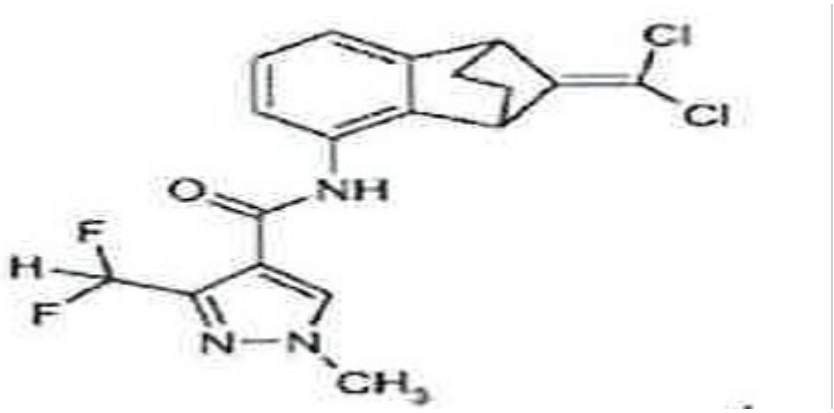
**ANALYSIS AND CONCLUSION:-**

25. The present invention is directed to a crystalline polymorph of compound of formula I which is a monohydrate containing 4.3 ± 0.2% w/w water. This polymorph has a dehydration/melting point of between 80 and 125°C. The polymorphs of the present invention can be used for the control of plant pathogenic fungi on a number of plant species. The invention of IN' 1900 relates to a new solid form of I, 3-difluoromethyl-1-methyl-lH-pyrazole-4-carboxylic acid (9-dichloromethylene-1,2,3,4-tetrahydro-l,4-methano-naphthalen-5-yl)-amide which is compound of formula I. The structure of formula I is as follows:




26. The claims refused *vide* impugned order are as follows:

*"We claim:*

*1. A crystalline polymorph of the compound of formula I*

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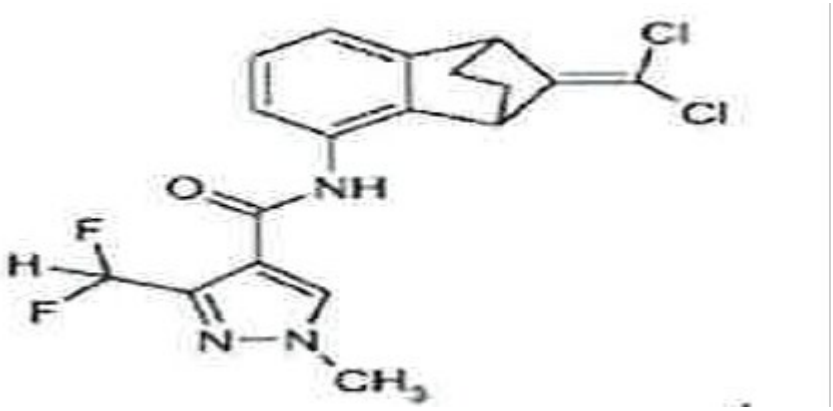


*which has a powder X-ray diffraction pattern comprising at least three d values, measured in Å, selected from the group consisting of 10.45 ± 0.2, 7.45 ± 0.2, 6.71 ± 0.2, 6.31 ± 0.2, 5.99 ± 0.2, 5.42 ± 0.2, 5.23 ± 0.2, 4.78 ± 0.2, 4.60 ± 0.2, 4.53 ± 0.2, 4.33 ± 0.2, 4.14 ± 0.2, 3.97 ± 0.2, 3.86 ± 0.2, 3.73 ± 0.2, 3.62 ± 0.2, 3.49 ± 0.2, 3.37 ± 0.2, 3.30 ± 0.2, 3.23 ± 0.2, 3.19 ± 0.2, 3.14 ± 0.2, 3.06 ± 0.2 and 3.00 ± 0.2 and which has no peak in the powder X-ray diffraction pattern at d = 16.58 ± 0.2 and d = 16.84 ± 0.2, wherein said polymorph is a monohydrate containing 4.3 ± 0.2% w/w water.*

*2. The crystalline polymorph as claimed in claim 1, which has the following lattice parameters: a=18.28(5), b=12.65(5), c=7.81(5), a = 90.00, β = 90.00, γ = 90.00 and volume = 1805.0(5)* $A^2$.

*3. An agricultural composition comprising a polymorph as claimed in any one of claims 1 to 2 and at least one agriculturally acceptable carrier or diluent."*

27. The CS of the subject application specifies the problem in prior art that if the existing form of a compound is not stable in such an SC formulation, polymorphic conversion might occur leading to unwanted crystal growth. Such crystal growth is detrimental because it leads to, for example, thickening and potentially solidification of the formulation which can lead to blockages in application equipment, e.g. in spray nozzles in agricultural application machinery. Using a stable polymorphic form would overcome these issues.

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28. Further, the CS of the subject application at page 124 specifies how the issues present in the prior art can be overcome using the present invention. For better understanding, the relevant para of the CS is reproduced hereunder:

> *"For example, a suspension concentrate (SC) formulation may be preferred over an emulsion concentrate (EC) because the lack of solven 5 in the SC often means that the formulation is likely to be less phytotoxic than an equivalent EC formulation - however, if the existing form of a compound is not stable in such an SC formulations, polymorphic conversion might occur leading to unwanted crystal growth. Such crystal growth is detrimental because it leads to, for example, thickening and potentially solidification of the formulation which can lead to blockages in application 10 equipment, e.g. in spray nozzles in agricultural application machinery. Using a stable polymorphic form would overcome these issues."*

29. Further, the CS of the subject application at page 123 specifies that the structure of different polymorphs of a compound has different arrangements of atoms/molecules in their crystal structure and therefore, properties of any of these crystal forms is challenging to predict. The relevant portion of the same is extracted hereunder:

> *"……Different polymorphs of a compound have different arrangements of atoms and or molecules in their crystal structure. When the compound is a biologically active compound, such as a fungicide, the difference in crystal structures can lead to different polymorphs having differing chemical, physical and biological properties. Properties which may be affected include crystal shape, density, 25 hardness, colour, chemical stability, melting point, hydroscopicity, suspensibility, dissolution rate and biological availability. As such, a specific polymorph may have properties which make it more advantageous in a particular use relative to another polymorph of the same compound: in particular, the physical, chemical and biological properties listed above can have a significant effect on the development of production methods and formulations and the 30 quality and efficacy of plant treatment agents, such as fungicides. It is noted that predicting whether the solid state of a compound may be present as more than one polymorph is not possible and nor is it possible to predict the properties of any of these crystal forms."*

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30. The learned Controller has rejected the subject application on the grounds of lack of inventive step under Section 2(1)(ja) and non-patentability under Section 3(d) of the Act. In the aforesaid backdrop, the merits of the present appeal need to be examined.

**OBJECTION UNDER SECTION 2(1) (ja) OF THE ACT:-**

31. This Court has heard the learned counsel for the parties and has perused the record. This Court shall now proceed to analyse the submissions made and the material on record.

32. Before this Court adverts to the merits of the present appeal, since the issue relates to a polymorph it would be appropriate to refer to certain articles which have been collated after deep research into the behaviour of a polymorph. It is important to note that the impugned order notes that thermal stability is an inherent property of polymorphs.

33. In the Article "Facts and Fictions about Polymorphism" (Chem Soc Rev, 2015, 44, 8619-8635) written by Auror J. *et al*, the authors quote "in spite of an impressive array of contributions across a broad spectrum of their chemical and physical aspects, polymorphic systems are in a many ways still enigmatic, echoing the 1937 observation by Buerger and Bloom '*with the accumulation of data, there is developing the gradual realization of the generality of polymorphic behavior, but to many chemists polymorphism is still a strange and unusual phenomenon*.'" It is noted in the Article that among the many solid state forms of a drug substance, a form that is both thermodynamically stable and meets the design requirements of the drug product is generally progressed in pharmaceutical development. Therefore, the importance of identifying the thermodynamically stable form in early drug

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product development cannot be overstated. The authors in the concluding paragraph have stated "*many fictions have entered in the literature about the connection between the molecular nature of compounds and their propensity for polymorphism. Although, we have shown that there may be some possible trends, the truth remains that polymorphism is unpredictable on the basis of molecular structure*". For better understanding, the relevant paras from pages 6 and 18 of the document are reproduced hereunder:

> ***"In spite of an impressive array of contributions across a broad spectrum of their chemical and physical aspects, poly-morphic systems are in many ways still enigmatic, echoing the 1937 observation by Buerger and Bloom "with the accumula-tion of data, there is developing a gradual realization of the generality of polymorphic behavior, but to many chemists polymorphism is still a strange and unusual phenomenon."***
> **** **** ****
> *"Many fictions have entered in the literature about the connection between the molecular nature of compounds and their propensity for polymorphism.* ***Although we have shown that there may be some possible trends, the truth remains that polymorphism is unpredictable on the basis of molecular structure".***

[emphasis supplied]

34. John F. Bauer, in his Article "Polymorphism- A Critical Consideration in Pharmaceutical Development, Manufacturing and Stability" (Journal of Validation Technology 2008) has conducted an in depth study of various features, forms and laboratory studies to determine polymorphism and based his Article on the API "ritonavir" which was the active ingredient in the Norvir Capsule. The Ritonavir case was a classic example where the API Ritonavir was identified as the key component in various protease inhibitor cocktails used for the successful treatment of HIV infections. This enhanced the therapeutic effectiveness of many aids therapies. After a number of lots of

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the Norvir capsules had been successfully manufactured, in the summer of 1998, a sudden change in the physical properties of Ritonavir brought production to a halt. The crystal form of Ritonavir had unexpectedly changed. The said change resulted in solubility change for the drug which in turn resulted in a bioavailability change and affected the **therapeutic** effect of the drug. This only shows that though the drug would remain the same entity and have the same chemical properties of stability, reactivity etc., it may not always act in the same way in the solid state. The Ritonavir problem was caused by a change in the solubility of Ritonavir that caused the drug to precipitate from the capsule formulation and reduced its bioavailability to less than 5%. The reason attributed to this change is stated to be a phenomenon called polymorphism. Various polymorphs are chemically identical but can have different physical properties. The conclusion of the abovementioned document is reproduced hereunder:

> *"CONCLUSIONS*
> *Although the chemical and physiological properties of a pharmaceutical compound determine the potential of the compound as a commercially viable drug product, the solid state properties of the compound are extremely important in determining whether it can be reproduc-ibly manufactured. Laboratory studies are key to deter-mining the potential of a compound to form multiple polymorphs, under what conditions the polymorphs are formed, the physical properties of each polymorph, and the stability of each polymorph. Awareness, knowl-edge, and understanding of polymorphism is important throughout the product lifecycle. Polymorphism may impact product development, clinical studies, product manufacturing, product quality, and product stability. The large majority of manufacturing problems encoun-tered in commercial scale manufacturing are related to the physical properties of the APL and/or excipients. These problems may be caused by polymorphic changes. Change management and validation in API manufacturing and product manufacturing should address the potential impact of formulation and process changes on API polymorphism."*

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35. In the Ritonavir case, the change in solid form had a great effect on solubility which in turn drastically reduced the bioavailability.

36. The author has also stated that as to which polymorph of a crystalline drug will form under certain conditions cannot be predicted. It would be apposite to extract relevant portion of the said Article to emphasize the aforesaid observation, which is as under:

> *"POLYMORPHISM*
>
> *The ritonavir problem was caused by a change in the - solubility of ritonavir that caused the drug to precipi--tate from the capsule formulation, and reduced its bioavailability to less than 5%. The reason for this change is a phenomenon known as polymorphism. As described previously, solids can exist as crystal-line, amorphous, solvate (hydrate), and desolvated - (dehydrated) forms. Complicating this situation is the fact that crystalline solids (and solvates/hydrates anddesolvated/dehydrated solvates/hydrates) can exist in L what are known as polymorphs. Crystals exist with the molecules arranged in a repeating pattern with an identifiable symmetry However, there can be more than one possible repeating pattern for many drugs. This can be demonstrated by visualizing a number of identical Lego pieces of a specific shape. Each Lego piece represents a drug molecule. These individual Lego pieces can be assembled in several different ways to form different symmetrical patterns. Each of the different patterns contains the same number and type of individual Lego pieces.*
>
> *Each of these different patterns would represent a different polymorph of the drug. These various polymorphs are chemically identical but can have significantly different physical properties. Because the molecules are arranged differently in the different polymorphs, it is possible to have different portions or functional groups of the molecule exposed at the surfaces of the crystal. These differences, especially when they involve hydrogen bonding groups, can cause the crystal to interact differently with solvents and therefore change the solubility of the drug. This was the case with ritonavir. A much less soluble poly-morph having five times lower solubility was formed. The significantly different solubility of the new rito-navir polymorphmadeitimpossible to manufacture the original Norvir formulations.*

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***Different crystal arrangements or crystal lattices are possible for any particular compound. Under particular temperature, pressure, and humidity conditions, the various polymorphs of a drug have different energies, There is one polymorph that has the lowest energy and is considered the most stable.*** *All other forms are referred to as metastable, although they may be quite stable under that particular combination of temperature, pressure, and humidity. Theoretically any metastable form will convert to the stable form under particular conditions. However, this conver-sion will be extraordinarily slow unless mediated by a solvent. In the case of ritonavir, the solvent system in the capsule mediated the crystal form change. The stability referred to here is the ease with which one solid form converts to another solid form, for example, conversion of amorphous solid to crystalline form or one polymorph to another. Crystal polymorphs can also differ in chemical stability because the groups present on the surface of the molecule will be more or less labile or reactive. The tendency of a compound to attract water from the atmosphere (i.e. hygroscopicity) is also the result of surface groups.*

*LABORATORY STUDIES TO DETERMINE POLYMORPHISM*

***Which polymorph of a crystalline drug will form under certain conditions cannot be predicted****. However, labora-tory experiments can be conducted that will determine the potential for formation of multiple polymorphs. These studies are performed by crystallizing the drug from multiple solvents of differing polarities, different solvent combinations, at different temperatures, at differ-ent rates of cooling, and other experimental conditions. These studies are conducted in solid state laboratories using a laboratory robot system.*

*The crystal form that will be easiest to form is the one closest in arrangement to the drug in solution under the same environmental conditions. This transition requires the least energy, and the form produced is called the kinetic form. There may also be other forms that are not as closely related to the dissolved drug but can also form under the specific environmental conditions. The form that has the strongest internal attractions within the crystal is the most stable form under these conditions and is referred to as the thermodynamic form Given enough time and especially if solvent mediated, the thermody-namic form of the crystal would be the final and-most stable polymorphic crystal form produced. When dif-ferent temperatures are involved, more complexity may be introduced. For example, the simplest situations are those in which a single polymorph is always the most stable polymorph regardless of temperature, these systems are called monotropic systems. However, there*

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*may be situations in which a different polymorph is the most stable polymorph at a higher temperature; these systems are called enantiotropic systems.*

*When multiple polymorphs of a drug are formed it is necessary to understand their conditions of for-mation and the physical properties associated with each form, Polymorphic interconversions have been reported in the solid state caused by mechanical stress and/or high temperature. The stability of each form must be studied. The information learned in these studies is used in the selection of the appro-priate form for development. Thereafter, laboratory information is useful for development of the active pharmaceutical ingredient (API) manufactur-ing process. When multiple-polymorphic-forms-are possible, it is critical to understand the conditions under which they can interconvert In many cases the forms do not differ enough to affect the manu-facture, stability, and/or efficacy of the compound. However, this information is only known through appropriate laboratory investigations.*
*One other important benefit of understanding the various polymorphs and methods of preparation of dif-ferent polymorphs is that polymorphs are patentable. This knowledge may thus provide commercial benefit for the organization."*

[emphasis supplied]

37. Further under the heading *"Polymorphs in pharmaceutical product manufacturing"*, the author states as under:

*"POLYMORPHS IN PHARMACEUTICAL PRODUCT MANUFACTURING*
*There are many reported examples of changes in solid form due to conditions typical of product manufacturing processes. Examples of processing that may cause poly-morphic changes including grinding, milling, heating, and compressing. Manufacturing conditions that include a solvent (e.g., wet granulation, polymorphs in solution, polymorphs in suspension) may also facilitate conversion to the thermodynamic polymorph. An often-cited article entitled "Disappearing Polymorphs" (3) describes mul-tiple cases where a crystal form was developed and even patented and marketed when a new polymorph suddenly appeared, and the first form could no longer be produced. The extreme example of ritonavir (Norvir) exemplifies the criticality of solid-state investigations during the development of a new drug entity and manufacturing process development.*

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*This has been an important area of concern and emphasis by FDA and International Conference on Harmonisation (ICH) in recent years.*
**** **** ****

*The Norvir polymorph example discussed previously suggests an additional concern in the formulation of liquid solution products.Conventional wisdom suggests that since the drug is in solution, polymorphic forms should be of no concern. However, extraneous materials can sometimes seed new thermodynamic crystal forms that may precipitate from solution. When solution prod-ucts are formulated, the drug concentrations should be well below the saturation concentrations of any of the known drug product polymorphs.*
**** **** ****

*Any changes to the API manufacturing process or to the product manufacturing process should address the potential for polymorphic changes to the API crystal. The original API development work is helpful in addressing the impact of these changes. Experimental research and development studies should indicate whether there is potential for the API molecule to form multiple poly-morphs, and the ease of interconversion between poly-morphic forms. This information will form the basis for appropriate testing in process validation."*

38. In another Article "Rapid Conversion of API Hydrates to Anhydrous Forms in Aqueous Media" (Journal of Pharmaceutical Sciences, Vol. 98, No. 11.11.2009, by Petrova *et al*.), the authors have, in the abstract stated as under:

*"ABSTRACT: Three anhydrous polymorphs, a monohydrate and a dihydrate of an active pharmaceutical ingredient, N-([(5S)-3-(4-(6-[(1R,5S)-6-cyano-3-oxabicyclo[3.1.0]hex-6-yl)pyridin-3-yl)phenyl)-2-oxo-1,3-oxazolidin-5-yl]methyl)acetamide (Compound 1), have been crystallized and characterized. Slurry experiments and thermal data have been used to determine their relative thermodynamic stability. The hydrates of Compound 1 were found to be less stable than the most stable anhydrous Form I and converted into Form I in water within 15 min. The rate of conversion in a dry state was found to depend on the relative humidity (RH) and was highest at the two RH extremes examined, 5% and 97.5% RH. 2009 Wiley-Liss, Inc. and the American Pharmacists Association J Pharm Sci 98-4111-4118, 2009."*

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39. From the above, it appears that there are multiple factors to be considered by an entity while manufacturing a drug for therapeutic purposes involving API where the occurrence of polymorphism is not unknown. It also appears that various polymorphs are chemically identical but may have significantly different properties. Specially, when they involve hydrogen bonding groups, the differences can cause the crystal to interact differently with solvents and therefore change the solubility of the drug which was the case with Ritonavir. Thus, under a particular temperature, pressure and humidity conditions, various polymorphs of a drug may have different energies.

40. Further, the learned Controller has not cited any source while relying on the common general knowledge. In ***AGFA NV** (supra)*, this Court emphasised that while relying on 'common general knowledge' as a ground for refusing a patent application, it is essential to specify the source of the said knowledge. The relevant paras of the decision is reproduced hereunder:

> *"34. From the above extract, for the Controller to rely on 'common general knowledge' as a ground for refusing a patent application, it is essential to specify the source of the said knowledge. It would be essential that the said source of the 'common general knowledge' would have been published before the priority date of the patent application. In addition, the fact that a theory or principal or knowledge has become common knowledge needs to be substantiated by some evidence. The said evidence could be in the form of references to the 'common general knowledge' textbooks or research articles or standard documents.*
>
> **** ***** ****
>
> *37. In the present case, however, the Controller has failed to give any source of the common knowledge that has been considered. Therefore, it cannot be construed as to what precise element of 'common general knowledge' has been considered along with the cited prior art to claim that the combination of the teachings of the prior art and the 'common general knowledge' led to a finding of lack of inventive step."*

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41. Therefore, the statement of the learned Controller that thermal stability is an inherent property of polymorphs cannot be accepted in view of the above cited documents as well as failure of the learned Controller to cite any sources to support such statement.

42. It is the case of the respondent that the prior art documents D1 to D4 were considered as the closest prior arts. D1 discloses the crystalline form of the compound of present formula-I (3-difluoromethy1-1 –methyl- 1 H-pyrazole-4/carboxylic acid (9-dichloromethylene-1, 2, 3, 4-tetrahydro-1, 4-methano- nephthalen-5-yl)-amide) and intermediates alongwith their preparation process. It was also contended that prior art D2 to D4 also disclose the same compound of formula-1, and its process for preparation. It is further stated that the compound of formula-1 prepared in cited literature D1 to D4 generally involved in the crystallization and/or recrystallization process in non-aqueous medium (hexane, xylene/methycyclohexane etc.) which led to the formation of final crystalline product.

43. The respondent acknowledged that the distinguishing feature of the subject application in comparison to the cited prior arts is the “monohydrate” form of compound of formula-1 instead of “non-hydrate” form of compound of formula-1. The respondent also admitted that none of the cited prior art documents disclose the monohydrate form of compound of formula-1 and thereby accepted the novelty of the claimed invention of the subject application. However, the respondent found lack of evidence for any surprising effect over the cited prior arts D1 to D4. According to the respondent, the evidence which ought to have been furnished by the appellant

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could be in the form of a comparative data in terms of lowering phytotoxicity between the monohydrate form of compound of formula-1 and the non-hydrate form as disclosed in the prior art D1 to D4. Since the appellant did not provide the comparative data, there was no credible evidence of a surprising effect over prior art D1 to D4. It was on this basis that the respondent did not find any inventive step under Section 2(1)(ja) of the Act.

44. As per the respondent, the x-ray diffraction pattern provided by the appellant was only a characterization data which could not be considered as a technical feature. Respondents claim that the diffraction pattern may provide information about the compound structure, however, does not contribute to the technical advancement.

45. The respondent also stated that the claimed composition does not comprise any component that has its own technical feature and rather it comprises only excipient and carrier which is commonly known to the person skilled in the art.

46. It is important to note that the appellant conducted experiments to determine thermal stability of the hydrate and anhydrous form using Differential Scanning Calorimetry (DSC). The Example 3 and Table 3 of the CS of subject application disclose the experiment where slurries of both anhydrous polymorph form 1 and the monohydrate crystalline polymorph of compound of formula I were prepared in different water/methanol mixtures and at different temperatures. Table 3 from the CS of the subject application is reproduced below which provides the results of the experiments:

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| | Temperature (°C) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Water in Methanol (%) | 5 | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 | 50 | 55 | 60 |
| 35 | - | - | - | - | - | - | - | - | - | - | - | H |
| 30 | - | - | - | - | - | - | - | - | - | | - | - |
| 25 | - | - | - | - | - | - | - | - | - | H | - | H |
| 20 | - | - | - | H | - | H | H | H | H | - | - | H |
| 15 | H | - | H | - | - | - | - | - | - | H | - | A |
| 12.5 | H | - | - | - | - | - | - | - | - | - | - | - |
| 10 | H | - | H | U | - | U | A | A | A | - | - | A |
| 7.5 | H | - | H | - | - | - | - | - | - | - | - | - |
| 5 | A | - | - | A | - | - | A | A | A | - | - | A |
| 1 | A | - | - | A | - | - | A | A | A | - | - | A |

47. Further, as per the CS of the subject application, a phase diagram as shown below in FIG. 3 is plotted with the water activities from the abovementioned Table 3:

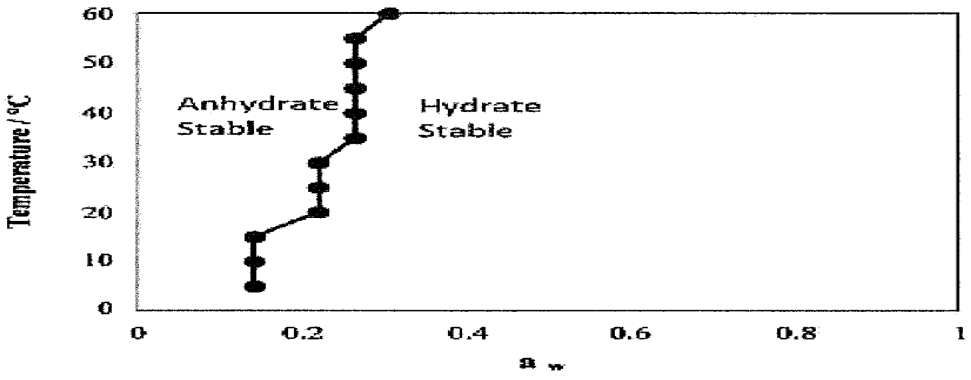


**Figure 3**

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48. The aforesaid phase diagram demonstrates that temperature in excess of 60 °C would be required to dehydrate the hydrate of compound of formula I at normal ambient relative humidities which indicates that the hydrate of formula-1 would be the stable form of compound I in suspension concentrate formulations and would also be more stable in other, non-aqueous, formulations upon their dilution with water in the spray tank. In case the anhydrous form-1 is used under these conditions, it is likely to lead to polymorphic conversion to the hydrate and resultant crystal growth which would potentially result in blocked nozzles in spray equipment.

49. The CS of the subject application under Example 5 also compares the stability of the formulations of polymorphs. Here, two standard SC formulations were prepared separately using the anhydrous Form 1 polymorph and the hydrated polymorph. The SC of the anhydrous Form 1 was contaminated with 5% of the hydrated form and was placed in a temperature cycling oven varying in the range 0°C to 40°C over a period of 12 hours. Thereafter, the sample was inspected after two weeks and microscopy showed that the size of the crystals had increased substantially. Some crystals were removed from the formulation and dried. The powder X-ray diffraction pattern was collected which showed that all of the anhydrous polymorph Form 1 were completely converted into the hydrated form. The comparative powder X-ray diffraction trace is shown in FIG. 7 and is reproduced below:

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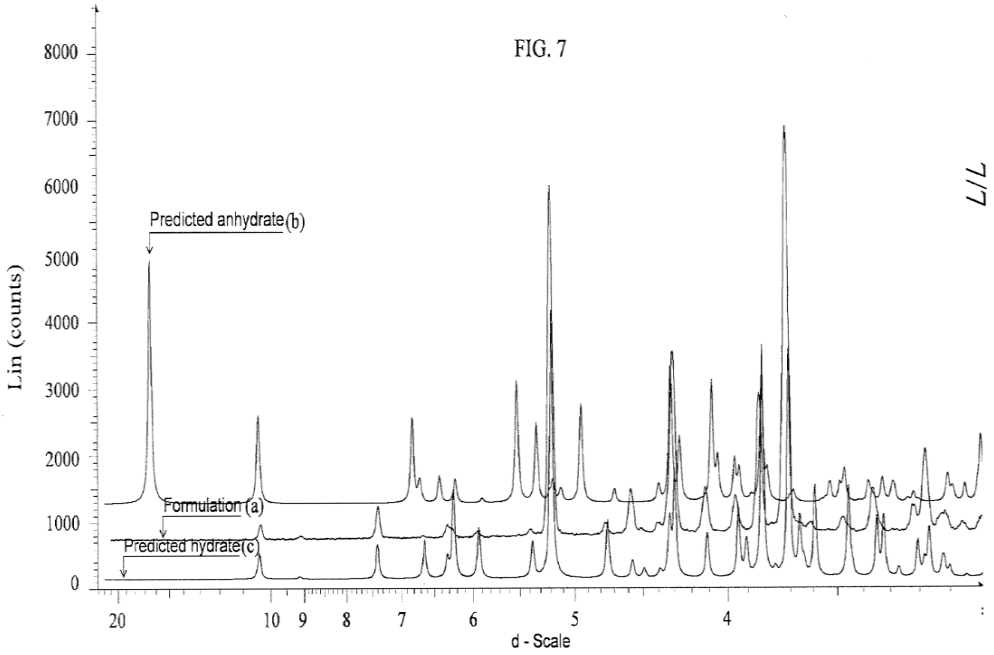
FIG. 7




7/7

50. The appellant had demonstrated that the suspension concentrate of crystalline polymorph of compound of formula-1 which is a monohydrate containing 4.3 ± 0.2 % w/w water is more stable than the suspension concentrate of the comparative anhydrous form. Since the suspension concentrate used less chemicals, it was presumed that the suspension concentrate would have a reduced phytotoxicity. In order to show the distinction between the subject application and that of the prior documents D1 to D4, it appears necessary to extract hereunder the disclosures in such documents:

> *"5.3.7. Documents D1 to D4 cited by the Respondent disclose the following:*
> *- D1 (WO 2011/131544A1) relates to a process for the preparation of 3-difluoromethyl-lmethyl-I H-pyrazole-4-carboxylic acid (9-dichloromethylene-l ,2,3,4-tetrahydro-1 ,4methano-naphthalen-5-yl)-amide which is the compound of formula I. D1 at step f) of the examples at*

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*lines 8-9 of page 327 of the appeal states that the product was extracted and crystallized in mixture of xylene/methylcyclohexane. Therefore, the compound of D1 is anhydrous and the monohydrate crystalline form of IN `1900 is not disclosed in D1.*

*- D2 (WO 2011/131545A1) also relates to a process for the preparation of 3- difluoromethyl-l methyl-I H-pyrazole-4-carboxyIic acid (9-dichloromethylenel ,2,3,4-tetrahydro-1 ,4methano-naphthalen-5-yl) amide which is the compound of formula I. D2 at step g) of the examples at line 15 of page 357 of the appeal states that the product was extracted and crystallized in mixture of xylene/methylcyclohexane. Therefore, the compound of D2 is anhydrous and the monohydrate crystalline form of IN `1900 is not disclosed in D2.*

*- D3 (WO 2011/131546A1) also relates to a process for the preparation of 3- difluoromethyl-l methyl-I H-pyrazole-4-carboxyIic acid (9-dichloromethylenel ,2,3,4-tetrahydro-1 ,4methano-naphthalen-5-yl) amide which is the compound of formula I. D3 at step d) of the examples at lines 24-25 of page 383 of the appeal states that the product was extracted and crystallized in mixture of xylene/methylcyclohexane. Therefore, the compound of D3 is anhydrous and the monohydrate crystalline form of IN `1900 is not disclosed in D3.*

*- D4 (US 2012/136162A1) relates to a process for the preparation of compound of formula I. D4 at example P6 [para 82] at page 399 of the appeal states that the crude material was dissolved in mixture of xylene and methylcyclohexane. Therefore, the compound of D4 is anhydrous and the monohydrate crystalline form of IN `1900 is not disclosed in D4."*

51. As per the respondent, the statement in the affidavit of Dr. John Hone states that the use of the compound of the present invention might be advantageous, however, is not definite. It indicates that it might not be advantageous or the crystal may not form in every case.

52. From the affidavit, the respondent submits that the expert does not give a definitive opinion that there is a problem which is solved. The respondent has also emphasised that Dr. John Hone does not opine that there is an enhancement of efficacy. The relevant paragraph of the said affidavit is extracted hereunder:

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> *"Technical Solution provided by the Current ApplicationIt is important to mention that the use of a specific polymorph allows the use of new formulations compared with existing polymorphic/amorphous forms of a compound. This might be advantageous for a number of reasons. For example, a suspension concentrate (SC) formulation may be preferred over an emulsion*
> *Nonetheless, if the existing form of a compound is not stable in such an SC formulation, polymorphic conversion might occur leading to unwanted crystal growth. Such crystal growth is detrimental because it leads to, for example, thickening and potentially solidification of the formulation which can lead to blockages in application equipment, e.g. in spray nozzles in agricultural application machinery. Using a stablepolymorphic form would overcome these issues."*

53. After going through the said affidavit, this Court agrees with the submissions of the respondent that a specific conclusion cannot be drawn. Therefore, it appears appropriate to not take into consideration the opinion in the affidavit at this stage.

54. From the above, it can be gathered that the respondent does not dispute that the monohydrate crystalline polymorph of compound of formula-1 of the subject patent application was not known; the specifications clearly provided the thermal stability data to demonstrate that the monohydrate crystalline polymorph of formula-1 is more stable than the anhydrous form-1 which would indicate a technical advance over the cited documents D1 to D4. The improved thermal stability can be presumed to be the technical effect that ensures the compound can be delivered as a SC provided the same is present as monohydrate crystalline polymorph of compound of formula-1 and not in any other form. Since the formulation is in SC, the enhanced thermal stability would be linked to the lowering of phytotoxicity. The learned Controller has

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to provide reasoning as to how the provided data is not sufficient/relevant to show the inventive step.

55. It is relevant to also consider at this stage whether thermal stability of a polymorph would be a relevant consideration in order to determine efficacy. As noted by this Court in the preceding paragraphs containing excerpts of various Articles regarding polymorphism, it is clear that polymorphic forms are unpredictable in nature. It is verily not possible to predict whether a compound can be present in more than one polymorphic form nor is it possible to predict the properties of any of the crystal forms. Prior to the research and study conducted by the appellant, it could not be stated with conviction that the monohydrate crystalline polymorph would be thermally more stable than the anhydrous form. It can be safely presumed that preparation of a polymorphic compound is highly unpredictable and would require extensive research in order to achieve a desired polymorphic compound. It is in this context that the learned Controller ought to have seen that none of the prior arts disclose that a monohydrate crystalline polymorph of compound of formula-1 of the subject patent invention could exist or that the said polymorph would be more stable than its anhydrous form.

56. Thus, the conclusion of the objection regarding the lack of inventive step under Section 2(1)(ja) of the Act was not satisfactorily explained, is unmerited and untenable.

57. In the aforesaid circumstances, it appears apposite to examine the enquiries which are to be conducted by the learned Controller for the determination of obviousness. This Court in ***F-Hoffmann-la Roche Ltd. &***

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***Anr. vs. Cipla Ltd.*:*2015:DHC:9674-DB*** held the following enquiries necessary to be conducted for determination of obviousness:

> *"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,*
> *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 hindsight approach."*

58. Similarly, in so far as the determination of lack of inventive step is concerned, this Court in ***Agriboard International LLC vs. Deputy Controller of Patents and Designs: 2022 SCC Online Del 940*** held as under:

> *"24. In the opinion of this Court, while rejecting an invention for lack of inventive step, the Controller has to consider three elements-*
>
> - *the invention disclosed in the prior art,*
> - *the invention disclosed in the application under consideration, and*
> - *the manner in which subject invention would be obvious to a person skilled in the art.*
> -
>
> *25. Without a discussion on these three elements, arriving at a bare conclusion that the subject invention is lacking inventive step would not be permissible, unless it is a case where the same is absolutely clear. Section 2(1)(ja) of the Act defines `inventive step' as under:*
>
> > *(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.*
>
> *26. Thus, the Controller has to analyse as to what the existing knowledge is and how the person skilled in the art would move from the existing knowledge to the subject invention, captured in the application under consideration. Without such an analysis, the rejection of the patent application under Section 2(1)(ja) of the Act would be contrary to the*

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*provision itself. The remaining prior arts which are cited by the ld. Counsel having not been considered in the impugned order, the Court does not wish to render any opinion in this regard."*

59. Since the learned Controller has failed to cite the documents while stating that the thermal stability is an inherent property of the polymorphs, it can be concluded that the abovementioned steps are not followed.

60. Based on the above discussion and data provided by the appellant, it has demonstrated that the crystalline polymorph of compound of formula I which is a monohydrate containing 4.3 ± 0.2 % w/w water is more stable than SC of the comparative anhydrous form. Further, as per the CS of the subject application, such stable SC are less phytotoxic. Based on the documents discussed above, it is pertinent that it was difficult to prepare a stable SC of base compound of formula 1. Therefore, in view of the above, it appears that the learned Controller could not have concluded with conviction that the appellant has not been able to overcome the objection under Section 2(1)(ja) of the Act.

**OBJECTION UNDER SECTION 3(d) OF THE ACT**

61. The other objection raised by the learned Controller is under Section 3 (d) of the Act. The counsel for the respondent submitted that under Section 3 (d) of the Act, polymorphs shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. For better understanding Section 3(d) of the Act is reproduced as follows:

*"(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such*

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*known process results in a new product or employs at least one new reactant.*

*Explanation.—For the purposes of this clause, salts, esters, ethers,* ***polymorphs,*** *metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance,* ***unless they differ significantly in properties with regard to efficacy."***

[emphasis supplied]

62. The other argument under objection of Section 3(d) of the Act raised by the Patent Office was in respect of lack of evidence regarding therapeutic efficacy of the subject patent application. In other words, the enhancement of thermodynamic stability of the monohydrate crystalline polymorph of compound of formula-1 at temperatures around 50°C to 60°C which may result in non-clogging of the spraying equipment, however, does not enhance the therapeutic efficacy of the compound itself. The respondent had vehemently objected that in pharmaceutical preparations or agro chemicals, the efficacy has to be measured in terms of enhancement in the therapeutic efficacy of the compound alone. Since admittedly, there is no enhancement in the therapeutic efficacy of the compound itself, the enhancement in the thermodynamic stability of the monohydrate crystalline polymorph of compound of formula-1, by itself, cannot satisfy the objection under Section 3(d) of the Act. The respondent had relied upon the judgment of the Supreme Court in ***Novartis AG*** (*supra*).

63. It is important to determine the applicability of the 2005 amendment of the Section 3(d) of the Act. In ***Novartis AG*** (*supra*), the Supreme Court held that the amended portion of Section 3(d) of the Act clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products

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to leave the door open for genuine inventions and also to check evergreening. The relevant para is reproduced hereunder:

> *" 87. We are clearly of the view that the importance of the amendment made in section 3(d), that is, the addition of the opening words in the substantive provision and the insertion of explanation to the substantive provision, cannot be under-estimated. It is seen above that, in course of the Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products.* ***The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds."***
>
> [emphasis supplied]

64. No doubt that what was engaging the attention of the Supreme Court in ***Novartis AG*** *(supra)* was the significance of amendment in the year 2005 to Section 3(d) of the Act. The Supreme Court had, in detail, considered the amendment, the Parliamentary debates, the TRIPS agreement and the public health interest involved while rendering its opinion in the said judgment. The Supreme Court had also noted that 80% of the parliamentary debates revolve around pharmaceutical preparations, medicines and drugs; and 20% were in respect of agro chemicals. The Supreme Court also noted that the apprehension of "Evergreening" of certain inventions though is made out, yet, encouragement of incremental inventions ought to also to be taken into consideration. It is to be noted that the Supreme Court was considering and had rendered its judgment in the context of pharmaceuticals and medicines, though it also referred to agro chemicals but more, in the humble opinion of

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this Court, in the passing. The Supreme Court in para 157 of the judgment had considered what "Efficacy" would mean. It would be beneficial to extract para 157 of the said judgement as hereunder:

> *"157. What is "efficacy"? Efficacy means "the ability to produce a desired or intended result". Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce.* ***In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy".*** *The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly. Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there are sufficient internal evidence that leads to the same view. It may be noted that the text added to section 3(d) by the 2005 amendment lays down the condition of "enhancement of the known efficacy". Further, the explanation requires the derivative to "differ significantly in properties with regard to efficacy". What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy."*
>
> [emphasis supplied]

65. From a plain understanding of para 157, it appears that the Supreme Court had considered enhancement in "therapeutic efficacy" as the test to pass the objection in Section 3(d) of the Act. In other words, unless there is an enhancement in therapeutic effect of the known substance, the patent application would be barred under the provisions of Section 3(d) of the Act. The sentence "*Therefore, in the case of a medicine that claims to cure a*

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*disease, the test of efficacy can only be "therapeutic efficacy"* indicates that the efficacy would be therapeutic efficacy in case of the medicine. Therefore, it can be stated that in other cases, the test of efficacy would be determined as per their function, utility or the purpose of the product under consideration. It would also be relevant to extract para 164 of the abovementioned judgement:

> *"164. In whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy. 188. This leaves us to consider the issue of increased bioavailability. It is the case of the appellant that the beta crystalline form of Imatinib Mesylate has 30 per cent increased bioavailability as compared to Imatinib in free base form. If the submission of Mr. Grover is to be accepted, then bioavailability also falls outside the area of efficacy in case of a medicine. Leaving aside the submission of Mr. Grover on the issue, however, the question is, can a bald assertion in regard to increased bioavailability lead to an inference of enhanced therapeutic efficacy? Prof. Basheer quoted from a commentator1 on the issue of bioavailability as under:*
>
> > *"It is not the intent of a bio-availability study to demonstrate effectiveness, but to determine the rate and extent of absorption. If a drug product is not bioavailable, it cannot be regarded as effective.* ***However, a determination that a drug product is bio-available is not in itself a determination of effectiveness."***

[emphasis supplied]

66. Clearly, the Supreme Court spelt out what would not amount to enhancement of the therapeutic effect of a medicinal preparation or a drug. In that, neither the more beneficial flow properties nor better thermodynamic stability or lower hygroscopicity would fall within the meaning of "therapeutic efficacy". It is in that context that the respondent appears to have raised the objection that the mere enhancement of the thermodynamic stability of the

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monohydrate crystalline polymorph of the compound of formula 1 of the subject patent application would not come within the definition of therapeutic efficacy as defined by the Supreme Court in ***Novartis AG*** (*supra*).

67. In the present case, it is not disputed that the subject patent invention claims primarily thermodynamic stability of a polymorph at temperatures ranging upto 50°C – 60°C. It is also to be noted that the subject patent application concerns an agrochemical. The respondent does not dispute that the thermodynamic stability which is the subject matter of the patent application is likely to prevent formation of crystals in the compound which causes the formation of lumps which is used in the tank of the spraying machine which in turn clogs the spray gun preventing spraying of agro chemical on the plants. One cannot lose sight of the fact that the agricultural sector in India, largely are in regions where temperatures ordinarily would be above 35°C to 48°C–50°C. In which case, the monohydrate crystalline polymorph of compound of formula-1 of the subject application would enhance the efficacy of the compound to be sprayed on the plants without the crystallization of the compound itself, which would prevent formation of clogs in the spray gun itself. The mere fact that the fungicide could be made available to be used in such regions with such high temperatures, in the considered opinion of this Court, would be an enhancement in the efficacy under Section 3(d) of the Act. In the opinion of this Court, in the context of present agro chemical, enhancement of efficacy of a known substance, particularly in view of the present polymorph, would also include the thermodynamic stability at high temperatures. The Court is rendering this opinion on the basis of excerpts of the Articles referred to above in the

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preceding paragraphs, which are based on detailed research and opined that polymorphs are unpredictable in nature. Therefore, stability of the polymorph at high temperature such as claimed in the subject application, the said thermodynamic stability preventing the crystal formation, by itself would be an enhancement in efficacy.

68. The Madras High Court in ***Novozymes*** *(supra)* interpreted the ratio laid down in ***Novartis AG*** *(supra)* to hold that the Supreme Court had tested the definition of efficacy in the context of pharmaceutical products and therefore, so far as efficacy in the context of biochemical substances/phytase variant is concerned, which was the subject matter of the petition before the Madras High Court, the learned Single Judge held that the expression "the enhancement of known efficacy of that substance" does not limit such enhancement to any particular type of efficacy. The learned Single Judge had also held that an increase of thermostability would mean that the enzyme can resist and survive exposure to higher temperature and as a consequence, it enables pelletization without deactivation or denaturation of enzymatic activity. Thus, the thermostability enables products, storage and sale in pellet form would amount to an enhancement in efficacy. The Court, based on the ***Novartis AG*** *(supra),* emphasized that the test of efficacy would be different depending on the function, purpose or utility of the product. The relevant paras are reproduced hereunder:

> *"20. From the data set out in Table 5 of the complete specification, it is discernible that the thermostability of the reference phytases was much lower than the thermostability of the variants. While Section 3(d) uses the expression "the enhancement of the known efficacy of that substance", there is nothing in the text that limits such enhancement to any specific type of efficacy. As discussed earlier, in Novartis SC, the Supreme Court*

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*concluded that* ***the test of efficacy would be different depending on the function, purpose or utility of the product. The respondent contended that phytase is an enzyme and that, therefore, the enhancement of efficacy means no more than enhancement of the enzymatic activity of the variant of phytase.***

***** ***** *****

*22.* ***Without doubt, the primary function of phytase is to act as a catalyst that aids digestion. That does not mean that enhanced hydrolysis of phytate by the variants of phytase should be established as an essential pre-requisite to pass through the filter of enhancement of the known efficacy of phytase. An increase in thermostability admittedly means the enzyme can Dresist and survive exposure to higher temperature. As a consequence, it enables pelletization without de-activation or denaturation of enzymatic activity.*** *The application of molecular techniques to prospect thermostable phytases appears to be critical for the animal feed and fuel industries and reference may be made, in such regard, to the article by Ushashree Mrudula Vasudevan, Amit K.Jaiswal, Shyam Krishna, Ashok Pandey, "Thermostable phytase in feed and fuel industries"in Bioresource Technology, Volume 278, 2019, pages 400-407.* ***Since increased thermostability precludes denaturation and enables production, storage and sale in pellet form, it enhances the known efficacy of the enzyme in aiding digestion especially when used in animal feed. In my view, there is nothing in the text or context of Section 3(d) which supports the interpretation that enhancement of known efficacy of the substance should be restricted to engineering or prospecting variants of phytase with inherently greater enzymatic activity over the reference phytase."***

[emphasis supplied]

69. It is important to note that the Court also held that there is nothing in the text/context of Section 3(d) of the Act which supports the interpretation that enhancement of known efficacy of the substance should be restricted to engineering/prospecting variants of phytase with inherently enhanced enzymatic activity as compared to the reference phytase.

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70. Similarly, in the present case, the monohydrate crystalline polymorph of the compound of form-1, which is the subject matter of subject patent application ensures that the compound "Benzovindiflupyr" remains stable even at temperatures between 50°C–60°C and does not form crystals which would result in the formation of lumps clogging the spraying machine and is available for being sprayed on the plants even in high temperature zones. The mere fact that the fungicide named above is made available to be used and sprayed at regions where the temperature would ordinarily go beyond 40°C without crystallisation would clearly be an enhancement in the efficacy of the compound. Therefore, as per this Court, there is a reasonable enhancement of efficacy under the claimed invention of the subject application and satisfies the requirement of enhancement of the efficacy under Section 3(d) of the Act. It is in this context that the non-enhancement of therapeutic efficacy in the claimed invention of the subject application would not be a bar under Section 3(d) of the Act.

**CONCLUSION:-**

71. Therefore, without going into the merits of the issues arising out of prior art documents D1 to D4, and other cited documents, in the opinion of this Court, the omission of the submitted data by the Patent Office without any sufficient reasoning and reliance on the existing knowledge without citing the relevant source, vitiates the impugned order.

72. Accordingly, in view of the above discussion, the impugned order dated 21.07.2023 passed by the learned Controller is set aside, and the matter is remanded back to the Patent Office for fresh consideration. The learned

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Controller shall afford a fresh opportunity of hearing to the appellant before deciding the subject application.

73. The learned Controller shall decide the matter on the merits in accordance with the law, uninfluenced by any observations in respect of the objection raised under Section 2(1)(ja) of the Act. However, as far as the objection under Section 3(d) of the Act is concerned, this Court has made a clear opinion. The learned Controller shall reconsider and decide the matter accordingly within a period of six months from the date of this decision.

74. A copy of the Order also be brought to the notice of the learned Controller General of Patents, Designs and Trademarks for the necessary administrative action.

75. The appeal is disposed of in the aforesaid terms.

**TUSHAR RAO GEDELA**
**(JUDGE)**

**MAY 04, 2026**
*yrj/rl*

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