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

Reserved on: April 23, 2025
% Pronounced on: May 27, 2025

\+ **C.A.(COMM.IPD-PAT) 452/2022**

ZERIA PHARMACEUTICAL CO. LTD. .....Appellant
Through: Mr. Ankush Verma, Mr. Debashish Banerjee, Mr. Vineet Rohilla, Ms. Vaishali Joshi, Mr. Rohit Rangi, Mr. Tanveer Malhotra and Ms. Gurneet Kaur, Advs

Versus

THE CONTROLLER OF PATENTS ....Controller
Through: Ms. Pratima M. Lakra, CGSC with Mr. Chandan Prajapati and Mr. Shailendra Kumar Mishra, Advs.

CORAM:
HON'BLE MR. JUSTICE SAURABH BANERJEE

J U D G M E N T

Preface:

1. This judgment addresses the issue of refusal of Indian Patent Application No.3630/DLNP/2011 titled "**A COMPOUND REPRESENTED BY FORMULA (5a)**", filed on 13.05.2011 as a divisional patent application out of Indian Patent Application number 1090/DELNP/2007[1], by the Assistant Controller of Patents & Designs.[2]

[1] Hereinafter referred to as the "***subject application***"
[2] Hereinafter referred to as the "***Controller"***

vide order dated 20.10.2016[3] under the provisions of the Patents Act, 1970 (as amended from time to time)[4].

2. The invention under the subject application relates to a novel intermediate compound formula (5a), represented as A 2- [(2-hydroxy-4,5-dimethoxybenzoyl) amino]-1, 3-thiazole-4-carboxylic acid methyl ester compound in which is a ring "A" represents a benzene ring/ a 6-membered aromatic heterocycle containing one or two selected from a nitrogen atom, an oxygen atom, and a sulphur atom, containing:-

- *R1 as a hydrogen atom,*
- *R2 and R3 are each a methoxy group, and*
- *R4 is a hydrogen atom.*

Brief Narrative:

3. The Controller issued a First Examination Report[5] raising both formal and technical objections to the subject application on 24.02.2015. The major objection was that the subject matter of Claims 1 and 2 did not constitute an invention under *Section 2(1)(ja)* of the Act in view of prior art document ***D1***: EP 0994 108 A 1(ZERIA PHARMA CO. LTD. [JP] (2000-04-09) and the prior art document ***D2***: US 5981 557 A (NAGASAWA MASAAKI[JP] *ET AL.*) (1999-11-09) and the other objection was that the subject matter of Claims 1 and 2 fell within the scope of *Section 3(d)* of the Act.

4. The appellant, upon filing a response thereto on 23.07.2015 was accorded a hearing on 12.06.2016. Thereafter, vide the impugned order the Controller refused the subject application on the grounds that the

[3] Hereinafter referred to as the "***impugned order***"
[4] Hereinafter referred to as the "***Act***"
[5] Hereinafter referred to as the "***FER***"

subject application does not fulfil the criteria envisaged under *Section 2(1)(ja)* of the Act, since the invention therein lacked novelty and under *Section 3(d)* of the Act over disclosure made in the prior art document **D2** and the inventive step in view of disclosure made in the prior art documents **D1** and **D2**. In effect, in view of the compounds disclosed in the prior art documents **D1** and **D2**, the subject application was held not liable to proceed for grant.

Submissions for and on behalf of appellant:

5. As per Mr. Ankush Verma, learned counsel for the appellant, the impugned order is erroneous since the Controller has not comprehended the technical problem and solution provided by the claimed invention.

6. Mr. Ankush Verma submitted that the Controller has failed to evaluate the merits of the invention by erroneously relying upon the prior art document **D1** ignoring the fact that the same has been in "A" category of the International Search Report (ISR) and has not been considered to be relevant to the inventive step of the claimed invention. Further, the prior art document **D1** "teaches away" from the claimed invention since it teaches a reaction wherein a compound of formula (5a) is avoided and therefore cannot help a *Person Skilled In The Art*[6] to arrive at the compound of formula (5a) in Claim 1 of the subject application.

7. Mr. Ankush Verma submitted that the methyl ester having the methoxycarbonyl group as claimed is not produced in the prior art document **D2**, and such compound is not specifically described. Also, when starting from the generic disclosure of formula (II) to arrive at the

[6] PSITA

claimed compound it takes a selection from multiple lists, which cannot be considered obvious.

8. Mr. Ankush Verma further submitted that the impugned order suffers from impermissible hindsight analysis in accordance with Chapter 9, paragraph 09.03.03.02 of the Indian Manual of Patent Office Practice and Procedure, 2019 and therefore ought to be remanded to the Indian Patent Office for re-adjudication. Relying upon ***F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd.***[7] and ***Agriboard International LLC v. Deputy Controller of Patents and Designs***[8], Mr. Ankush Verma submitted that the impugned order does not contain any reasoning as to HOW/ WHY a PSITA would be motivated to modify the teachings of the prior art documents **D1** and **D2** in order to arrive at the subject matter of the present invention claimed in the subject application.

9. Mr. Ankush Verma then submitted that the impugned order is vitiated since the Controller, during the prosecution stage, has not considered the data submitted through the expert affidavit deposed by Dr. Takeshi Watanabe affirming that the invention claimed in the subject application involves an inventive step under *Section 2(1)(ja)* of the Act.

10. Mr. Ankush Verma finally submitted that while dealing with provisions of *Section 3(d)* of the Act, the Controller has gravely erred in concluding that the claimed compound exhibits "*… …no enhanced efficacy in terms of its effect on process wherein it is used as an intermediate……*", since the experimental data submitted by the

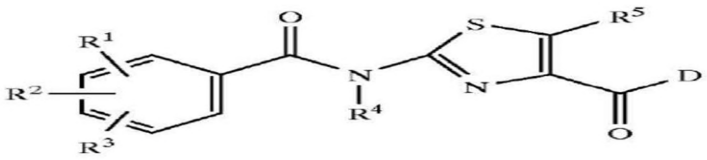
[7](2015 SCC OnLine Del 13619)
[8](2022 SCC Online Del 940)

appellant demonstrates that the superiority of the claimed invention intermediate over the compounds in the prior art document **D2**.

Submissions for and on behalf of the Controller:

11. *Per Contra*, as per Ms. Pratima M. Lakra learned CGSC for the respondent submitted that the subject application was barred from registration under *Section 2(1)(ja)* and *Section 3(d)* of the Act. In fact, the prior art document **D2** discloses 2- [N-(4,5-dimethoxy-2-hydroxybenzoyl) amino]-4-(ethoxycarbonyl)-1, 3-thiazole acetate in Example 6 as follows:-

TABLE 1



Ref. Ex.	R^1	R^2	R^3	R^4	R^5	D	Melting point (° C.)
1	3-MeO	4-MeO	H	H	H	OEt	132–134
2	2-MeO	4-MeO	5-MeO	H	H	OEt	229.0–231.0
3	2-MeO	4-MeO	5-MeO	H	H	OH	243.0–245.0
4	3-MeO	4-MeO	H	Me	H	OEt	
6	2-OH	4-MeO	5-MeO	H	H	OEt	211.0–213.0 (acetate)

As per Ms. Pratima M. Lakra, the only difference between Example 6 therein with the claimed compound of the subject application is the presence of "ethoxycarbonyl" in the prior art document **D2** instead of "methoxycarbonyl".

12. Ms. Pratima M. Lakra submitted that the prior art document **D2** also discloses a compound formula (II) where "D" represents a hydroxy or a lower alkoxy group or salt, and the compound formula (II) is useful as an intermediate for preparation of the invention compound (I). Additionally, "methoxy" is specifically mentioned in col. 31.26 as a lower alkoxy group for "D" in the compound formula (II). Similarly, the

prior art document **D1** also discloses an intermediate compound of formula III used to prepare 2-hydroxybenzoylaminothiazole derivatives in which "A" represents a hydroxyl or lower alkoxy group, including methoxy and ethoxy.

13. Ms. Pratima M. Lakra submitted that both the prior art documents **D1** and **D2** relate to the same field of invention, and moreover, the applicant in both the prior art documents **D1** as well as **D2** and the applicant in the subject application is the same. Therefore, it appears to be an attempt by the appellant for mere extension of protection for known process intermediates, which is not permissible.

14. Ms. Pratima M. Lakra further submitted that Claim 1 of the subject application falls within the scope of *Section 3(d)* of the Act as the claimed compound is a mere discovery of new form in respect of the prior art document **D2** and since the claimed compound has no enhanced efficacy in terms of its effect on the process wherein it is used as an intermediate, the claimed compound of the subject application is merely a derivative of the known compound disclosed therein.

15. Ms. Pratima M. Lakra then submitted that the data provided by the appellant in Annexure I to the written submission dated 26.08.2016 filed before the Controller is pertaining to the process used for the preparation of hydrochloride of a compound of formula (7) rather than the compound of formula (7) whereas the subject application mainly relates to a process for preparation of the compound of formula (7) or 7(a), not to the hydrochloride form of formula (7) or 7(a). Further, the claim granted in the main/ parent application relates to a process for

preparation of the compound of formula (7) that may optionally be converted to the hydrochloride form.

Discussion, Analysis & Reasoning:

16. Having heard the learned counsel for appellant and the respondent Controller at considerable length as also having gone through the pleadings on record along with the relevant case laws qua the issues involved, the prime issue for consideration is the sustainability of findings based upon *Section 2(1)(ja)*[9] and *Section 3(d)*[10] of the Act qua the inventive step.

17. At the outset, this Court finds that though the Controller, in the impugned order, has accepted that the claimed compound is novel under *Section 2(1)(j)* of the Act, however, it has also been held that the same can still be objected under *Section 3(d)* of the Act, as these two provisions are not exceptions to each other. Reliance in this regard is placed on the judgment of the Hon'ble High Court of Madras in ***Novozymes v Assistant Controller of Patents & Designs***[11] as under:-

> *"As is evident from the opening the following are not inventions" expression, which applies to all clauses [(a) to (p)] of Section 3, the provision incorporates a legal fiction by which claims for patent that fall within the clauses of Section 3 will not qualify as inventions,*

---

[9] *"Section 2(1)(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"*

[10] *"Section 3 (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 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"

[11](T) CMA (PT) No.33 of 2023 (OA/6/2017/PT/CHN)

even if such claims meet the requirements of Section 2(1)(j) of the Patents Act, unless they pass through the exemption filters that are built into some of the clauses therein."

18. It is thus fortified that while dealing with the provisions of *Section 3(d)* of the Act, this Court has to tread with caution and care, more so, since it involves a responsibility on the part of the applicant, who has to establish that the claimed compound in the subject application has enhanced efficacy as compared to the prior art documents and the Controller has to first identify the prior art documents and then describe how the claimed compound is a new form of the prior art. Also, as held by a learned Single Judge of this Court in ***Novartis Ag v Natco Pharma Ltd***.[12], *Section 3(d)* of the Act is not an exception to *Section 2(1)(ja)* of the Act, this Court is to first assess the objection under *Section 3(d)* of the Act and then examine the patentability thereof under *Section 2(1)(j)* and *Section 2(1)(ja)* of the Act.

Section 3(d) of the Act:

19. In response to the contention of the appellant in its response to the Hearing Notice on 26.08.2016 wherein the appellant claimed that the compound is a novel intermediate and not a new form of a known substance and therefore the provisions of *Section 3(d)* of the Act were not applicable, the Controller held that Claim 1 of the subject application fell within the scope of *Section 3(d)* of the Act as the claimed compound was a mere discovery of new form and a derivative of known compound disclosed in the prior art document **D2**, having no enhanced efficacy in terms of its effect. Further, both the prior art

[12] *2021 SCC Online DEL 5340.*

documents **D1** and **D2** define lower alkoxy group as methoxy and ethoxy, etc. and therefore, using methoxy in place of ethoxy is one of the straightforward possibility, while developing alternative intermediate compounds based on the compound disclosed in Example 6 of the prior art document **D2** as part of routine experimentation.

20. Further, though in its response to the Hearing Notice of 26.08.2016, the appellant submitted that the closest compound under prior art document **D2** is not the compound mentioned by the Controller, but the Controller after dealing with Example 6 in the impugned order, has found it to be the closest compound under the objection of the inventive step as under:-

> *"5. With reference to paragraph 1 of the hearing notice the claimed invention is considered to be novel as none of the prior art documents DI and D2 specifically discloses the claimed compound of formula (5a). However the submission provided by the agent for the applicant is not found to be persuasive and in the light of the disclosure of DI and D2 the invention is considered to be obvious for a person skilled in the art. Both DI and D2 generically disclose claimed compounds. D2 discloses 2-[N-(4,5-dimethoxy-2-hydroxybenzoyl)amino]-4-(ethoxycarbonyl)-1,3-thiazole acetate in example 6 (table 1). The difference in said compound and claimed compound lies in the ester moiety attached to the thiazole ring ie "ethoxycarbonyl" in D2 whereas its "methoxycarbonyl" in the claimed invention. Further D2 discloses compounds of formula (II) (col. 2 1. 53- col. 3 1. 2) wherein lower alkoxy groups for "D" in compounds of formula (II) i.e. "methoxy" is specifically mentioned in col. 31. 26. D2 also suggest that such compounds are useful in the synthesis of compound 38 for example. Hence it is obvious for a person skilled in the art to replace "ethoxy" from "methoxy as part of routine experimentation in order to provide alternative intermediates useful in the synthesis of aminothiazole derivatives. Thus claim-1 lacks inventive step under section 2(1)(ja) of the Patents Act, 1970.*
>
> *Further claim-1 falls within the scope of section 3(d) of the Patents Act, 1970 as the claimed compound is considered to be mere discovery of new form ie. derivative of known compound as disclosed in D2 with no*

enhanced efficacy in terms of its effect on process wherein it is used as an intermediate.

With reference to paragraph 2 of the hearing notice the agent for the applicant has filed the amended claims.

6. Based on the above facts and circumstances of the case, it is observed that the objection raised in paragraph 1 vide official hearing notice w.rt. inventive step and section 3(d) still stands. Therefore, the instant application No. 3630/DELNP/2011 is hereby refused for grant of patent u/s 15 of the Patents Act, 1970."

21. The aforesaid clearly reflects as to how the claimed compound of the subject application is a derivative of the compounds disclosed under the prior art document **D2**. In fact, Example 6 of the prior art document **D2** and the claimed compound of the subject application share the same core structure, consisting of:-

- 1,3-thiazole ring
- A 2-hydroxy-4,5-dimethoxybenzoyl group attached to the thiazole ring via an amino linkage
- A carboxylic acid ester group at position 4 of the thiazole ring

22. The only structural difference between the two compounds is in the ester group, which is the presence of an ethoxycarbonyl group in the prior art document **D2** and a methoxycarbonyl group in the claimed compound under the subject application. These compounds differ by only one CH_2 unit in their ester groups. Under *Section 3(d)* of the Act, these two compounds are derivatives of each other as they are differing only by methoxy and ethoxy group and the appellant was unable to show the enhanced efficacy in the claimed compound of the subject application over the compounds in the prior art documents.

23. Qua the data analysis thereof, since the analysis of the comparative data as provided by the appellant itself does not discuss the enhancement of the "*therapeutic efficacy*" in the claimed compound under the subject application, therefore, it would still not be an invention under *Section 3(d)* of the Act. In any event, the applicant was required to show the "*therapeutic efficacy*" of the product in question, which, as per the impugned order, was missing since the data submitted by the appellant did not mention anything about it. The same is of utmost relevancy, in view of the Hon'ble Supreme Court, while dealing with similar circumstances, in ***Novartis v Union of India***[13] held as under:-

> *"180. What is "efficacy"? Efficacy means1 "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 laysdown 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.*

[13]Novartis AG v. Union of India, (2013) 6 SCC 1

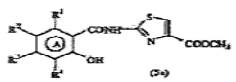
xxx xxx

187. 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."

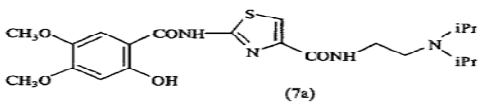
[Emphasis supplied]

24. It is noteworthy that the appellant itself, in the reply submitted on 26.08.2016, after the hearing before the Controller, stated that since the claimed compound is an intermediate, it is not possible to determine the "*therapeutic efficacy*" in the following terms:-

*"**Regarding the objection under Section 3(d)-** The Applicant humbly resists the learned Controller's objection and submits that the claimed compound does not relate to a "new form of a known substance" as envisaged under Section 3 (d) of the Act. The claimed compound is a novel intermediate of formula (5a):"*



for the preparation of a compound of formula (7a):



(7a)

"The novel intermediate of the present invention cannot be considered to be "a new form of a known substance" as envisaged under Section 3 (d) of the Act. The Applicant submits that the claimed compound is a novel intermediate and not a derivative of a known substance.

***The learned Controller will appreciate that as the claimed compound is an intermediate, it is not feasible to demonstrate the therapeutic effect of the claimed compound.** Nevertheless, as shown in the experimental data in Annexure I, the claimed synthetic*

intermediate has higher efficiency and is significantly useful compared to the compounds of the prior art owing to reduced reaction time, higher isolation yield and reduced amount of impurities. In this study, a comparison was made between a compound of formula (5a) of the present invention wherein R1 and R4 each represents a hydrogen atom and R2 and R3 each represents a methoxy group, with a compound which has the same structure as the compound of the present invention except that it is substituted by an ethoxy group instead of methoxy group at the carboxyl group. Accordingly, the learned Controller is requested to reconsider and withdraw the objection in this regard."

[Emphasis supplied]

25. Since the aforesaid leads to the conclusion that "*therapeutic efficacy*" of the claimed compound cannot be determined by the data submitted by the appellant, it is verily established that the appellant failed to demonstrate the "*therapeutic efficacy*" of the claimed compound over the prior art documents **D1** and **D2**. As such, the objection under *Section 3(d)* of the Act remained unsatisfied and existed leaving the subject application vulnerable to being patentable, particularly under *Section 3(d)* of the Act.

26. In view thereof, the claim of the appellant that the compound (5a) claimed under the subject application, when reacted with N, N-diisopropylethylenediamine (6), the corresponding compound of formula (7a) is obtained at a yield of 97% and the property of the reaction with N, N-diisopropylethylenediamine is specific to the methoxycarbonyl derivative and that using the claimed compound, formula (7a) is obtained at a yield of 97%, and that the subject application is better in terms of reduced reaction time, and has higher isolation yield and reduction in impurities, altogether fails.

Inventive step under Section 2(1)(ja) of the Act:

27. Qua *Section 2(1)(ja)* of the Act, the contentions of the appellant that (i) the compound of formula (5a) claimed in Claim 1 of the subject application is reacted with N, N-diisopropylethylenediamine (6) to provide a compound of formula (7a); and (ii) the differentiation from the prior art document **D2** that, being the closest prior art, an ethoxycarbonyl group is present instead of the methoxycarbonyl group in the subject application; and (iii) methyl ester having the methoxycarbonyl group as claimed in the subject application is not produced or specifically described, and, while starting out from the generic disclosure of formula (II), it requires a selection from multiple lists to arrive at the claimed compound, which cannot be considered obvious; and (iv) according to the Example 7 of the present invention, the reaction of compound (5a) of the present invention with N, N-diisopropylethylenediamine (6) results in the corresponding compound of formula (7a) at a yield of 97% and that the property of successfully reacting with N, N-diisopropylethylenediamine is specific to the methoxycarbonyl derivative according to Claim 1; and (v) the prior art document **D2** does not motivate, teach, or suggest, either alone or in combination, to arrive at the claimed compound; and (vi) unlike Claim 1 of the subject application, the closest prior art being document **D2**, does not disclose a methyl ester having a methoxycarbonyl group; this Court finds that they all have been rejected by the Controller in the impugned order on the basis of the disclosure made in the prior art documents **D1** and **D2**.

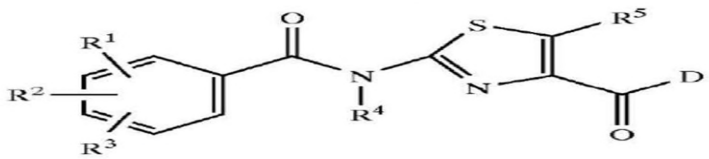
28. The Controller, in light of formula III of the prior art document **D1** as also Example 6 of the prior art document **D2**, mentioning of the *"methoxy"* group in formula (II) therein and the suggestions mentioned therein, held that Claim 1 of the subject application lacks inventive step under *Section 2(1)(ja)* of the Act as under:-

> *"5. With reference to paragraph 1 of the hearing notice the claimed invention is considered to be novel as none of the prior art documents DI and D2 specifically discloses the claimed compound of formula (5a). However the submission provided by the agent for the applicant is not found to be persuasive and in the light of the disclosure of DI and D2 the invention is considered to be obvious for a person skilled in the art. Both DI and D2 generically disclose claimed compounds. D2 discloses 2-[N-(4,5-dimethoxy-2-hydroxybenzoyl)amino]-4-(ethoxycarbonyl)-1,3-thiazole acetate in example 6 (table 1). The difference in said compound and claimed compound lies in the ester moiety attached to the thiazole ring ie "ethoxycarbonyl" in D2 whereas its "methoxycarbonyl" in the claimed invention. Further D2 discloses compounds of formula (II) (col. 2 1. 53- col. 3 1. 2) wherein lower alkoxy groups for "D" in compounds of formula (II) i.e. "methoxy" is specifically mentioned in col. 31. 26. D2 also suggest that such compounds are useful in the synthesis of compound 38 for example. Hence it is obvious for a person skilled in the art to replace "ethoxy" from "methoxy as part of routine experimentation in order to provide alternative intermediates useful in the synthesis of aminothiazole derivatives. Thus claim-1 lacks inventive step under section 2(1)(ja) of the Patents Act, 1970.*
>
> *Further claim-1 falls within the scope of section 3(d) of the Patents Act, 1970 as the claimed compound is considered to be mere discovery of new form ie. derivative of known compound as disclosed in D2 with no enhanced efficacy in terms of its effect on process wherein it is used as an intermediate.*
>
> *With reference to paragraph 2 of the hearing notice the agent for the applicant has filed the amended claims.*
>
> *6. Based on the above facts and circumstances of the case, it is observed that the objection raised in paragraph 1 vide official hearing notice w.rt. inventive step and section 3(d) still stands. Therefore, the instant application No. 3630/DELNP/2011 is hereby refused for grant of patent u/s 15 of the Patents Act, 1970."*

29. Interestingly, though as per the appellant, the substituent "D" is defined as "lower alkoxy groups" which by definition provided in the prior art document **D2**, includes both methoxy an ethoxy, although it is specifically provided in Example 6 Table 1 of the prior art document **D2** that it has "ethoxy" as "D", has been rejected by the Controller after holding that the aforesaid is part of routine experimentation to provide alternative intermediates useful in the synthesis of aminothiazole derivatives, and therefore it is considered obvious for a PSITA to replace "ethoxy" with "methoxy."

30. In fact, as per the Controller, the prior art document **D2** discloses 2-[N-(4,5-dimethoxy-2-hydroxybenzoyl) amino]-4-(ethoxycarbonyl)-1, 3-thiazole acetate in Example 6 as under:-

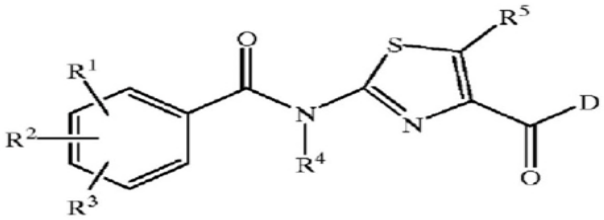
TABLE 1



Ref. Ex.	R^1	R^2	R^3	R^4	R^5	D	Melting point (° C.)
1	3-MeO	4-MeO	H	H	H	OEt	132–134
2	2-MeO	4-MeO	5-MeO	H	H	OEt	229.0–231.0
3	2-MeO	4-MeO	5-MeO	H	H	OH	243.0–245.0
4	3-MeO	4-MeO	H	Me	H	OEt	
6	2-OH	4-MeO	5-MeO	H	H	OEt	211.0–213.0 (acetate)

31. Additionally, as per the Controller, the prior art document **D2** discloses compounds of formula (II) under which "methoxy" is mentioned as lower alkoxy group for "D" in compounds of formula (II). The structure of the said formula (II) is given as follows:

(II)



wherein R^1, R^2, R^3, R^4 and R^5 have the same meanings as defined above, and D represents a hydroxy or a lower alkoxy group or salt thereof which is useful as an intermediate for the preparation of the invention compound (I).

32. The same is also clear from the below reference contained in page 3 of the prior art document **D2** (US005981557A):-

> *"Examples of the "lower alkoxy group" include linear, branched or cyclic alkoxy groups having 1 to 6 carbon atoms (which may hereinafter be fter be abbreviated as "C1-6 alkoxy") such as methoxy, ethoxy, propoxy, cyclopropoxy, isopropoxy, butoxy, isobutoxy, sec-butoxy, tert-butoxy, cyclobutoxy, pentyloxy, 1-methylbutoxy, 2-methylbutoxy, isopentyloxy, tertpentyloxy, 1,2-dimethylpropoxy, neopentyloxy, 1-ethylpropony, cyclopentyloxy, hexyloxy 1-methylpentyloxy, 2-methylpentyloxy, 3-methylpentyloxy, isohexyloxy, 1-ethylbutoxy, 2-ethylbutoxy, 1,1-dimethylbutoxy, 1,2-dimethylbutoxy, 1,3-dimethylbutoxy, 2,2-dimethylbutoxy, 2,3-dimethylbutoxy, 3,3-dimethylbutoxy, 1-methyl-1-ethylpropoxy, 1-ethyl-2-methylpropoxy, 1,1,2-trimethylpropoxy, 1,2,2-trimethylpropoxy and cyclohexyloxy. Among them, preferred are linear or branched C1.4 alkoxy groups."*

The aforesaid clearly establishes that the reference to "methoxy" is mentioned as lower alkoxy groups for "D" in compounds of formula (II). Therefore, it is undeniable that "methoxy" was/ is indeed mentioned therein.

33. Turning to the aspect of consideration by the Controller while rejecting the subject application under *Section 2(1)(ja)* of the Act, the prospects and the analysis thereof have been ably summed up by a

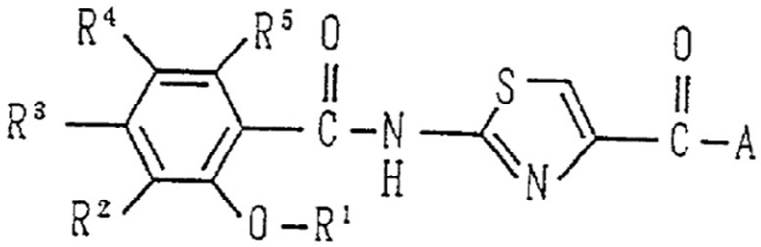
learned Single Judge of this Court in ***Agriboard International LLC vs Deputy Controller of Patents and Designs***[14] as under:-

> *"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:"*

34. In effect, the Controller has to consider the element of *"the invention disclosed in prior art"*, *"the invention disclosed in the subject application"* and *"the manner in which the claimed invention would be obvious to a person skilled in the art"*.

35. Considering the factual matrix involved herein, this Court finds that the Controller has not only considered the invention under the prior art documents as well as the invention under the subject application but has also mentioned the closest prior art, i.e. Example 6 of prior art document **D2**. Therefore, there is adequate justification while raising an objection under the "*inventive step*". In fact, the Controller, while referring to the prior art document **D1**, has also held that the same also discloses an intermediate compound of formula III that is used to prepare 2-hydroxybenzoylaminothiazole derivatives as under:-

[14] *2022 SCC OnLine Del 940,*



(3)

Wherein

A represent a hydroxyl or lower alkoxy group (which includes methoxy, ethoxy-), and other variables are as follows:

R2 represent OCH3
R3 represent H
R4 represent OCH3
R5 represent H
R6 represent OCH3

36. Based on the disclosure in the prior art documents **D1** and **D2**, for any PSITA, it is part of the routine experiment to reach the claimed compound of the subject application. Following the disclosure of formula (II) in the prior art document **D2**, which specifically mentions "methoxy" and the suggestions/ teachings thereunder (specifically compound 38), it renders obvious for PSITA to reach the claimed compound from the compound mentioned under Example 6 therein.

37. Lastly, though it is the case of the appellant that the prior art document **D1** "*teaches away*" from the claimed invention, as it is qua a reaction in which the compound of formula (5a) is not mentioned, however, the mere fact that the prior art document **D1** teaches a reaction or proposes an alternate solution and does not teach towards the other, does not in itself signify/ mean that the same actually "*teaches away*" from the claimed invention under the subject application. Moreover,

since merely because there is teaching towards one solution and not the other, the same in itself is not sufficient to consider the principle of "*teaches away*". Reliance in this regard is placed upon ***Astrazeneca AB and Another vs Torrent Pharmaceuticals Ltd.***[15], wherein a learned Single Judge of this Court while dealing with similar issue has held as under:-

> *"105. According to the plaintiff there is no motivation to look at Example 12 when 80 examples have been given of which Examples 1 and 2 were synthesized on a large scale, there is no motivation to change methyl group, there are no teachings towards substitution with ethoxy, efficacy data of Example 12 was not known, the teaching of IN "147 were to have hydrogen on central phenyl ring and no ethoxy on the distal phenyl in any of the 80 examples. As noted above, for preparation of the structure in Example 12, four methods have been noted and in the said example though methoxy was used and even though there was no teaching towards ethoxy, there were no teachings even away from ethoxy. Both ethoxy and methoxy being loweralkyl, a person with ordinary skill in the art would have been motivated to bring this single change of substitution of methoxy to ethoxy to find out if predictable results ensue. Consequently, this Court is of the prima facie opinion that the suit patent is vulnerable on the grounds of obviousness in view of Example 12 of IN "147."*

38. Thus, the Controller has rightly held in the impugned order that the prior art document **D2** suggests that such compounds, specifically "compound 38", are useful in the synthesis of aminothiazole derivatives recorded, and which is sufficient to motivate a PSITA to choose compounds therein, including Example 6 thereof being the closest compound. This is sufficient to conclude that it is obvious for a PSITA to replace "ethoxy" with "methoxy" to provide alternative intermediates useful in the synthesis of aminothiazole derivatives. The prior art

[15] *2020 SCC OnLine Del 1446*

documents **D1** and **D2** and the subject application relate to the same field of invention, and in each of them, one of the inventors, Mr. Masaaki Nagasawa, is the same, which is of much relevance.

39. Legally also, as per *Section 2(1)(ja)* of the Act, an "*inventive step*" is/ has to be more than just a variety and/ or add on variation as it should be beyond the known to anyone who is belonging/ known to the relevant field in which the patent is connected for grant. As such, any trivial mill on the run improvement/ change/ modification, which is not reflective of any creativity and/ or invention, is not within the realm of an "*inventive step*", as per *Section 2(1)(ja)* of the Act.

Conclusion:

40. In view of the aforesaid, the subject application is neither falling within *Section 3(d)* nor *Section 2(1)(ja)* of the Act. Thus, this Court is in agreement with the findings of the Controller whereby the subject application of the appellant has been refused.

41. Accordingly, there is no merit in the present appeal which is dismissed with no order as to costs.

SAURABH BANERJEE, J.

MAY 27, 2025
AB