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

% ***Judgment Reserved on: 23.04.2025***
Judgment pronounced on: 15.05.2025

\+ C.A. (COMM.IPD-PAT) 6/2022

TAIHO PHARMACEUTICAL CO. LTD. .....Appellant

Through: Mr. Ankush Verma, Mr. Debashish Banerjee, Ms. Vaishali Joshi, Mr.Vineet Rohilla, Mr. Pankaj Soni, Mr.Rohit Rangi, Mr. Tanveer Malhotra & Ms. Gurmeet Kaur, Advocates.

versus

THE CONTROLLER OF PATENTS .....Respondent

Through: Mr. Premtosh K. Mishra, CGSC with Mr. Manish Vashisht, Ms. Sanya Kalsi and Mr. Prakhar Singh, Advocates.

CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL

JUDGMENT

AMIT BANSAL, J.

1. The present appeal has been filed under Section 117A of the Patents Act, 1970 (hereinafter 'Act') and is directed against the order dated 18th June, 2021 (hereinafter 'impugned order') passed by the Assistant Controller of Patents and Designs (hereinafter 'Controller'), whereby the Indian Patent Application No. 7283/DELNP/2014 titled *'Novel Piperidine Compound or Salt thereof'* (hereinafter 'subject patent application') has been refused.

BRIEF FACTS

2. Brief facts necessary for deciding the present appeal are set out below:

2.1. The appellant, Taiho Pharmaceutical Co. Ltd., is an entity based in Japan.

2.2. The subject patent application was filed as a national-phase application under the Patent Cooperation Treaty ('PCT'), claiming priority from a Japanese Patent Application with a priority date of 27th August, 2012. The appellant had filed the subject patent application on 29th August, 2014, with the Indian Patent Office, Delhi. The bibliographic details of the application are given below:

Indian Application No.	7283/DELNP/20 14
Applicant	TAIHO PHARMACEUTICAL CO. LTD.
Priority Application No. & Date	JP2012186534; Dated 27th August, 2012
International Application No. & Filing Date	PCT/JP2013/055064; Dated 27th February, 2013
PROSECUTION	
India Filing Date	29th August, 2014
Date of publication u/s 11A	24th April, 2015

Request for Examination	29th August, 2014
First Examination Report Issue Date	28th March, 2018
First Examination Report Response Filed on	20th September, 2018
Hearing Notice Issued Date	10th October, 2019
Date of Hearing	18th November, 2019
Written Submissions under Section 14 filed by Applicant on	29th December, 2019
Controller Decision	18th June, 2021

2.3. A request for examination of the said application was filed by the appellant on 29th August, 2014, and the First Examination Report (hereinafter 'FER') was issued on 28th March, 2018. The following substantive objections were communicated to the appellant *via* the said FER:

a. Lack of inventive step under Section 2(1)(ja) of the Act;

b. Non patentable under Section 3(d) and 3(i) of the Act;

2.4. In reply to the objections raised in the FER, the appellant's agent submitted a detailed response *vide* letter dated 20th September, 2018.

2.5. Thereafter, a hearing was scheduled for 10th October, 2019, and the

following objections were communicated to the appellant *vide* the hearing notice:

a. Lack of inventive step under Section 2(1)(ja) of the Act;

b. Non patentable under Section 3(d) of the Act;

2.6. Post hearing, written submissions along with amended claims were filed by the appellant before the Patent Office on 29th November, 2019.

3. The impugned order was passed by the Patent Office on 18th June, 2021, refusing the subject patent application on the ground that the claims of the subject patent application lack inventive step as required under Section 2(1)(ja) of the Act and is non patentable under the Section 3(d) of the Act.

4. The impugned order holds that the compound claimed in the subject patent application constitutes a new form of known substances already disclosed in the prior art D1[1], and fails to demonstrate enhanced therapeutic efficacy over the compounds disclosed therein as required under Section 3(d) of the Act. Furthermore, the claimed compound in the subject patent application is considered obvious to a person skilled in the art in view of the closest prior art D1, particularly with reference to Examples 15 and 16, and therefore does not meet the requirement of inventive step under Section 2(1)(ja) of the Act.

5. The relevant extracts from the impugned order are set out below:

5.1. Regarding objection under Section 2(1)(ja) of the Act, the Controller has held as under:

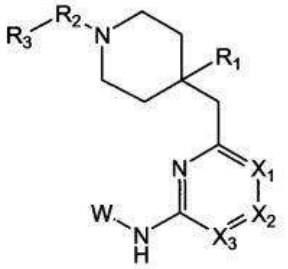
"E. Disclosures from closest Cited Prior art Dl.

[1] (WO 2009/104802 A1, BANYU PHARMA CO. LTD [JP]; KATO TETSUYA [JP]; KAWANISHI NOBUHIKO [JP], dated 27 August 2009

_D1 WO 2009/104802 A1 (BANYU PHARMA CO LTD [JP]; KATO TETSUYA [JP]; KAWANISHI NOBUHIKO [JP];) 27 August 2009 (2009-08-27)

D1 is most relevant and closest prior art. D1 relates to amino-pyridine derivatives which are useful in the pharmaceutical field, and more particularly, to those which inhibit the growth of tumor cells based on an Aurora A selective inhibitory action and exhibit an antitumor effect, and also to an Aurora A selective inhibitor and an antitumor agent containing them having molecular formula I as given below,

1. A compound of general formula I:

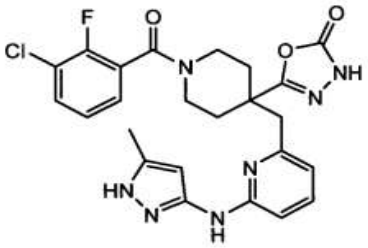


(I)

X3 is CH, CX3a, or N wherein X3a is a lower alkyl which may be substituted; provided, however, that among X1, X2 and X3, the number of nitrogen is 0 or 1;

Example 15

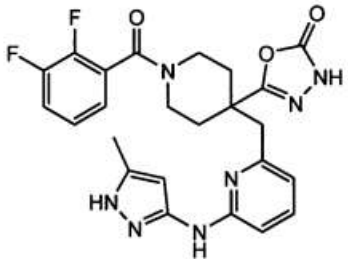
Synthesis of 5-(l-(3-chloro-2-fluorobenzoyl)-4-((6-((5-methyl-lH-pyrazol-3-yl)amino)pyridin-2-yl)methyl)piperidin-4-yl)- 1,3,4-oxadiazol-2(3H)-one



(1) Synthesis of 1-tert-butyl 4-ethyl 4-((6-((l-tert-butyl-3-methyl-lH-pyrazol-5-yl)amino)pyridin-2-yl)methyl)piperidine- 1,4-dicarboxylate

Example 16

Synthesis of 5-(l -(2,3-difluorobenzoyl)-4-((6-((5-methyl-lH-pyrazol-3-yl)amino)pyridin-2-yl)methyl)piperidin-4-yl)- 1,3,4-oxadiazol-2(3H)-one



From above disclosed information molecular formula of compounds of D1 it is clear that the said pharmaceutical/ therapeutic activity is because of substituted amino pyrimidine ring wherein the amino substituted pyrimidine of formula I is having substitution X1,X2,X3.

Thus, the provision of compounds encompassed by the general teaching of D1 for the same use has to be seen as obvious therefore the problem of the present application has to be seen in the provision of further substituted piperidine compounds with an aurora A kinase inhibitory effect, and their use in cancer therapy exhibiting superior unexpected effects in relation to the rest of the range of D1.

The presently claimed subject matter in claims 1-4 does not appear to comply the requirements Section (2)(1)(ja) of The Patents Act, 1970 because the application relates to substituted piperidine compounds with an aurora A kinase inhibitory effect, and their use in cancer therapy. Similarly the compounds of D1 are described to have selective Aurora A inhibitory action from same backbone chemical structure (skeleton) of the compounds from D1. *In present application the derivatization occurred in terms of R1,R2,R3, R4 at different sites of the molecule of formula (I) however the basic backbone structure remained same as of disclosure of D1.* ***As for as substituents in terms of R1,R2,R3, R4 concern in the present formula, it is obvious selection from the narrow range of same substituents available in Prior art D1. Further, Selection of substitution at R groups again, is very comfortable choice from narrow range.*** *For instance,* ***the compounds 15, 16 of D1 are closest compounds as claimed in instant application which is considered as obvious choice to the person skilled in art to come to the compounds of present application therefore claims lacks inventive step and does not comply the requirements of section 2(1)(ja) of the Act.***

Measurements of the activity of Aurora B from prior art D1.

Table 1

Example	Inhibitory activity for Aurora A (IC_{50}, nM)	Inhibitory activity for Aurora B (IC_{50}, nM)
Example 2	0.91	368.7
Example 3	1.60	400
Example 4	1.14	>1000
Example 5	0.63	554.9
Example 6	1.57	>1000
Example 7	0.61	134.8
Example 8	0.79	554.9
Example 9	0.25	35.8
Example 10	0.27	165.8
Example 11	0.26	235.8
Example 13	2.55	608.9
Example 14	0.40	>1000
Example 15	0.25	77.5
Example 16	0.41	156.7
Example 17	0.30	380.8
Example 18	1.23	>1000
Example 19	1.27	>1000

Table 2

	Cell growth inhibitory effect (HeLaS3) (IC_{50}, μ M)
Example 2	0.78
Example 9	0.22
Example 10	0.28
Example 14	1.73
Example 17	0.10
Example 19	1.01

,,

[Emphasis supplied]

5.2. Regarding the objections under Section 3(d) of the Act, the Controller has held as under:

> *"The subject matter of claims 1-14 describes the piperidine compound having Aurora-A-selective inhibitory activity and useful as an anti-cancer agent. Aurora-A is a member of serine-threonine kinase and the inhibiting activities of these compounds are due to the presence of nitrogenated saturated heterocyclic group skeleton which is known in prior arts D1.*

Applicant has provided the comparison of activates of compounds of instant application with Paclitaxel which is not from same group of compounds or it is not having similar skeleton as of compounds of instant application. Because the closed available compounds from D1 share the same backbone structure with that of Instant application and that skeleton is basically responsible for the desired activity therefore compounds of instant application are considered the further/ other derivatives of the known compounds from prior art D1 as discussed above. *A new form of compounds of instant application of a known substance from prior art D1 which does not result in the enhancement of the known efficacy of that substance for a known substance is considered to be the same substance, therefore subject matter of claims 1-14 falls within the scope of section 3(d) of the Patents Act 1970.*

[Table 22]

	Day 11	
Group	RTV	BWC
Control	7.24	7.2
Paclitaxel	2.90	5.4
Compound 13	6.54	6.0
Compound 13/Paclitaxel	0.72	4.2

[0128]

[Table 23]

	Day 11	
Group	RTV	BWC
Control	5.68	10.9
Paclitaxel	3.05	7.8
Compound 22	4.66	6.9
Compound 22/Paclitaxel	1.73	2.8

"

[Emphasis Supplied]

SUBMISSIONS BY THE PARTIES

6. The counsel appearing on behalf of the appellant has made the following submissions:

6.1. Regarding the objection under Section 2(1)(ja) of the Act, the Respondent has cited D1 as the closest prior art, which fails to provide a clear and explicit suggestion as to how a person skilled in the art will be directed

towards the subject patent application.

6.2. The specific examples 15 and 16 of the prior art D1 do not have a halogen atom or a C1–C6 alkoxy group at the 3-position (R2 position). Instead X_3 or lower alkyl group is present in D1.

6.3. The presence of R2 in the compound claimed in the subject patent application provides increased oral absorbability and enhanced therapeutic activity compared to prior art D1.

6.4. Regarding the objection under Section 3(d) of the Act, the Controller has failed to identify the 'known substance' in the closest prior art D1 while referring to it in the hearing notice and in the impugned order. Reliance is placed on the judgment passed by this court in ***DS Biopharma Ltd.*** **v.** ***Controller of Patents & Designs***[2]**.**

6.5. The Controller has also not considered the research data of enhanced efficacy due to increased oral absorbability provided in Table 21 of the Complete Specification of the subject patent application.

6.6. Patent applications corresponding to the subject patent application have been granted in major jurisdictions, thereby affirming the patentability of the subject patent application.

7. *Per Contra*, Mr. Premtosh K. Mishra, CGSC, appearing on behalf of the respondent, has made the following submissions:

7.1. The compounds similar to those of the subject patent application with the same core chemical structures are already disclosed in the closest prior art D1. The only change made in the subject patent application is in the derivatisation carried out at the positions R1, R2, R3 and R4 of the molecule

[2] 2022 SCC OnLine Del 5206

represented by formula (I). This substitution appears to be an obvious choice from a narrow range of similar substituents disclosed in prior art D1, for instance, compounds 15 and 16 of the prior art D1. Hence, the claimed compounds lack inventive step and do not comply with the requirements of Section 2(1)(ja) of the Act.

7.2. The appellant has provided a comparison of the activities of the claimed compounds with Paclitaxel, which is not related to the compounds of the subject patent application. The claimed compounds are derivatives of the known compounds from prior art D1. A new form of a known substance from the prior art D1, which does not result in the enhancement of the known efficacy of that substance, is considered to be the same substance. Therefore subject matter of claims 1-14 falls within the scope of Section 3(d) of the Act.

ANALYSIS AND FINDINGS

8. I have heard the learned counsel for the parties and examined the records of the case.

9. From a perusal of the impugned order, it is apparent that the subject patent application has been rejected under Sections 3(d) and 2(1)(ja) of the Act.

10. The Supreme Court in ***Novartis AG* v. *Union of India***[3] has held that Section 3(d) of the Act places the threshold for patentability, particularly in relation to pharmaceutical and chemical substances, on a higher pedestal in comparison to the general standard under Section 2(1)(j) of the Act. The relevant extract from ***Novartis*** (supra) is given below:

> *"104. We have so far seen section 3(d) as representing "patentability", a concept distinct and separate from "invention". But if clause (d) is isolated*

[3] (2013) 6 SCC 1

*from the rest of section 3, and the legislative history behind the incorporation of Chapter II in the Patents act, 1970, is disregarded, then it is possible to see section 3(d) as an extension of the definition of "invention" and to link section 3(d) with clauses (j) and (ja) of section 2(1)**. In that case, on reading clauses (j) and (ja) of section 2(1) with section 3(d) it would appear that the Act sets different standards for qualifying as "inventions" things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in section 3(d) in the year 2005.**"*

[Emphasis supplied]

11. From the above-extracted paragraph, it is clear that Section 3(d) of the Act plays an important role in determining the patentability of pharmaceutical or chemical substances. However, the focus of Section 3(d) is on the 'new form of known substance'. For clarity, Section 3(d) of the Act is reproduced hereunder:

"3. What are not inventions.—The following are not inventions within the meaning of this Act,—

***

*(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;"

[Emphasis supplied]

12. A reading of Section 3(d) of the Act would show that Section 3(d) bars the patentability of a 'new form' of a 'known substance' unless it demonstrates

enhanced therapeutic efficacy. In this regard, a reference can be made to ***DS Biopharma*** (supra) wherein a coordinate bench of this Court has laid down the steps to be followed by the Patent Office before holding an invention to be barred by Section 3(d) of the Act. Relevant extracts from ***DS Biopharma*** (supra) are given below:

> *"15. The Appellant in the reply to the hearing notice submits that the Ld. Controller has not specified under which part of Section 3(d) of the Act does the objection fall. The Appellant goes on to assert that as per its understanding of the Fresenius Kabi judgement (supra), for an objection under non-patentability to be raised, the patent office needs to specifically allege and identify at least the following:*
>
> ***(i) What is the specific 'known' substance in question?***
>
> ***(ii) How and why the claimed molecule(s) or substance(s) is a derivative or is otherwise a new form of a known substance?***
>
> ***(iii) Basis to assert that the alleged 'known' substance and the claimed molecule or substance have the same 'known' efficacy?***
>
> ***16. The Ld. Controller in the hearing notice has failed to identify any of the above three factors. It is also submitted by the Appellant that in the absence of identification of the 'known' compound it is unable to respond clearly to this objection, severely hampering its right to be given a reasonable opportunity to defend its patent application. It further submits that it is under no legal obligation under Section 3(d) of the Act to demonstrate the efficacy of the claimed compound in the absence of identification of the 'known' compound.***
>
> *17. In the present case, the finding of the Controller is as under:*
>
> > *"The claimed compounds differ from the compounds of the prior art only on the account of minor modifications, namely the presence of an oxo group at position 15 of the carboxylic acid chain instead of a OH group of H atom with respect to the compounds of D1 and D4 respectively, and the presence of a double bound between C17-C18 of the carboxylic acid chain instead of a single bond with respect to the compound of D6."*

18. Thus, the Controller clearly holds in the impugned order that the identified compounds are in D1 and D4 in which at position 15, a substitution has been made by the Appellant. The identified known substances are also in D6 where the presence of double bond between C17 and C18 of the carboxylic acid chain, instead of the single bond in the claim of the Appellant. These facts could have been contained in the hearing notice, upon which, the Appellant could have responded as to how the objection under Section 3(d) was not attracted. The Appellant could have also established that the subject compounds had enhanced therapeutic efficacy to satisfy the pre-conditions under Section 3(d).

19. ***Therefore, holistically read, the Appellant has not had adequate opportunity to deal with the objection under Section 3(d) in as much as apart from merely specifying the said objection for the first time in the hearing notice, the manner in which the said objection was attracted was completely absent.***

*20****. In the absence of the proper identification of the known substance in the hearing notice and a lack of proper opportunity being afforded to respond to the objection under Section 3(d), the impugned order is not sustainable****."*

[Emphasis supplied]

13. From the above extracted paragraphs, it can be inferred that in order to sustain an objection under Section 3(d) of the Act, the following factors have to be clearly identified by the Controller:

i) the 'known substance' with 'known efficacy';

ii) clear explanation as to how and why the claimed substance is a derivative or otherwise a new form of a 'known substance';

iii) an objective comparison between the *therapeutic efficacy* of the claimed invention and that of the known substance.

14. The aforesaid aspects have to be identified by the Controller in the hearing notice, so as to afford a reasonable opportunity to the applicant to respond to it.

15. The ratio of ***DS Biopharma*** (supra) is fully applicable in the facts and circumstances of the present case. In the present case as well, the hearing notice failed to properly identify the 'known substance'. The hearing notice only refers to D1 as the closest prior art and makes a general observation regarding structural similarity between the compounds of the subject patent application and those disclosed in D1. To be noted that the prior art D1 identified by the Controller in the hearing notice is a Markush structure encompassing numerous potential compounds with various substitutions at multiple positions. The Controller in the hearing notice failed to identify a specific 'known substance' from D1 against which the claimed invention was being assessed. The appellant cannot be expected to infer a 'known substance' and furnish efficacy data based on such inference.

16. By not identifying any particular 'known substance' in the hearing notice, the appellant was not afforded a fair opportunity to respond to the same, by demonstrating, through comparative research data, that the claimed compound possesses enhanced therapeutic efficacy over the particular 'known substance'. In the absence of such identification, the rejection on the ground of Section 3(d) is not sustainable and warrants a remand for fresh consideration.

17. In light of the analysis above, the Controller's rejection under Section 3(d) of the Act is not sustainable.

18. With regard to the objection under Section 2(1)(ja) of the Act, the Controller, in the impugned order, has relied on the closest prior art D1, particularly referring to Examples 15 and 16 as the closest compounds. Since the reasoning under Section 2(1)(ja) of the Act, pertaining to lack of inventive step, is closely intertwined with the assessment under Section 3(d) of the Act,

the objection under Section 2(1)(ja) also warrants reconsideration upon proper identification of the 'known substance' from the closest prior art and comparison of the enhanced efficacy data thereof by the appellant.

19. Accordingly, while reconsidering the objection under Section 3(d), any research data demonstrating enhanced therapeutic efficacy, if submitted by the appellant, may also be duly considered while examining the inventive step under Section 2(1)(ja) of the Act.

20. In light of the foregoing analysis, the impugned order is set aside in the above terms, and the matter is remanded back to the Patent Office for fresh consideration.

21. The Controller would afford a fresh opportunity of hearing before deciding the subject patent application, after giving a hearing notice to the appellant.

22. Needless to state that the fresh order passed by the Controller will deal with valid submissions raised on behalf of the appellant.

23. The present appeal stands disposed of in terms of the aforesaid.

24. The Registry is directed to supply a copy of the present order to the office of the Controller General of Patents, Designs & Trade Marks of India on the e-mail- *llc-ipo@gov.in* for compliance.

AMIT BANSAL
(JUDGE)

MAY 15, 2025
at/ds