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

\+ C.A.(COMM.IPD-PAT) 167/2022

ADAMA MAKHTESHIM LTD ..... Appellant

Through: Mr. Debashish Banerjee, Mr. Vineet Rohilla, Mr. Ankush Verma, Mr. Venkatesh Naik, Mr. Rohit Rangi and Mr. Tanveer Malhotra, Advocates.

versus

THE CONTROLLER OF PATENTS ..... Respondent

Through: Mr. Harish Vaidyanathan Shankar, Central Government Standing Counsel with Mr. Srish Kumar Mishra, Mr. Sagar Mehlawat and Mr. Alexander Mathai Paikaday, Advocates.

CORAM:
HON'BLE MR. JUSTICE SANJEEV NARULA

O R D E R

% 01.05.2023

1. The present appeal relates to Appellant's patent application No. 201617025525 for the invention titled "5-FLUORO-4-IMINO-3-(ALKYL/SUBSTITUTED ALKYL)-1-(ARYLSULFONYL)-3, 4-DIHYDROPYRIMIDIN-2(lii)- ONE AND PROCESSES FOR THEIR PREPARATION" [*hereinafter*, "*subject invention*"], which has been refused under Section 15 of the Patents Act, 1970 [*hereinafter*, "*the Act*"] *vide* order dated 18th February, 2021 [*hereinafter*, "*impugned order*"] on the ground that claim specifications do not fulfil the criteria laid down under Section 10(4)(a) of the Act.

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2. Mr. Debashish Banerjee, counsel for Appellant, argues that a jurisdictional error has been committed by the Assistant Controller of Patents and Designs inasmuch as the objection under Section 10(4)(a) was discussed for the first time in the impugned order and Appellant was not afforded any opportunity to meet the said objection. Relying on decision of this Court in ***Perkinelmer Health Sciences Inc. and Ors. v. Controller of Patents***,[1] he submits that the impugned order deserves to be set aside.

3. *Per contra*, Mr. Harish Vaidyanathan Shankar, counsel for Respondent, defends the impugned decision, contending that same was arrived at after affording sufficient hearing to the Appellant. However, the Appellant failed to satisfy the Assistant Controller *qua* clarity of claim specifications with working examples. Thus, the subject invention has been rightly rejected.

4. The Court has considered the afore-noted contentions. The substantive technical objections raised in the First Examination Report ["*FER*"] issued on 26th April, 2019 read as under:

> "***(1). INVENTIVE STEP:***
> *Claim(s) (1-11) lack(s) inventive step, being obvious in view of teaching (s) of cited document(s) above under reference for the following reasons:*
> *The alleged invention describes 5-fluoro-4-imino-3-(alkyl/substituted alkyl)-1-(arylsulfonyl)-3,4-dihydropyrimidin-2(1h)-one and processes for their preparation. Document D1(WO2013/025795 A1) discloses the preparation of a compound falling within the alleged Formula III from a compound falling within alleged Formula II using an alkylating agent and potassium carbonate (example 1, step 2) or lithium carbonate (example 3, step 1). Also, document D2(US2011/263627 A1) discloses the preparation of a compound falling within the alleged Formula III from a compound falling within alleged Formula II using an alkylating agent and potassium carbonate (examples 1-3). D1 and D2 are silent about the use of alkali alkoxide. However no technical advancement could be recognized from the abovementioned difference and hence it would be imperative to consider the it is a mere alternative or replacement of the alkali carbonate as taught in cited documents*

[1] Order dated 04th January, 2023 in C.A.(COMM.IPD-PAT) 311/2022.

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with an alkali alkoxide base which is known to any person skilled in the art. Also, document D3(Dilip Birari et al.: "Synthesis of Cytosine Derivatives and Study of their Alkylation under Mild Conditions", Organic Preparations and Procedures International: The New Journal for Organic Synthesis, vol. 41, no. 6, 2009, pages 515-532) teaches the N-alkylation of compounds which are similar in structure to the alleged Formula II (page 517). Any person skilled in the art would have obviously been motivated to replace the alkali carbonate of D1 or D2 with the potassium t-butoxide (as taught in D3) and would have easily standardized the reaction conditions using routine experimentation without exceeding his normal capabilities. Also, it is noted that there are no examples of the method of claims 1-11 in the present application and furthermore example 2 is shown to use lithium carbonate as the base, rather than an alkali alkoxide. Hence claims 1-11 do not involve an inventive step u/s 2(1)(j) and 2(1)(ja) of the Indian Patents Act, 1970 (as amended) over documents D1 or D2, when combined with the teachings of document D3 and common general knowledge.

(2). SUFFICIENCY OF DISCLOSURE:

आपत्तियां /Objections	टिप्पणी /Remarks
Power of Attorney (Whether GPA, SPA, Stamped, requisite fee etc.)	The power of attorney submitted by the applicant should contain the registration number(s) of the authorized attorney(s).
Statement & Under Taking (Form 3 Details)	Details regarding the corresponding co-pending foreign applications have not been updated as prescribed u/s 8 and rule 12 of Indian Patents Act 1970 and Patent Rules, 2003(as amended).
Other Deficiencies	1. Form 1 has not been submitted at the time of filing of application and also not within the time limit of entering the national phase in India i.e. 31 months from the date of priority as prescribed u/s 7 and rule 20 of the Indian Patents Act, 1970 and Patent rules, 2003(as amended). 2. Form 5 has not been given in the proper format as it is not signed by the applicant's attorney and the nationalities of the inventors have not been provided, as prescribed u/s 10(6) and rule 13(6) of Indian patents Act 1970 and Patents rules, 2003(as amended). 3. Form 18 has not been submitted in the proper format as prescribed u/s 11-B and rules 20(4)(ii), 24-B(1)(i) of the Indian Patents Act, 1970 as the name and signature of the attorney are missing.

5. The objections listed in the Hearing Notice dated 22nd October, 2020, are as follows:

"***Clarity and Conciseness***

1. 1. The terms Alkali alkoxide, alkylating agent in claim 1, about in claims 6, 7, 9, 12 are vague and not clear as they have no limiting effect on the said claims. Hence the said claims are not allowable u/s 10(4)(c) and 10(5) of the Indian Patents Act, 1970 (as amended).

2. The expression and/or in claim 2 is vague and not clear as it questions the essentiality of the alleged technical feature for the claimed invention. Hence the said claim is not allowable u/s 10(4)(c) and 10(5) of the Indian Patents Act, 1970 (as amended).

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Formal Requirement(s)

1. 1. Requisite/Balance fees have not been paid by the applicant as prescribed u/s 142 and rule 7 of the Indian Patents Act, 1970 and Patents rules, 2003 (as amended) as per the no. and pages of the claims when the claims were amended from 1-11 to 1-13 dated 16-09-2019.

2. The power of attorney dated 18-09-19 submitted by the applicant should contain the registration number(s) of the authorized attorney(s).

3. Form 1 dated 26-07-16 should be submitted to the office.

4. Form 1 dated 16-09-19 has not been submitted to the office in the proper format as prescribed u/s 7, 54 & 135 and rule 20(1) of Indian patents Act 1970 and Patents rules, 2003(as amended) as the nationalities of inventors, and country of residence have not been mentioned. Also the international PCT application no. is incorrect.

5. Form 5 dated 16-09-19 has not been given in the proper format as nationalities of the inventors have not been given, as prescribed u/s 10(6) and rule 13(6) of Indian patents Act 1970 and Patents rules, 2003(as amended).

Invention u/s 2(1)(ja)

1. The alleged invention describes 5-fluoro-4-imino-3-(alkyl/substituted alkyl)-1-(arylsulfonyl)-3,4-dihydropyrimidin2(1h)-one and processes for their preparation. Document D1(WO2013/025795 A1) discloses the preparation of a compound falling within the alleged Formula Ill from a compound falling within alleged Formula II using an alkylating agent and potassium carbonate (example 1, step 2) or lithium carbonate (example 3, step 1). Also, document D2(US2011/263627 A1) discloses the preparation of a compound falling within the alleged Formula Ill from a compound falling within alleged Formula II using an alkylating agent and potassium carbonate (examples 1-3). D1 and D2 are silent about the use of alkali alkoxide. However no technical advancement could be recognized from the abovementioned difference and hence it would be imperative to consider the it is a mere alternative or replacement of the alkali carbonate as taught in cited documents with an alkali alkoxide base which is known to any person skilled in the art. Also, document D3(Dilip Birari et al.: "Synthesis of Cytosine Derivatives and Study of their Alkylation under Mild Conditions", Organic Preparations and Procedures International: The New Journal for Organic Synthesis, vol. 41, no. 6, 2009, pages 515-532) teaches the N-alkylation of compounds which are similar in structure to the alleged Formula II (page 517). Any person skilled in the art would have obviously been motivated to replace the alkali carbonate of D1 or D2 with the potassium t-butoxide (as taught in D3) and would have easily standardized the reaction conditions using routine experimentation without exceeding his normal capabilities. Also, it is noted that there are no examples of the method of claims 1-13 in the present application and furthermore example 2 is shown to use lithium carbonate as the base, rather than an alkali alkoxide. Hence claims 1-13 do not involve an inventive step u/s 2(1)(j) and 2(1)(ja) of the Indian Patents Act, 1970 (as amended) over documents D1 or D2, when combined with the teachings of document D3 and common general knowledge.

Other Requirement(s)

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1. Voluntary amendment such as "molar ratio of the compound of formula II to the alkylating agent is from about 1:1 to about 1:3" in claim 6 is not allowable under section 59 of the Patents Act, 1970 (as amended) as said amendment fall beyond the scope of original disclosure and do not fall under category of correction, explanation and disclaimer.

Scope

1. 1. Claim 1 is broad as no relative molar ratios of the reactants and the reagents is given. The claim should be restricted to be within the scope of examples disclosed in the specification."

6. Apart from the afore-extracted, no other technical or substantive objections were ever raised, yet, the subject invention has been rejected under Section 10(4)(a) by Assistant Controller, holding as under:

"After hearing the case and in view of the applicant's agent written submission, and the amended claims (1-13) available on record, the following conclusion is drawn on the patentability aspect of the instant invention in the patent application. Further, declaration of Gal Suez, as Exhibit 2 cannot be taken on record as per discussion during the hearing as the base (lithium carbonate) used has already been disclosed in prior art.

Now, I turn my attention to the subject matter claimed in amended claim 1, wherein the feature the molar ratio of the compound of Formula II to the alkali alkoxide is from 3:1 to 1:1 has been added. The applicant argued during the hearing that the invention lies in the molar ratio of the compound of Formula II to alkali alkoxide, and is the distinguishing feature of the subject application. As per applicant's agent argument the crux of the invention is lies in the use of alkali alkoxide with the compound of Formula II however there are no examples illustrating the presently claimed process. Example 2 employs a lithium carbonate base rather than the claimed alkali alkoxide. There is no working example where the alkali alkoxide (KOtBu, CH3ONa, CH3CH2ONa, CH3CH2OLi, CH3OLi, CH3CH2OK, and CH3CH2ONa) as mentioned in claims have been disclosed. Therefore the examples given therein are not fully enabling to the subject matter claimed in claims. Hence, due to lack of guidance as set forth above, undue quantity of experimentation would be required by the person skilled in the art to practice the claimed invention.

No credible evidence is provided in the specification regarding the sensitivity and the specificity of the claimed alkali alkoxide in the claimed method. Thus, the specification fails to meet the requirements of Section 10 (4) (a) of the Act.

Upon consideration of all the documents available on record as well as based on the discussion had during the course of hearing and subsequent amendments and submissions made thereof, and in view of above findings, the subject matter of the above original claims and the revised claims, invention not patentable u/s 10 (4) (a) of the Patent Act.

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Based on the above facts and on the circumstances of the case, it is hereby ordered that the invention disclosed and claimed in the instant application 201617025525 entitled "5-FLUORO-4-IMINO- 3-(ALKYL/SUBSTITUTED ALKYL)-l-(ARYLSULFONYL)-3,4-DIHYDROPYRIMIDIN- 2(lii)-ONE AND PROCESSES FOR THEIR PREPARATION" has been refused to proceed further."

7. The Assistant Controller has observed that the claimed process lacks illustrative examples, and the examples submitted by the Appellant are not sufficient to enable the subject matter claimed in the application. Despite the specification being found non-compliant with Section 10(4)(a), it is worth noting that this objection was not raised in either the FER or the Hearing Notice. The first time that Appellant was confronted with this objection was in the impugned order, which raises concerns over the fairness of the process. Although a hearing was provided, it does not absolve the Respondent of their obligation to communicate all objections prior to refusal. Therefore, the Appellant's right to due process has been violated.

8. On the afore-mentioned issue, Mr. Vaidyanathan argues that an objection regarding the scope of the claims was raised in the Hearing Notice, thereby affording the Appellant an opportunity to address the objection. However, it should be noted that while the Hearing Notice did state that the claim should be restricted to the scope of examples disclosed in the specification, it did not explicitly cite Section 10(4)(a) of the Act as an objection. In response to the Hearing Notice, the Appellant amended its claim 1 to include the molar ratio and limit the claim. Therefore, Mr. Vaidyanathan's submission does not sustain as the objection under Section 10(4)(a) was only raised for the first time in the impugned order, after the Appellant had already amended their claim in response to a different

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objection.

9. For the foregoing reasons, and relying upon ***Perkinelmer Health Sciences Inc*** (*Supra*), the Court is of the opinion that the procedural irregularity (noted above) vitiates the impugned order and accordingly, following directions are issued:

9.1. Without getting into the merits of other grounds of challenge and objections raised in the impugned order, the impugned order dated 18th February, 2021, is set aside.

9.2. The matter is remanded back to Respondent for fresh consideration.

9.3. A fresh notice of hearing raising all the objections shall be issued to the Appellant, within a period of four weeks from today, in accordance with law.

9.4. The hearing shall thereafter be conducted within a period of four months from the date of issuance of the notice of hearing.

10. Before parting, the Court would like to address an issue that has been observed in several other appeals arising from the refusal of patent applications. It is well-known that patent applications have a limited term, a substantial portion of which is spent in the office of the Controller of Patents and Designs. In the instant case, the application for the subject invention was filed in 2016, and nearly half of the life of the patent has already elapsed. Although the Hearing Notice raised objections under several sections of the Act, the application has been rejected only on one ground, without addressing the other objections. Therefore, while exercising appellate jurisdiction at this stage, the Court cannot delve further into the matter as no reasoning is discernible on the other grounds of

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objections, and the matter must be remanded back for fresh consideration.

11. Thus, it must be observed that since the orders of the Controller under Section 15 of the Act are subject to judicial review in appeal, it would be advisable for the Controller to examine all grounds of objection while deciding an application, even if the application is found to be non-patentable on any one of the preliminary or technical grounds. This approach would expedite the process of granting patents by allowing the Courts to assess the patentability of inventions if the technical objection is overruled. Only if the merits of the claims and issues relating thereto are interlinked with technical grounds, this approach may not be feasible, and an observation should be recorded to that effect. However, in situations where the grounds of refusal mentioned in the Hearing Notice are independent and can be examined as such, a comprehensive order should be passed addressing all of the objections.

12. With the above observations, the present appeal is disposed of.

SANJEEV NARULA, J

MAY 1, 2023
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