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

% ***Judgment Reserved on: 25.03.2025***
Judgment pronounced on: 16.04.2025

\+ C.A.(COMM.IPD-PAT) 44/2023 & I.A. 23895/2023

ABBVIE BIOTHERAPEUTICS INC & ANR. .....Appellants

Through: Ms. Archana Shankar and Mr. Pravin Anand, Advocates.

versus

ASSISTANT CONTROLLER
OF PATENT DESIGNS .....Respondent

Through: Ms. Manisha Agrawal Narain, CGSC with Mr. Abhishek Kumar and Mr. Nipun Jain, 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 31st July, 2023 (hereinafter 'impugned order') passed by the Assistant Controller of Patents and Designs (hereinafter 'Controller'), whereby the Indian Patent Application No. 201817047767 titled *'ANTI-cMet ANTIBODY DRUG CONJUGATES AND METHODS FOR THEIR USE'* (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 appellants, AbbVie Biotherapeutics Inc. and AbbVie Inc. are biopharmaceutical companies.

2.2. The subject patent application was filed as a national phase application in Indian Patent Office, Delhi on 17th December, 2018 under the Patent Cooperation Treaty (hereinafter the 'PCT') with PCT application number PCT/US2017/033176 dated 17th May, 2017, claiming priority from a US Patent application US 62/337,796 dated 17th May, 2016.

2.3. A request for examination of the said application was filed by the appellant on 15th May, 2020, and the First Examination Report (hereinafter the 'FER') was issued on 5th November, 2020. The following objections were communicated to the appellant *via* the said FER:

a. Lack of industrial applicability under Section 2(1)(j) of the Act;
b. Non patentable under Section 3(i) of the Act;

2.4. In reply to the objections raised in the FER, the appellant's agent submitted a detailed response along with a new set of amended Claims containing 8 Claims *via* Form 13 dated 5th May, 2021.

2.5. Thereafter, a hearing was scheduled for 6th December, 2022, and the following objections were communicated to the appellant *via* the hearing notice:

a. Lack of industrial applicability under section 2(1)(j) of the Act.
b. Not an invention under Section 3(i) of the Act;
c. Broader scope under Section 59(1) of the Act;

2.6. A hearing took place on 6th December, 2022. Post-hearing, written submissions were filed by the appellant before the Patent Office on 19th January, 2023.

3. Thereafter, the impugned order was passed by the Patent Office on 31st July, 2023, refusing the subject patent application under sections 2(1)(j), 3(i) and 59(1) of the Act.

4. On October 26, 2023, the appellant filed a review petition under Section 77(1)(f) of the Act. However, the said petition was dismissed as being time-barred *vide* order dated 6th March, 2024.

SUBMISSIONS BY THE PARTIES

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

5.1. The appellants did not lose the opportunity to amend the Claims under the Act simply because the appellant did not make amendments at the PCT stage. Under Section 57(6) and Section 59 of the Act, amendments to the patent application including documents and Claims can be filed anytime during the life of the patent application/patent.

5.2. An international application designating India has the effect of filing a patent application for grant of the patent in India and also requires the title, description, claim and abstracted drawings filed in the international application to be taken as the complete specification for the purposes of the Patents Act. Therefore, the appellants could not be faulted for the national phase application being filed by not having the amended product Claims for '*anti-cMet antibody-drug conjugate (ADC)*'.

5.3. Since the amended Claims that are directed to anti-cMet drug conjugates are disclosed in the patent specification and the as-filed Claims of the specification, the same should be permissible under section 59(1) of the Act and objections under Sections 2(1)(j) and 3(i) of the Act should be waived off. Reliance is placed on a decision by this court in ***Allergan Inc.* v. *Controller of Patents***[1], which was based on similar facts as the present appeal and was decided in favour of the appellant.

6. *Per Contra,* the counsel appearing on behalf of the respondent has made the following submissions:

6.1. According to Section 138(4) of the Act, any application filed as a PCT national phase application in India should be identical as filed in PCT, with some exceptions that allow deletion of certain Claims. Since appellants had not amended Claims at the PCT level in Chapter II, they entered the national phase in India with the same Claims (all related to a method of treatment).

6.2. Although original Claims were deleted and revised by the appellants at national phase entry, the revised Claims were still method of treatment Claims, and none of those were product Claims even at that stage.

6.3. The proposed amendments sought by the appellant in response to the FER notice were beyond the scope of the amendment under Section 59(1) of the Act. Reliance is also placed on the judgement of this court in ***Nippon A & L Inc.* v. *Controller of Patents***[2].

6.4. The Controller has passed a well-reasoned order and no interference thereof is required by this court.

ANALYSIS AND FINDINGS

[1] 2023 SCC OnLine Del 295
[2] 2022 SCC OnLine Del 1909

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

8. The as-filed specification of the subject patent application focused extensively on the therapeutic methods using anti-cMet antibody-drug conjugate (ADCs) in treating cMet-overexpressing cancers, dosing schedules (once every 2 or 3 weeks), dosage ranges (0.15 mg/kg to 3.3 mg/kg), and strategies for resistant tumours. The detailed focus in the as-filed Specification on dosing intervals, administration strategies, patient selection via IHC scores, and efficacy results in animal or clinical models underscores that the original invention was both intended and claimed as a method of treatment. There was no reference to a stand-alone product/composition claim without these treatment details. Consequently, the as-filed Specification, when read in its entirety, reflects that the original invention squarely resided in how to use these antibody-drug conjugates (ADCs) to achieve the therapeutic benefit, rather than attempting to protect the antibody-drug conjugate (ADC) molecules themselves as a separate patentable product. Thus, the specification squarely supported a method-of-use invention, with no standalone product Claims originally proposed.

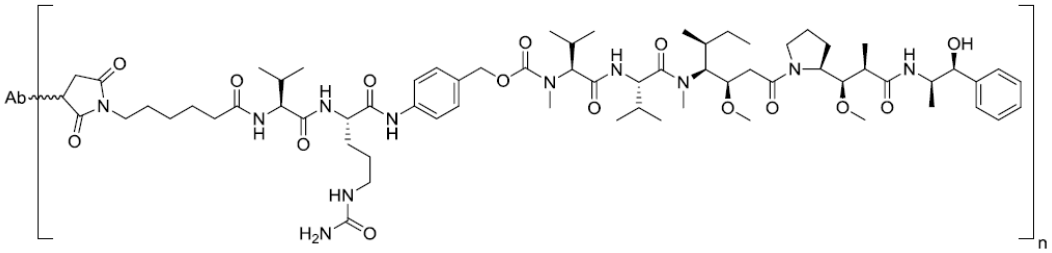
9. At this juncture, a reference may be made to the Claims filed as part of the PCT application. The PCT application had 137 Claims. Out of 137 Claims, seven (7) independent Claims covering the method of treatment filed as per the PCT application are set out below:

> "*1.* ***A method of treating a solid tumor cancer that overexpresses cMet,*** *comprising* ***administering to a human subject having said cancer an anti-cMet antibody drug conjugate ("ADC") in an amount and for a period of time sufficient to provide a therapeutic benefit****.*
> **** ****

*64. **A method of treating a human patient diagnosed with non-small cell lung cancer ("NSCLC")** comprising **administering to the patient an anti-cMet antibody drug conjugate ("ADC") in an amount and for a period of time sufficient to provide therapeutic benefit.***

*** ****

*122. **A method of treating a human subject having a NSCLC tumor** with an IHC score of at least 2+ or an H score of 150 or greater in at least one tumor biopsy from the subject**, comprising administering to the subject an anti-cMet ADC in an amount of about 2.7 mg/kg once every two weeks or once every 3 week**s, in which the anti-cMet ADC is a compound according to the following structure:*



or a pharmaceutically acceptable salt thereof, in which n has a value ranging from 2-4 and Ab is a full-length anti-cMet antibody.

**** ***

*133. **A method of treating a human subject having a NSCLC adenocarcinoma,** comprising **administering to the subject ABBV-399 once every 3 weeks in an amount of about 2.7 mg/kg, in which the adenocarcinoma has an H-score of at least 225.***

*134. **A method of treating a human subject having a NSCLC adenocarcinoma, comprising administering to the subject ABBV-399 once every 3 weeks in an amount of about 2.7 mg/kg, in which the adenocarcinoma has an IHC score of 3+.***

*** ****

*136. **A method of treating a human subject having a NSCLC squamous cell carcinoma, comprising administering to the subject ABBV-399 once every 2 weeks in an amount of about 1.6 mg/kg or 1.9 mg/kg**, in which the squamous cell carcinoma has an H-score of from 150 to 224.*

*137. A **method of treating a human subject having a NSCLC squamous cell carcinoma, comprising administering to the subject ABBV-399 once every 2 weeks in an amount of about 1.6 or 1.9 mg/kg,** in which the squamous cell carcinoma has an IHC score of 2+."*

[Emphasis is mine]

10. The above extracted Claims and the dependant Claims as originally filed were entirely drawn to methods of treating various cMet-overexpressing

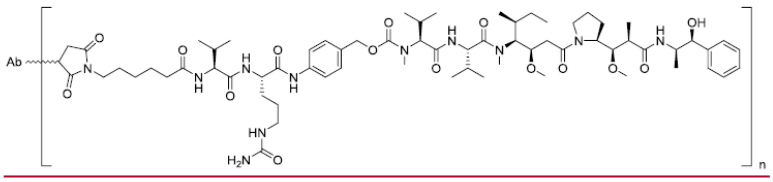
cancers. They recited dosing regimens, frequency of administration, specific patient populations, and details such as combination therapy with other anti-cancer agents (e.g., erlotinib, PD1 inhibitors).

11. None of the original independent Claims claimed an anti-cMet antibody drug conjugate (ADC) product in isolation or a pharmaceutical composition per se. Instead, the Claims always referenced the act of "administering" the anti-cMet antibody drug conjugate (ADC) to a subject, thereby focusing on therapeutic use (i.e., a method of treatment).

12. Even though the specification mentioned certain antibody sequences, linkers, drug-to-antibody ratios (DAR), and so on, the Claims themselves did not independently protect those compositions as standalone inventions. They only encompassed such anti-cMet antibody-drug conjugates (ADCs) in the context of a medical treatment protocol.

13. Since the as-filed specification and Claims covered a method of treatment which is not patentable in India, the Controller raised objection in the FER under Section 2(1)(j) and Section 3(i) of the Act. To overcome this objection, the appellants filed a new set of amended Claims (Claims 1 to 8). Out of these eight (8) Claims, Claim 1 is the independent claim and the remaining seven (7) Claims are the dependent Claims. The proposed amendments as filed by the appellant before the Patent Office along with the response to the FER are reproduced below in a marked-up manner:

1. ~~The method of claim 26 in which the~~ An anti-cMet antibody drug conjugate ("ADC"), wherein the drug conjugate is monomethyl auristatin E ("MMAE"), and the ADC has the following structure:



~~8.~~ wherein Ab is an anti-cMet antibody ~~comprises~~ comprising a V_H chain comprising three CDRs, namely V_H CDR #1 (SEQ ID NO:112), V_H CDR #2 (SEQ ID NO:113) and V_H CDR #3 (SEQ ID NO: 114); a V_L chain comprising three CDRs, namely V_L CDR #1 (SEQ ID NO:-115), V_L CDR #2 (SEQ ID NO:-116) and V_L CDR #3 (SEQ ID NO:-117); and a modified hinge region of SEQ ID NO:-170, n has a value ranging from 2 to 8, and attachment to the Ab is via a thioether linkage formed with a sulfhydryl group of a cysteine residue.

~~29.~~2. The ~~method of claim 26 in which~~ADC as claimed in claim 1, wherein the anti-cMet antibody comprises a V_H chain of SEQ ID NO:-78~~;~~ and a V_L chain of SEQ ID NO:-79~~; and a modified hinge region of SEQ ID NO: 170~~.

~~30.~~ The ~~method of claim 29~~ADC as claimed in claim 1, ~~in which~~wherein the anti-cMet antibody is an IgG~~1~~.

~~31.~~3. ~~The method of claim 26 in which the anti-cMet~~ antibody ~~comprises a~~ consisting of heavy chains each consisting of the amino acid of SEQ ID NO:-86 and ~~a~~ light chains each consisting of the amino acid sequence of SEQ ID NO:-87.

4. The ADC as claimed in any one of claims 1-3, wherein n is 2 or 4.

~~41.~~ ~~The method of claim 26 in which~~A composition comprising the ~~anti-cMet~~ ADC as claimed in any one of claims 1-4, wherein the composition has an average drug-to-antibody ratio ("DAR") in the range of ~~1-4.~~

~~42.~~5. ~~The method of claim 41 in 0077hich the anti-cMet ADC has a DAR in the range of~~ 2-4.

~~43.~~ The ~~method of claim 41 in which the anti-cMet ADC~~composition as claimed in claim 5, ~~has~~ having a DAR of about ~~3.1.~~

~~44.1. The method of claim 41 in which the anti-cMet ADC has an about 1:1 ratio of E2 and E4 ADC.~~

~~45.~~6. ~~The method of claim 41 in which the anti-cMet ADC has a DAR of~~ 3.0.

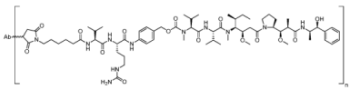
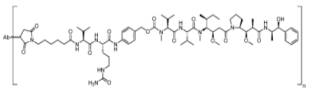
7. The ~~method of claim 41 in which the anti-cMet ADC has~~composition as claimed in claim 5, having an about 1:1 ratio of E2 and E4 ADC.

8. A pharmaceutical composition, comprising the ADC as claimed in any one of claims 1-4, or the composition as claimed in any one of claims 5-7, and a pharmaceutically acceptable carrier.

14. The aforesaid amendments were rejected by the Controller as being impermissible under Section 59(1) of the Act. The relevant extracts from the impugned order reflecting the findings of the Controller, regarding the above reproduced Claims are set out below:

> ***"10. I am of the opinion that the amendments sought by the applicant are not in nature of correction or explanation or disclaimer neither to incorporate actual fact but it's a cleaver*** [sic: clever] ***move to avoid the provisions of section 59 (1) of the Act which expressly bars the amendment which results in enlargement of scope of the claims than the originally filed claims.*** *I have also dissenting opinion with the learned agent on issue of enlarged scope, in her submission learned agent submitted that the scope of product claims which were allegedly inherent component of original claims which are actually directed to "method of treatment of human" claims by using a fixed dosage of ADC(anti cMet conjugate).*
>
> *11. I am not able to grasp the interpretation of* ***enlarged scope of claims*** *presented before me when in fact just looking at the both versions of claims* ***it is abundantly clear that "Product without any limitation of method of treatment…" has larger scope than the "Product limited by its use in a specific method of treatment". It means proposed set of amended claims 1-8 now can be used in any treatment /method for treating of any disease and no longer limited to specific treatment/method (solid tumor cancer that overexpresses cMet) as originally claimed.*** *It can be observed from the following table:*

Claim(s) in PCT	***Claim(s) at the national phase entry***	***Claim(s) after amendment with FER reply/written submission***
Claim 1 Reproduced out of 137 claims. All claims limited to method of treatment.	***Claim 122 reproduced and dependent claims 123-127, 133-34 and 136-137 all having same scope (MOT).***	***Claims 1-8 all related to compound/composition without limitation of purpose/method claim 1 reproduced:***
Claim 1. *A method of treating a solid tumor cancer that overexpresses cMet, comprising administering to a human subject*	***Claim 122.*** *A method of treating a human subject having a NSCLC tumor with an IHC score of at least 2+ or an H score of 150 or greater in at least one tumor biopsy from the*	***Claim 1.*** *An anti-cMet antibody drug conjugate ("ADC"), wherein the drug conjugate is monomethyl auristatin E ("MMAE"), and the ADC has the following structure:*

having said cancer an anticMet antibody drug conjugate ("ADC") in an amount and for a period of time sufficient to provide a therapeutic benefit.	*subject, comprising administering to the subject an anti-cMet ADC in an amount of about 2.7 mg/kg once every two weeks or once every 3 weeks, in which the anti-cMet ADC is a compound according to the following structure:*  *or a pharmaceutically acceptable salt thereof, in which n has a value ranging from 2-4 and Ab is a full-length anti-cMet antibody.*	 *wherein Ab is an anticMet antibody comprising a VH chain comprising three CDRs, namely VH CDR #1 (SEQ ID NO:112), VH CDR #2 (SEQ ID NO:113) and VH CDR #3 (SEQ ID NO: 114); a VL chain comprising three CDRs, namely VL CDR #1 (SEQ ID NO:115), VL CDR #2 (SEQ ID NO:116) and VL CDR #3 (SEQ ID NO:117); and a modified hinge region of SEQ ID NO:170, n has a value ranging from 2 to 8, and attachment to the Ab is via a thioether linkage formed with a sulfhydryl group of a cysteine residue.*

12. ***In the present case the scope of original claims relate to "A method of treating a human subject having a NSCLC tumor with an IHC score of at least 2+ or an H score of 150 or greater in at least one tumor biopsy from the subject, comprising administering to the subject an anti-cMet ADC ….." whereas the amended claims 1-8 filed with hearing submission relate to a Product claim i.e. "An anti-cMet antibody drug conjugate ("ADC"), and composition comprising the same.", which is a Product claim which has larger scope than the originally filed method of treatment claims.***

13. It is found that this claim defined a method for treatment of the human body and therefore was not allowable u/s 3(i). The composition claim of the amended claims was not allowable under section 59(1) of the Patents Act 1970. The subject-matter protected by the original claim was a compound of formula 1(anti-cMet antibody drug conjugate ("ADC")", when used in a specified amount and time to provide a therapeutic benefit.; in contrast, the final pending claims 1-8 only included technical features which defined structural/constitutional characteristics of the compound and composition itself. It is explained that in general terms, if a [sic: the] claims only included claims defining the [sic] a method of treating a solid tumor cancer that overexpresses cMet in a human subject and therefore containing both "compound/composition" and "features of method of

treatment", and the proposals to amend the claims during proceedings included claims which only contained "compound i.e. ADC and composition congaing same", ***the proposed amendment was not allowable having regard to u/s 59(1) of the Patents Act 1970, because the claims as originally filled conferred protection upon the compound/composition only when it was in use so as to carry out the method, whereas the proposed amended claims would confer protection upon the compound/composition(Product) whether or not it was in use, and Scope of amended claims significantly enlarged and would therefore confer additional protection compared to the claims as originally filled.***

... ...

19. Applicant/Agent amended the claims once original claims were hit by provisions of section 2(1)(j) of the Indian Patents Act, which do not recognize claims directed to Method of treatment as "invention" since claims related to method of treatment of human neither fits in to the category of Product or Process defined in section 2(1)(j) and also due to lack of industrial applicability for MOT claims, and section 3(i) of Indian Patents Act which categorically bars method of treatment of human from being Patentable, *now the arguments are being presented by the learned agent that the scope are not being changed/enlarged and the An anticMet antibody drug conjugate and composition of same with specific dosage 2.7 mg/kg was part of the original claims.* ***But the interesting fact is, despite having all the liberty to claim that compound/composition without any limitation/method limited claim, it was chosen not to claim the same and was disclaimed by the applicant himself at the very beginning at pct stage, and now due to operations of section 59(1) of the Indian Patent Act amendment of such nature which enlarges the scope of claims than the originally filed claims shall not be allowable. Allowance of such amendments would defy the purpose of section 59 of the Act."***

[Emphasis is mine]

15. The findings in the impugned order of the Controller rejecting the patent application can be summarized as under:-

(i) The appellant is seeking to convert the method of treatment Claims into product Claims.

(ii) The proposed amendments sought to be made by the appellant are not in the nature of correction or explanation or disclaimer, nor are they to incorporate an actual fact.

(iii) The original Claims dealt with the method of treatment of a particular disease, whereas the proposed amendments do not have any limitations with respect to a particular disease. Therefore, the proposed amendments enlarge the scope of the Claims.

(iv) The proposed amendments cannot be allowed under Section 59(1) of the Act as the amended Claims confer additional protection as compared to the originally filed Claims.

(v) The original Claims as filed did not satisfy the requirements of Section 2(i)(j) as well as Section 3(i) of the Act.

(vi) The proposed amendments seek to enlarge the scope of original Claims and are not permissible under Section 59(1) of the Act.

(vii) The proposed amendments are in the nature of clever drafting to avoid the rigours of Section 59 of the Act.

16. In sum, the Controller has disallowed the amended set of Claims 1 to 8, as being impermissible under Section 59(1) of the Act. The Controller goes on to hold that the unamended or original set of Claims directed to the method of treatment fall under the excluded subject matter under Section 3(i) of the Act and lack industrial application under Section 2(1) (j) of the Act.

17. The moot question arising in the present appeal is whether the proposed amendments carried out by the appellant are permissible under Section 59(1) of the Act.

18. Sections 57 to 59 of the Act deal with the amendments made in the patent application and/or the specification. Section 57 of the Act empowers the Controller to permit amendments in the patent application or the specification subject to the limitations provided under Section 59(1) of the Act. The limitations provided under Section 59(1) of the Act are reproduced below:

> *"59. Supplementary provisions as to amendment of application or specification. — (1) No amendment of an application for a patent or a complete specification or any document related thereto shall be made except by way of* ***disclaimer, correction or explanation****, and no amendment thereof shall be allowed, except* ***for the purpose of incorporation of actual fact****, and no amendment of a complete specification shall be allowed, the effect of which would be that* ***the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment****, or that* ***any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment****."*
>
> [Emphasis is mine]

19. The scope and ambit of Section 59 of the Act has been interpreted by a coordinate bench of this court in ***Nippon*** (supra). The relevant paragraphs of this judgement are:

> **"*40.*** *A perusal of Section 59(1) shows that an amendment of an application, specification or any document related thereto would be permissible only if the following conditions are satisfied:*
> ***(i) The amendment has to be by way of disclaimer, correction or explanation; And***
> ***(ii) The amendment has to be for the purpose of incorporation of actual facts; And***
> ***(iii)(a) The effect of the amendment ought not*** [sic: to] ***be to amend the specification to claim or describe any matter which was not disclosed in substance or shown in the originally filed specification, And***
> ***(iii)(b) The amended claims have to fall within the scope of claims as originally filed.***
>
> ***41. Thus, for an amendment to be allowed all conditions have to be satisfied.***

Any amendment falling foul of (i), (ii), (iii)(a) or (iii)(b) above cannot be allowed."

[Emphasis is mine]

20. The aforesaid observations of the coordinate bench in ***Nippon*** (supra) have been followed in ***Ovid Therapeutics* v. *Controller of Patents & Designs***[3]. In ***Ovid*** (supra), the court was dealing with a patent application in relation to a method of treatment claim as also a composition claim. The Controller, in the FER, raised an objection of non-patentability under Section 3(i) of the Act. In response, the appellant therein sought to amend the Claims of the subject patent application to limit the invention to a composition. The Controller, *vide* the impugned order, refused the patent application *inter-alia* on the ground that by the proposed amendment, the appellant was broadening the scope of the Claims in violation of Section 59(1) of the Act. The aforesaid impugned order was challenged by the appellant before this Court in the said appeal.

21. The court in paragraph 24 of the ***Ovid*** (supra) noted the difference between the originally filed claim and the amended claim. For ease of reference, paragraph 24 of the judgment is set out below:

"*There are three differences between the originally filed Claim 1 and the amended Claim 1. The same are as under:*

(i) that the amended Claim omits the limitation and also reference to the specific disease for which the composition is intended;

(ii) that the amended Claim pertains to a composition Claim, while the initially filed Claim relates to a method as also a composition Claim;

(iii) that the amended Claim specifies the range of Gaboxadol that is to be used."

[3] 2024 SCC OnLine Del 875

22. Holding that the aforesaid amendment was not permissible in terms of Section 59(1) of the Act, the Court in ***Ovid*** (supra) observed as under: -

> *"26. A bare reading of the above stated* ***Section 59(1) of the Act shows that the amended Claim has to be within the amended scope of unamended Claims and within the complete specification. In this instance, the omission of the name of the disease in the amended claim expands the scope within which the composition can be applied and therefore, the amended Claim 1 expands the scope of the subject patent****.*
>
> ... ...
>
> *28.* ***In the present case the field of description clearly describes that this method and composition is to be used for the purpose of treating secondary insomnia and the fact that the medical condition is not written in the amended claims show that the same has gone beyond the specification as also the description of the invention****.*
>
> ... ...
>
> *30. As per the above judgement it is observed that while* ***the amended Claim has disclaimed the earlier broadly claimed feature by defining the necessary amount of composition that is to be used, overall, the amended Claim is not within the scope of the originally filed Claims as the limitation with respect to a specific class of diseases i.e., neurodegenerative diseases has been removed.*** *Accordingly, it is clear that the scope of the Claims before the Court at the stage of appeal are broader than the originally filed Claims as also the Claims of the corresponding PCT application"*
>
> [Emphasis is mine]

23. The aforesaid findings in ***Ovid*** (supra) are squarely applicable to the present case. In the present case, the original Claims, as filed, relate to a method of treatment. More specifically, the treatment was for non-small cell lung cancer (hereinafter 'NSCLC') with an immunohistochemistry ('IHC') score of 2+ or an H score of 150 or greater in at least one tumour biopsy from the subject.

24. On the other hand, the amended Claims 1 to 8 filed along with written submissions relate to a product claim, being an anti-cMet antibody-drug conjugate (ADC), where the drug conjugate is monomethyl auristatin E.

25. The differences between the originally filed Claims and the amended Claims are highlighted below:

a) The amended Claims cover an anti-cMet antibody-drug conjugate (ADC), while the originally filed Claim covered a method of treating solid cancer using anti-cMet antibody-drug conjugate (ADC);

b) The new Claims eliminate references to dosing schedules, specific patient populations, IHC thresholds, or combination therapies. Instead, they simply recite a structural ADC (antibody + MMAE + linker, with certain sequences) and compositions thereof.

c) The amended Claims omit the limitation and also reference to the cancer for which the anti-cMet antibody-drug conjugate (ADC) was intended;

d) The amended Claims add new Claims (Claims 5 to 8) related to composition and pharmaceutical composition which were not disclosed or covered in the originally filed Claims.

26. From the analysis above, it is apparent that the proposed amendments are not in the nature of a disclaimer, as the unamended Claims do not cover the product. A ‘disclaimer’ typically excludes some specific subject matter to narrow the scope and avoid prior art, or clarify what is not claimed. In the present case, the appellant did the opposite as they expanded to a product claim, rather than disclaiming any subject matter.

27. The amendments claimed are also not in the nature of explanation of unamended Claims. Rather the amendments are a complete transformation of a method of treatment to product Claims. The newly filed Claims go well beyond a mere explanation as they broaden the patent's scope by removing the original treatment limitations. Additionally, the amendment sought to be made by the appellant introduces new Claims, Claims 5 to 8, which cover a pharmaceutical composition, and were not even disclosed in the original set of Claims.

28. The only question that remains is whether the aforesaid amendment falls under the purview of a 'correction' of the unamended Claims. Clearly, correction cannot be a substantial change i.e., changing the scope of unamended Claims. Instead, it should be limited to correcting obvious mistakes or clerical errors, without broadening the scope of the unamended Claims. Changing an entire claim category from 'method' to 'product' can not be a mere correction of an error.

29. In the present case, the complete specification of the subject patent application before amendment discloses and covers the anti-cMet antibody-drug conjugate (ADC) for the treatment of a specific tumour/cancer, whereas the amended set of Claims removes that limitation and thereby the amended Claims go beyond the scope of originally filed specification and Claims.

30. The amendments shift the claimed invention from methods of treatment defined by specific therapeutic regimens to a wide-ranging product/composition. This kind of broadening, which introduces entirely new categories of Claims and expands legal protection beyond the original disclosure, is not a mere refinement or rectification of existing language.

Rather, it effectively rewrites the core of the patent application, creating a new type of claim that was never previously pursued.

31. Further, the new product Claims surpass the original disclosure intent. Even if the specification did contain the details of the anti-cMet antibody-drug conjugate (ADC) itself, it was introduced primarily as a tool for treating cMet-expressing cancers. By recasting it as a general product claim, the appellant seeks a monopoly over the anti-cMet antibody-drug conjugate (ADC) itself, in all fields and uses far beyond the originally claimed method scope.

32. This shift violates Section 59 of the Act, which mandates that amendments must not introduce subject matter that extends beyond the content of the originally filed specification, nor enlarge the scope of the Claims.

33. Since methods of treatment are not patentable under Section 3(i) of the Act, the appellant cannot sidestep that exclusion by later amending Claims to cover a product especially if that product coverage was never originally claimed in that manner.

34. The Supreme Court in ***Novartis AG* v. *Union of India***[4], underscored that Indian patent law does not condone artificially broadening Claims. Specifically, the Supreme Court noted that the patent system should not develop along lines "*where the scope of the patent is determined not on the* ***intrinsic worth of the invention but by the artful drafting of its claims.***"

35. Consequently, these amendments exceed the permissible scope of disclaimers, corrections, and clarifications, and thereby recast the patent in a

[4] (2013) 6 SCC 1

manner that the original specification and claim framework did not support. Hence, the Controller has correctly observed that the proposed amendments were outside the purview of Section 59(1) of the Act.

36. Counsel for the appellant has placed strong reliance on the judgment of the Coordinate Bench in ***Allergan*** (supra) wherein the court had permitted the amendment of a method of treatment Claims in a PCT Patent application to product Claims.

37. However, the judgment in ***Allergan*** (supra) did not address the nature of the amendment, whether it falls within the limited nature of amendments, i.e., correction, explanation or disclaimer. Instead, the Court came to the conclusion that the amendment was within the scope of the specification Further, the amended Claims in ***Allergan*** (supra) also pertained to the same disease as disclosed in the unamended Claims and the specification. In contrast, in the present case, the unamended Claims and specification refer to a particular disease i.e., NSCLC, however, the amended Claims do not refer to any disease. Therefore, unlike the case in ***Allergan*** (supra), the amendments in the present case were broadening the scope of the original specification and the Claims.

38. In view of the discussion above, there is no infirmity in the order of the Controller that the proposed amendments were beyond the scope of Section 59(1) of the Act. The Controller has correctly observed that the unamended Claims are in the nature of the method of treatment which are excluded under Section 3(i) of the Act and they do not fulfill the requirement of Section 2(1)(j) of the Act of being capable of industrial application.

39. In view of the discussion above, the impugned order passed by the Controller refusing the subject patent application under Section 15 of the Act is upheld. There is no merit in the present appeal and the same is dismissed.

40. The Registry is directed to supply a copy of the present order to the Office of the Controller General of Patents, Designs and Trade Marks on e-mail ID - llc-ipo@gov.in, for compliance.

41. All pending applications stand disposed of.

AMIT BANSAL
(JUDGE)

MARCH 25, 2025
ds