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

% *Date of Decision: 19th November, 2026*

\+ C.A.(COMM.IPD-PAT) 64/2024

BRISTOL MYERS SQUIBB COMPANY .....Appellant

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

versus

ASSISTANT CONTROLLER OF PATENTS DESIGNS .....Respondent

Through: Ms. Nidhi Raman, CGSC with Mr. Rishay Raj, Advocate.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

JUDGEMENT

JYOTI SINGH, J.

1. This appeal is filed by the Appellant challenging impugned order dated 28.02.2024 passed by the Respondent in relation to Indian Patent Application No. 201617012873.

2. To the extent necessary, case of the Appellant is that PCT Application No. PCT/US2014/056277 was filed on 18.09.2014 and Indian Patent Application No. 201617012873, which is the subject matter of this appeal was filed on 12.04.2016. Application concerns, treatment of solid tumors with two antibodies used together: one against a molecule called PD-1and the other called LAG-3. As summarized in the appeal, original claims 1–20 concerned methods of treating a solid tumor; claim 21 concerned a kit; and claims 22–23 concerned an anti-LAG-3 antibody for co-administration with anti-PD-1 antibody.

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3. First Examination Report (FER) was issued on 01.11.2021, to which response was filed by the Appellant on 01.08.2022. Respondent cited four prior art documents D1-D4 in the FER in support of its objection of lack of inventive step under Section 2(1)(ja) of Patents Act, 1970 (1970 Act) and also raised objection that claims 1-21 were not patentable under Section 3(i) and 3(f) of 1970 Act. Out of 23 claims filed originally, 1-17 were revised to overcome the objection under Section 57(6) of 1970 Act. Hearing was scheduled for 29.01.2024 vide hearing notice dated 27.12.2023 and after conclusion of oral hearing, Appellant filed written submissions on 13.02.2024.

4. It is stated that in the hearing notice, Respondent reiterated objections of lack of inventive step; non-patentability under Section 3(c), (e) and (i); sufficiency of disclosure under Section 10(4) in respect of claims 4-5 and 13-17; and scope of the claims vis-à-vis the amendment filed on 01.08.2022, whereby method for treatment claims were converted into pharmaceutical composition claims, as barred under Section 59. By impugned order dated 28.02.2024, Respondent refused to grant the patent and rejected the amended claims 1-14, which were as follows:-

> *"1. A pharmaceutical composition comprising:*
>
> *(a) 80 mg of an anti-LAG-3 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5;*
>
> *(b) 240 mg of an anti-PD-1 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21; and*
>
> *(c) a pharmaceutically acceptable carrier.*

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2. The pharmaceutical composition as claimed in claim 1, wherein the anti-LAG-3 antibody is a human antibody.

3. The pharmaceutical composition as claimed in claim 1 or 2, wherein the anti-PD-1 antibody is a human antibody.

4. The pharmaceutical composition as claimed in any one of claims 1-3, wherein the anti-LAG-3 antibody is an IgG1, IgG2, IgG3, IgG4, IgM, IgAl, IgA2, IgAsec, IgD, or IgE isotype.

5. The pharmaceutical composition as claimed in any one of claims 1-4, wherein the anti-PD-1 antibody is an IgG1, IgG2, IgG3, IgG4, IgM, IgAl, IgA2, IgAsec, IgD, or IgE isotype.

6. The pharmaceutical composition as claimed in any one of claims 1-5, wherein the anti-LAG-3 antibody and anti-PD-1 antibody are human, IgG4 isotype antibodies.

7. The pharmaceutical composition as claimed in any one of claims 1-6, wherein the anti-LAG-3 antibody comprises heavy chain variable region CDR1, CDR2 and CDR3 domains having the sequences set forth in SEQ ID NOs:7, 8, and 9, respectively, and light chain variable region CDR1, CDR2 and CDR3 domains having the sequences set forth in SEQ ID NOs:10, 11, and 12, respectively.

8. The pharmaceutical composition as claimed in any one of claims 1-7, wherein the anti-LAG-3 antibody comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:3 and 5, respectively.

9. The pharmaceutical composition as claimed in any one of claims 1-8, wherein the anti-LAG-3 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:1 and 2, respectively.

10. The pharmaceutical composition as claimed in any one of claims 1-9, wherein the anti-PD-1 antibody comprises heavy chain variable region CDR1, CDR2 and CDR3 domains having the sequences set forth in SEQ ID NOs:23, 24, and 25, respectively, and light chain variable region CDR1, CDR2 and CDR3 domains having the sequences set forth in SEQ ID NOs:26, 27, and 28, respectively.

11. The pharmaceutical composition as claimed in any one of claims 1-10, wherein the anti-PD-1 antibody comprises heavy and light chain variable regions comprising the sequences set forth in SEQ ID NOs:19 and 21, respectively.

12. The pharmaceutical composition as claimed in any one of claims 1-11, wherein the anti-PD-1 antibody comprises heavy and light chains comprising the sequences set forth in SEQ ID NOs:17 and 18, respectively.

13. The pharmaceutical composition as claimed in any one of claims 1-12,

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wherein the pharmaceutically acceptable carrier is a sterile liquid.

14. The pharmaceutical composition as claimed in any one of claims 1-13, wherein the pharmaceutically acceptable carrier is water, an oil, aqueous solution saline, aqueous dextrose, or a glycerol solution."

5. It is stated that Appellant filed review petition before the Respondent proposing further revision to the claims in accordance with EP Patent 3508502 since the citations in the FER with regard to lack of inventive step were also cited during examination of corresponding EP application 18209399 and sought to include in claim 1 complete variable region sequences of antibodies as previously recited in claims 8 and 11, however, no decision was taken and having no other remedy, Appellant filed the present appeal.

CONTENTIONS ON BEHALF OF THE APPELLANT

6. Respondent erroneously and illegally refused to grant the patent objecting on grounds of lack of inventive step under Section 2(1)(ja) of 1970 Act owing to prior arts D2-D4; non-patentability under Section 3(e); and sufficiency of disclosure under Section 10(4). Amendment to the claims after deleting claims 13-15 and retaining claims 1-12 and 16-17 (total 14 claims), was disallowed invoking Section 59 of 1970 Act on two-fold grounds. The first was that the amendment was not by way of disclaimer, correction or explanation and Appellant made no submission on this issue and second that paras on pages 7 and 23 of the specification only mention the composition comprising an anti-LAG-3 antibody, an anti-PD-1 antibody and a pharmaceutically acceptable excipient and page 4 mentions exemplary antibodies and pages 5 and 19 mention quantity of doses, however, further reading of the specification shows that the doses are administered individually and not as a composition and further, composition comprising:

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(a) 80 mg of an anti-LAG-3 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3 and CDR1, CDR2 and CDR3 domains of the fight chain variable region having the sequence set forth in SEQ ID N0:5; (b) 240 mg of anti-PD-1 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region, having the sequence set forth in SEQ ID NO:19 and CDR1, CDR2 and CDR3 domains of the light chain variable region, having the sequence set forth in SEQ ID N0:21; and (c) pharmaceutically acceptable carrier, is not disclosed in any of these pages of the specification. Simultaneous administration of two doses also cannot be considered as a composition because the doses are separate. Further, the examples and drawings in respect to combination therapy teach that the combination administered separately is effective for treatment. The examples do not teach the effectiveness of the combination of both doses in a single pharmaceutical composition and there is no data to show that the composition will have the same effect as achieved by separate administration of the two antibodies. Pages 13-16 indicated as support for the amended claims merely recite the possibilities of embodiments without actual demonstration of the invention. The specification does not particularly describe the invention or the best method of performing it. Therefore, the claims as amended are considered to describe matter not in substance disclosed or shown in the specification before the amendment and consequently, they are not allowable under Section 59. Case of the Appellant is not covered by the judgment in ***Allergan INC v. Controller of Patents, 2023 SCC OnLine Del 295,*** because the amended claims in the said case were well supported by the 0specification, whereas in the present case amended claims 1-14 do not find

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any support in the specification originally filed and hence, the amendment will be proscribed under Section 59. Both these grounds of rejection are untenable in law and are in teeth of the statutory provisions as also the judgment in ***Allergan (supra).***

7. The claimed invention in IN'873 is in relation to a combined preparation of two antibodies 80 mg of an anti-LAG-3 antibody comprising SEQ ID NOs:3 and 5 (heavy and light chain variable region sequences, respectively) and 240 mg of an anti-PD-1 antibody comprising SEQ ID NOs:19 and 21 (heavy and light chain variable region sequences, respectively) and a pharmaceutically acceptable carrier. The combined preparation is commercially marketed by the Appellant under the brand OPDUALAG, which is a fixed dose combination having the same amount of antibodies as claimed and is indicated for treatment of unresectable or metastatic melanoma in adult and paediatric patients. Technical advantage of the invention, as provided in the specification, includes treatment of tumors. Claims 13 and 14 are dependent claims and further define the pharmaceutically acceptable carrier. Respondent has completely disregarded the claimed amendments and overlooked the settled jurisprudence of Section 59 of 1970 Act. It is no longer *res integra* that Indian Patent Law allows method for treatment claims to be revised to product claims so long as the latter are disclosed in the patent specification originally filed and in this context, reference was made to the decision of this Court in ***Allergan (supra)*** as also of the Madras High Court in ***Starpharma Pty Ltd. Through its Authorized Representative v. Assistant Controller of Patents and Designs Bouddhik Sampada Bhawan, 2023 SCC OnLine Mad 8398.***

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8. In ***Allergan (supra),*** Court held that the very use of expression 'scope of a claim' in Section 59(1) of 1970 Act requires taking into consideration complete specifications of pre-amended claims and not merely a texture combined reading of the claims themselves, *de hors* the complete specifications as also that placing unduly restricted or hyper technical interpretation on provisions of Patents Act in a manner which would discourage inventiveness and entrepreneurship would be, counter-productive to its purpose. It was thus held that there is no bar in allowing amendment of method claim to a composition claim so long as it is not outside the original claims specification and therefore, there is a grave error in the impugned order of the Respondent in holding that the amendment is proscribed by Section 59(1) of 1970 Act.

9. In the instant case, Appellant sought to amend the method of treatment claim into a composition claim, which finds support in the specification titled "*Combination of anti-LAG-3 antibodies and anti-PD-1 antibodies to treat tumors*" and each amended claim was mapped to the original specification. Claim 1 has support in pages 7 and 23. Page 7 reads as "*kits that include a pharmaceutical composition containing an anti-LAG-3 antibody such as BMS-986016 and an anti-PD-1 antibody, such as BMS-936558 and a pharmaceutically acceptable carrier, in a therapeutically effective amount adapted for use in the methods described therein"* and Page 23 reads as: "*Also provided herein are kits which include a pharmaceutical composition containing an anti-LAG-3 antibody such as BMS-986016 and an anti-PD-1 antibody, such as BMS-936558 and a pharmaceutically acceptable carrier, in a therapeutically effective amount adapted for use in the preceding methods…Optionally, the kits include multiple packages of the*

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single-dose pharmaceutical compositions each containing an effective amount of anti-LAG-3 or anti-PD-1 antibody for single administration in accordance with the methods provided above" and Appellant took pains to demonstrate to the Respondent that each feature of the claimed pharmaceutical composition i.e., pharmaceutical composition; amount of anti-PD-1 antibody; amount of anti-LAG-3 antibody; and pharmaceutically acceptable carrier, was specifically disclosed in the complete specification and tabular representation mapping each feature is as follows:-

Features of claim 1 read with claims 13 and 14	**Specific Disclosure**	**Page/Line in internal page numbers of the complete Specification (as filed) and appeal book**
Composition	Antibodies "formulated together in a single formulation"	Page 7, line 26 (also restated page 19) Page 87 of the appeal book
	Kit comprising "a pharmaceutical composition containing an anti-LAG-3 antibody ... and an anti-PD-1 antibody ... and a pharmaceutically acceptable carrier"	Page 8, line 3 (Summary) Page 88 of the appeal book
	Section heading "III. Pharmaceutical Compositions"	Page 17, line 8 Page 97 of the appeal book
	General teaching that such compositions "typically comprise a pharmaceutically acceptable carrier"; formulation "in a liquid carrier" for parenteral administration	Page 17, lines 10, 16 Page 97 of the appeal book
	Section heading "VIII. Kits and Unit Dosage Forms" : composition + carrier language repeated, together with "single-dose pharmaceutical compositions"	Page 24, line 26 Page 103 of the appeal book
Amount of anti-PD-1 antibody	Four doses at 80 mg or 240 mg (fixed dose) OR 1-3 mg/kg body weight, per 8-week cycle	Page 6, line 19 (independent paragraph) Page 86 of the appeal book
	Specific paired dose combinations (a)–(e): 80 mg or 240 mg anti-PD-1 antibody together with stated anti-LAG-3 doses	Page 6, line 26; page 20, line 18 (also restated page 83, line 23 in claims) Page 86 of the appeal book
	Same fixed-dose / mg-per-kg doses restated in second independent aspect	Page 8, line 22; page 86, line 22 Page 89 of the appeal book
	Broader dose range: 50, 80, 100, 130, 150, 180, 200, 240 or 280 mg fixed dose; 0.1–10 mg/kg	Page 20, lines 9–13 Page 100 of the appeal book

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Features of claim 1 read with claims 13 and 14	Specific Disclosure	Page/Line in internal page numbers of the complete Specification (as filed) and appeal book
Amount of anti-LAG-3 antibody	3, 20, 80, or 240 mg (fixed dose) OR 0.03–3 mg/kg body weight, per 8-week cycle	Page 6, line 19 Page 86 of the appeal book
	Specific paired combinations (a)–(e): 3 mg / 20 mg / 80 mg / 240 mg anti-LAG-3 antibody	Page 6, line 26; page 20, line 18 (also restated page 83, line 23 in claims) Page 86 of the appeal book
	Same amounts restated in second independent aspect	Page 8, line 22; page 86, lines 22 et seq. Page 88 of the appeal book
	Broader dose range: 1, 3, 10, 20, 50, 80, 100, 130, 150, 180, 200, 240 or 280 mg fixed dose; 0.01–10 mg/kg	Page 20, lines 9–13 Page 100 of the appeal book
Pharmaceutically acceptable carrier	Kit/composition includes "a pharmaceutically acceptable carrier"	Page 8, line 3; page 24, line 26 Page 88 of the appeal book
	Definition: carrier is "a diluent, adjuvant, excipient, or vehicle"; exemplary carriers - sterile liquids (water; oils including peanut, soybean, mineral, sesame, glycerol polyethylene glycol ricinoleate); saline; aqueous dextrose/glycerol solutions; routes of administration (IV, IP, IM, intrathecal, subcutaneous)	Page 17, line 16 Page 97 of the appeal book
	General parenteral formulation teaching-formulation "in a liquid carrier," or for reconstitution into liquid solution/suspension for IV administration	Page 17, line 10 Page 97 of the appeal book
Supporting efficacy data (inventive concept)	Example 9 read with Figures 1 - murine Sa1N and MC38 tumor models: combination treatment produced 60–90%	Page 34, line 15, illustrated at Figure 1 (page 9, line 8) Page 114 of the appeal book

Features of claim 1 read with claims 13 and 14	Specific Disclosure	Page/Line in internal page numbers of the complete Specification (as filed) and appeal book
	tumor-free (TF) mice vs. 0–10% TF for anti-PD-1 alone; in the MC38 model, combination gave 80% TF vs. 40% TF for anti-PD-1 alone	

10. A plain reading of the aforesaid table would show that the amendment was wrongly declined contrary to the fact that the specification provides

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sufficient teaching to support the composition claims to a person skilled in the art (PSITA). Respondent also erred in rejecting the application on ground of lack of inventive step under Section 2(1)(ja) of 1970 Act, citing prior arts D2-D4. Stand of the Respondent was that disclosure in patent specification showed effectiveness in treatment when doses are given in combination but not as a single composition and therefore, the composition does not show any technical advancement over the cited prior arts. Reference was made to documents D2-D4 to suggest that they teach combination of anti-PD-1 and anti-LAG-3 immunotherapy for treatment of tumors and therefore, PSITA would have easily arrived at the claimed invention by combining treatment of administration of each individual antibody. While Respondent recognized that inventive feature resides in combination of two antibodies, yet it proceeded to reject the application as being combination of individual doses of antibodies. Respondent did not consider the document WO2014/008218 used by the Appellant as post-filing data to establish inventiveness and technical advance. Post published documents including data is permissible for purpose of determining inventive step as held in the decision in ***Oyster Point Pharma Inc. v. Controller of Patents and Designs and Another, 2023 SCC OnLine Cal 2141.*** This document was cited as D2 as post-filing data in EP application 18209399 and it was demonstrated that variable region sequences of anti-LAG-3 antibody provide improved stability without loss of efficacy. The claimed pharmaceutical compositions reciting these variable sequences were recognized as being inventive and patent was granted. PSITA through routine experimentation would not have been able to arrive at the specific composition of anti-LAG-3/anti-PD-1 antibodies, as claimed.

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11. The prior art documents D1-D4 cited by the Respondent do not dent the inventive step in the claimed invention. The anti-LAG-3 antibody of the pending claims (10 in number, after seeking revision), is inventive over 25F7 antibody of D1 as discussed in WO2014/008218, which states as under:-

> *"The present invention provides isolated monoclonal antibodies (e.g., human monoclonal antibodies) that bind LAG- 3 (e.g., human LAG-3) and have optimized physical stability compared to previously described anti-LAG-3 antibodies. In particular, the invention relates to a modified form of antibody 25F7 (US 2011/0150892 A1) which exhibits significantly improved thermal and chemical stability compared to the unmodified antibody. Specifically, by altering the critical binding region of the heavy chain CDR2 domain of antibody 25F7, it was shown that the modified antibody exhibited significantly higher physical and thermal stability, reduced deamidation, higher thermal reversibility, and lower aggregation. At the same time, it was unexpectedly observed that the modified antibody retained the same high binding affinity to human LAG-3 and functional activity of the unmodified antibody, including the ability to inhibit binding of LAG-3 to major histocompatibility (MHC) Class II molecules and stimulate antigenspecific T cell responses. The combined substantial increase in stability and retention of binding / biological activity of the modified antibody was surprising, particularly in view of the criticality of CDRs regions to antibody function."*

12. As can be seen US 2011/0150892 mentioned in WO2014/008218 is the corresponding US Application of D1. Thus, the difference in the sequence of anti-LAG-3 antibody recited in claims over the sequence of 25F7 antibody in D1, results in significantly higher physical and thermal stability and thermal reversibility as also lower aggregation. Moreover, the improved functions without loss of binding/biological activity were unexpected and surprising. D2-D4 do not teach or suggest the claimed anti-LAG-3 antibody and therefore, do not overcome deficiencies of D1 and also do not teach a pharmaceutical composition comprising anti-LAG-3 and anti-PD-1 antibodies having the claimed sequences, much less a

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pharmaceutical composition, having specific amount of these antibodies. Respondent completely overlooked that corresponding foreign applications have been granted in several jurisdictions, at least 47 countries and while grant in other jurisdictions may not bind the Respondent, but it had a persuasive value, particularly, in the context of lack of inventive step objection when the same prior art documents were cited by the Indian Patent Office.

13. Several embodiments of the inventive concept in the claimed invention are disclosed in the patent specification titled "*Combination of anti-LAG-3 antibodies and anti-PD-1 antibodies to treat tumors"*, including kits that include a pharmaceutical composition with antibodies and a pharmaceutically acceptable carrier in a therapeutically effective amount, adapted for use in the method prescribed therein. Pharmaceutical compositions suitable for administration of anti-LAG-3 and anti-PD-1 antibodies to human patients are also disclosed. Under the heading 'Pharmaceutical Composition' the term 'Carrier' refers to diluent, adjuvant, excipient or vehicle with which the compound is administered, which can be sterile liquid such as water and oil or synthetic such as peanut/soyabean oils. Combination therapy indicates that both antibodies anti-LAG-3 and anti-PD-1 can be administered in a single formulation. Saline and sterile liquid carriers for parenteral administration of monoclonal antibody biologics are within the common general knowledge of PSITA in this field. Respondent's reliance on the statement that doses are separate, conflates the mode of administering the combination in certain disclosed embodiments i.e., Examples 9 and 10, with the distinct and independently disclosed composition embodiments.

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14. Respondent erred in taking a view that there is insufficiency of disclosure and thus the application falls foul of Section 10(4) on the ground that Example 9 does not describe the administration of a composition comprising the two antibodies in a single composition and in the quantity as given in claim 1 as also that dependent features with different isotypes and formulation, as described in amended claims 12-14, are not shown in the specification, which is an erroneous reading. Similarly, Respondent's insistence on working example of the co-formulated composition is also flawed. Neither the statute nor any judicial precedent mandates the citing of working examples and their mere absence cannot render the patent application liable for rejection. In ***Bayer Pharm Aktiengesellschaft v. Controller General of Patents & Designs, 2024 SCC OnLine Del 2044,*** this Court held that working examples are provided to demonstrate practical implementation of the invention and are intended to show that invention is feasible and workable. They provide support and understanding of the claimed invention but do not define the scope of patent for which patent specification has to be read as a whole. In ***Titan Umreifungstechnik GMBH and Co. Kg v. Assistant Controller of Patents and Designs and Another, 2023 SCC OnLine Del 3369,*** this Court held that Patent Manual provides that invention must be described in sufficient detail so as to give complete picture of the invention and for which purpose, an Applicant may include examples or drawings in the specification. Court also held that working examples can be beneficial in understanding and assessing patentability of the invention but may not be strictly necessary. Nevertheless, Example 9 and Figure 1 establish beyond doubt the antitumor activity of anti-LAG-3 and anti-PD-1 antibodies in Murine Models. Figure 1 demonstrates that

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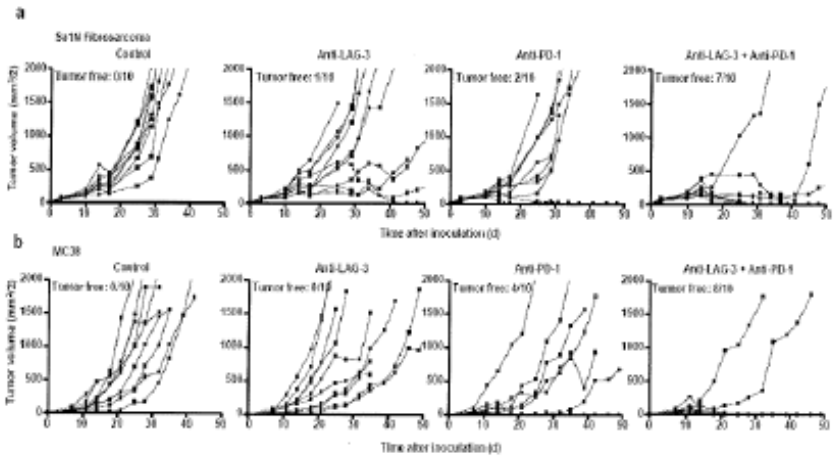
combination of antibodies in the claims results in enhanced antitumor activity of 80% vs 40% for anti-PD-1 antibody alone. The data establishes that inventive step lies in the combination of antibodies and technical effect of the combination is real, reproduceable and enabled. Figure 1 and comparative table are extracted hereunder for ready reference:-

Figure 1

Antitumor Activity of Anti-LAG-3 and Anti-PD-1 Antibodies in Murine Models



Tumor Model	TUMOR FREE COMPARISON			
	Control	Anti-LAG-3	Anti-PD-1	Anti-LAG-3 + Anti-PD-1 Antibodies
Sa1N Fibrosarcoma	0/10	1/10	2/10	7/10
MC38	0/10	0/10	4/10	8/10

15. Respondent has committed a grave error in concluding that the claimed invention is not patentable under Section 3(e) of 1970 Act as it relates to a mere admixture of known components i.e., anti-LAG-3 and anti-PD-1 antibodies. Inventiveness of the present application, as acknowledged by the Respondent, is in the synergistic effect of the two antibodies being dosed in a particular amount resulting in enhanced antitumor activity. Therefore, only because the trial design of the application

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was not for a single composition, it cannot take away the inventiveness. The reason for particular trial design was to show synergistic effect of combination of the two antibodies, which the application teaches can also be co-formulated in a single composition and this is evident from the drug label OPDUALAG and is in sync with Figure 1 and Example 10 as also WO2014/008218.

CONTENTIONS ON BEHALF OF THE RESPONDENT

16. Claimed invention relates to a method of treating a solid tumor in a human patient by administering anti-LAG-3 antibody and anti-PD-1 antibody. The pre-amendment claims relate to a method of treatment by administering the two antibodies in specific doses. Claims also relate to a kit comprising the two antibodies and instructions for their use. The claims further comprise the antibodies and their respective dosage cycle and the claims are analogous to EP 3046939, which was withdrawn and US Application US 2022185892 and also US Patent US 10081681B2, in which method of treatment claims were granted. After issuance of FER, Respondent amended the claims to a completely new set of claims comprising pharmaceutical composition, which are analogous to a different application EP 3508502, which is a divisional application of EP application EP 3046939 and US Patent US 11274152, indicating that these are separate inventions with different specifications. Even otherwise, the amendment cannot be allowed as the amended claims fall outside the ambit of unamended claims and specification, in light of proscription in Section 59 of 1970 Act. Appellant has not shown how the amendments fall within the categories of disclaimer, correction or explanation and reliance on the judgment in ***Allergan (supra),*** is thus misconceived.

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17. A composition, as claimed in the amended claims, comprising of: (a) 80 mg of an anti-LAG-3 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:3, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:5; (b) 240 mg of an anti-PD-1 antibody comprising CDR1, CDR2 and CDR3 domains of the heavy chain variable region having the sequence set forth in SEQ ID NO:19, and CDR1, CDR2 and CDR3 domains of the light chain variable region having the sequence set forth in SEQ ID NO:21; and (c) a pharmaceutically acceptable carrier, which are not disclosed in the complete specification. Moreover, in respect of the composition as claimed, there is no supporting data in the specification regarding preparation of formulation as claimed nor is there any indication of a study carried out using the composition. Further, the examples and drawings in respect of combination therapy teach that the combination when administered separately is effective for treatment. Examples do not teach the effectiveness of the combination of both doses in a single pharmaceutical composition and there is no data to show that composition as claimed will have the same effect as achieved by separate administration of the two antibodies. The disclosure states multiple possibilities in the embodiments, wherein anti-LAG-3 and anti-PD-1 antibodies can be simultaneously administered in a single formulation.

18. Contention of the Appellant that amended claims find support in the specification is misplaced as the originally filed claims merely recite the possibility of embodiments without actual demonstration of the claimed invention. Specification does not particularly describe the invention or the best method of performing it. The instant case differs from the case in

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Allergan (supra), since the amended claims therein were supported by complete specification, which is not the case here and thus, Respondent rightly held that amended claims are not allowable under Section 59 of 1970 Act.

19. *De hors* the objection under Section 59, the claimed invention also lacks inventive step in light of cited prior arts and PSITA would have easily arrived at the claimed invention by combining the treatment of administration of each individual antibody. From Example 9 and Phase I trial studies in Example 10, it is seen that administration of both antibodies for combination treatment is done as separate doses of each antibody and not as a single composition. Specification does not show any improvement in effectiveness in treatment, wherein doses are given as a single composition. Appellant has failed to demonstrate technical advance over existing knowledge in respect of pharmaceutical composition comprising the two antibodies in amended claim 1.

20. Respondent has rightly held that claims are not allowable under Section 3(e) as they relate to a mere admixture of known components anti-LAG-3 and anti-PD-1 antibodies and there is no data in the specification which indicates the synergistic effect of the composition. The effect of treatment of the claimed invention can be achieved even with separate administration of individual components. The claimed invention also falls under Section 10(4) of 1970 Act for insufficiency of disclosure. Appellant referred to Example 9 as the best mode of working the invention, however, the example does not describe administration of a composition comprising the two antibodies in a single composition and in the quantity given in claim 1. Dependent features with various isotypes and formulation

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as described in amended claims 12-14 are also not shown in the specification. No doubt, it is not necessary that all possibilities are demonstrated in the Examples, but whatever is exemplified must indicate that the claimed composition and its features of dependent claims can work in the manner claimed.

ANALYSIS AND FINDINGS

21. Present appeal is filed laying siege to impugned order passed by the Respondent refusing to grant patent in Indian Patent Application 201617012873 on multiple grounds. Originally 23 claims were filed by the Appellant and on objections being raised in the FER and hearing notice, Appellant filed amended claims and deleted claims 13-15, leaving total 14 amended claims. Amendment was disallowed by the Respondent invoking Section 59(1) relating to scope of the claims on the ground that the amended claims related to pharmaceutical composition, whereas none of the claims prior to amendment recited a pharmaceutical composition and were method of treatment claims. Appellant in response stated that the amendment was valid and it was legally permissible to amend method for treatment claims to composition claims, so long as the scope of amendment is not outside the original specification and placed heavy reliance on provisions of Sections 57 and 59 of 1970 Act as also the judgment of this Court in ***Allergan (supra)*** and of the Madras High Court in ***Starpharma (supra).*** Appellant filed a Review Petition to revise the claims and reduce the same to 10 claims, but as stated in the appeal, the same was pending when the appeal was filed.

22. In my view, there is merit in the submission of the Appellant that there is no blanket bar in law in allowing amendment of method of treatment claim to composition claim, subject of course to the limitations prescribed in

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law. In ***Allergan (supra),*** proposed amendment to the claims was rejected by the Patent Controller on the ground that originally filed claims pertained to method for treating an ocular condition (glaucoma), which involved providing biodegradable sustained release implants with different portions of the release of therapeutic agents or implant of therapeutic agents, but the amended set of claims pertained to an intracameral implant, which had no support in the original claims and specification. Rejecting this contention, the Court allowed the amendment sought and remanded the matter to the Controller for re-consideration of the application including the objection of non-patentability of the claimed invention.

23. Court noted that the failure of the Appellant therein to claim patent on 'compositions for intracameral implant' in the PCT application or while entering the National Phase was owing to a difference in the patent regime in US and in India and observed that method claims are patentable in US, whereas they are not patentable in India, by virtue of section 3(i) of 1970 Act. The original PCT claim as filed in US, which was for methods for treating ocular ailments using intra-cameral implants was, therefore, patentable in US, but would not have been patentable in India. Different countries have different patent regimes and it would be impractical, nay impossible, to expect that the claims in original PCT application, as filed in one country, would be patentable in every designated country. Court negatived the contention of the Respondent that claims are only part of and cannot be equated with the complete specification and thus resort to pre-amendment specification to examine whether amendment sought to a claim should or should not be allowed, is completely impermissible as it would conflate the claims and specifications and violate Section 10(4).

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24. Court held that this interpretation to Section 59(1), if accepted, will create an artificial distinction between the claims in a patent and complete specification that accompanies it and would discriminate between applications for amendment of claims and those for amendment of specifications, which will militate against the very ethos and philosophy of the 1970 Act. Purposive interpretation of statute being the golden rule must be applied, especially, in the case of statute dealing with intellectual property, the main aim and object of which is preservation of intellectual property rights. Court further observed that fostering of inventiveness is the very *raison d'etre* of patent law and placing unduly restricted, pedantic or hyper technical interpretation on provisions of the 1970 Act, in a manner which would discourage inventiveness and entrepreneurship, would be counterproductive to its purpose and will be impermissible.

25. It was further observed that if the interpretation to Section 59 given by the Respondent was accepted, the result would be that Appellant would be foreclosed from seeking a patent in respect of implants, which are a result of its own inventiveness and intended to cure variety of ocular ailments and therefore, public interest will also be adversely effected, which will be contrary to one of the cardinal aims of patent law, especially when the patent relates to pharmaceutical or therapeutic products. Court ruled that Section 59 disallows amendment of an application, where the amended claim falls wholly outside the scope of a claim or the specification before amendment and not otherwise. Court posed a question as to whether the Appellant should be completely foreclosed from seeking a patent in respect of implants merely because the original application sought a patent, not for implants but for the method by which the implants were to be used, even where all details

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of implants and every particular of the amended claims stood completely disclosed in the complete specification accompanying the original claims and answered it by holding that shutting out the Appellant from amending the claims would be contrary to ethos of 1970 Act and most elementary principles of claim construction and to so hold, placed reliance on the judgment of the Supreme Court in ***Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries, (1979) 2 SCC 511*** and the Division Bench of this Court in ***Merck Sharp and Dohme Corporation and Another v. Glenmark Pharmaceuticals, 2015 SCC OnLine Del 8227.***

26. Court also observed that a hyper technical view in this regard would be unjustified particularly when the divergence between the claims for which patent was originally sought and the claims as amended, was not wide and the amended claims were in respect of the very same implants in respect of which the original method of use claims were filed. Referring to Section 59(1) of 1970 Act, it was held that the section proscribes amendment that falls outside the scope of original specification and moreover, claims and complete specifications have to be read together and as a whole and claims have to be understood in the light of complete specifications as they form an integrated whole. The very use of expression 'scope of a claim' in Section 59(1) would require taking into consideration complete specification of pre-amended claim and not merely a textually cabined reading of pre-amended claims themselves, *de hors* the complete specification. This judgement was followed by this Court in the case of ***Vogenx v. Joint Controller of Patents and Design, C.A. (COMM. IPD-PAT) 75/2024,*** decided on 22.05.2026, to hold that there is no proscription in permitting method of treatment claims to composition claims, subject to legal limitations. In light of these judgments,

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I am of the view that Respondent erred in disallowing the amendment to the claims sought by the Appellant under a wrong impression that Section 59 proscribes amendment from originally filed method of treatment claims to composition claims.

27. The next question that needs consideration is whether the amended claims are beyond the scope of original specification, as filed. Appellant has with clarity brought forth that the original claims pertained to: (a) method for treating solid tumor in human patients (claims 1-20); (b) a kit (claim 21); and (c) an anti-LAG-3 antibody for co-administration with an anti-PD-1 antibody (claims 22-23) and how the features of claimed pharmaceutical composition map to corresponding disclosures in complete specification, with specific pages and lines references and a tabular representation to this effect is extracted in the earlier part of this judgment. Illustratively, there is specific disclosure of antibodies "*formulated together in a single formulation*" in line 26 of the specification and kit comprising "*a pharmaceutical composition containing an anti-LAG-3 antibody, such as BMS-986016 and an anti-PD-I antibody, such as BMS-936558, and a pharmaceutically-acceptable carrier"* in line 3 of summary in the specification. Line 8 is the section heading "*III. Pharmaceutical Compositions*". General teaching that such compositions *"typically comprise a pharmaceutically acceptable carrier"* and formulation *"in a liquid carrier"* for parental administration, are disclosed in lines 10 and 16. Similarly, the feature of amount of anti-PD-1 antibody i.e., 4 doses @ 80 mg or 240 mg or 1-3 mg/kg bodyweight, per 8-week cycle is disclosed in line 19 of the specification and specific paired dose combinations (a)-(e): 80 mg or 240 mg anti-PD-1 antibody together with stated anti-LAG-3 doses is

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disclosed at lines 26 and 28. The table further demonstrates specific disclosures in the specification of amount of anti-LAG-3 antibody as also pharmaceutically acceptable carrier, where carrier is a diluent, adjuvant, excipient or vehicle and exemplary carriers are sterile liquids such as water and oils including those of petroleum, animal, vegetable or synthetic origin or such as peanut/soyabean oil etc. There is sufficient disclosure of supporting efficacy data in Example 9 read with Figure 1 i.e., murine Sa1N and MC38 tumor models: combination treatment produced 60-90% tumor free (TF) mice vs. 0-10% TF for anti-PD-1 alone; in the MC38 model, combination gave 80% TF vs. 40% TF for anti-PD-1 alone. The specification therefore provides sufficient teaching for supporting the composition claims to a PSITA, to whom the patent specification is addressed. Considering that the amendment was sought at the pre-grant stage and relates to composition claim pertaining to method for treating solid tumor in human patients for which there is sufficient teaching in the original specification, I am of the view that the Respondent ought to have allowed the amendment sought and examined the amended claims on merits instead of shutting out the Appellant merely on a tenuous ground that the amendment was impermissible in view of Section 59(1) of 1970 Act. Therefore, the matter deserves to be remanded back to the Respondent for consideration of amended claims on merits and for this reason, I am not entering into the merits of the other objections of alleged lack of inventive step under Section 2(1)(ja) of 1970 Act; sufficiency of disclosure under Section 10(4) of 1970 Act; and non-patentability under Section 3(e) of 1970 Act.

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28. For all the aforesaid reasons, impugned order dated 28.02.2024 passed by the Respondent in Indian Patent Application No. 201617012873 is quashed and is set aside. Amendment sought by the Appellant is allowed and amended claims are taken on record. The matter is remanded back to the Respondent for consideration of the patent application afresh on the amended claims. Objections with respect to alleged lack of inventive step under Section 2(1)(ja) of 1970 Act; sufficiency of disclosure under Section 10(4) of 1970 Act; and non-patentability under Section 3(e) of 1970 Act, shall be considered by the Respondent in light of the amended claims and as per law and after granting opportunity of hearing to the Appellant. Decision shall be taken by the Respondent not later than 3 months from today. It is made clear that this Court has not expressed any opinion on the merits of the said objections and Respondent shall decide the said objections uninfluenced by any observation in this judgment.

29. Appeal stands disposed of in the aforesaid terms.

JYOTI SINGH, J

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