



2025:DHC:2778



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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**% *Date of decision: 16th April, 2025*+ **C.A.(COMM.IPD-PAT) 302/2022****FRESENIUS MEDICAL CARE
DEUTSCHLAND GMBH**

.....Appellant

Through: Mr. Pravin Anand, Ms.. Neeti Wilson
& Mr. Ashutosh Upadhyaya,
Advocates.

versus

**CONTROLLER GENERAL OF PATENTS,
DESIGNS AND TRADEMARKS AND ANR**RespondentsThrough: Ms. Arunima Dwivedi, CGSC with
Ms. Kritika Sharma, Ms. Piky Pawar,
Mr. Sainyan Bhardwaj, Ms. Aarti &
Mr. Aakash, Advocates.**CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL****AMIT BANSAL, J. (Oral)**

1. The present appeal has been filed against the order of the Respondent dated 27th February, 2020, refusing the grant of the Indian Patent Application No. 7493/DELNP/2012 (hereinafter referred to as the Subject Patent Application) dated 28th August, 2012, having priority date of 2nd March, 2010, in respect of the invention titled “*Microvesicles (MVs) derived from adult stem cells for use in the therapeutic treatment of a tumor disease*”.

2. The Subject Patent Application is a national phase application of PCT application no. PCT/EP2011/052945 with 20 claims with the independent



claims being:

***“1. A microvesicle (MV) derived from an adult stem cell for use in the therapeutic treatment of a tumour disease.*”**

10. A method of therapeutically treating a tumour disease, comprising administering to a patient in need thereof a therapeutically effective amount of a microvesicle derived from an adult stem cell.”

[Emphasis supplied]

3. The Patent Application was published under Section 11A of the Patents Act, 1970 on 1st January, 2016. The First Examination Report was issued by the Respondent on 28th June, 2017, which was replied to by the Appellant on 27th December, 2017. A new set of amended claims 1-9 were filed by the Appellant along with the reply. The independent claim of the amended set of claim is reproduced below:

“1. A pharmaceutical composition for use in the therapeutic treatment of a tumour disease comprising a microvesicle (MV) derived from an adult stem cell and one or more cytotoxic and/or cytostatic agents.”

[Emphasis supplied]

4. Thereafter, a hearing notice was issued by the Respondent to the Appellant on 13th August, 2019. The hearing was held before the Respondent on 6th October, 2019, and post hearing submissions were filed on 18th November, 2019. Along with post hearing submissions the Appellant had submitted a new set of amended claims 1-8 where the dependent claim 5 was merged to claim 1. The independent claim of the said claim set is reproduced hereinbelow:

“1. A pharmaceutical composition for use in the therapeutic treatment of a tumour disease comprising a microvesicle (MV) derived from an adult stem cell and one or more cytotoxic and/or cytostatic agents, said composition dose being between 0.1 to 200 micrograms/kg body weight of



the patient, preferably 1-150 micrograms/kg body weight of the patient, even more preferably 3-120 micrograms/kg body weight of the patient.”

[Emphasis supplied]

5. The Respondent *vide* order dated 27th February, 2020 (hereinafter referred to as the impugned order), rejected the subject patent application on the following grounds:

- a) Lack of Novelty u/s 2(1)(j) in claims 1-5 and 8 in view of D1. Claims 6 and 7 were considered Novel.
- b) Lack of Inventive step u/s 2(1)(ja) in view of documents D1 and D2.
- c) Lack of Sufficiency of Disclosure and Clarity.
- d) Non-Patentability under Section 3(e).
- e) Non-Patentability under Section 3(i).

6. The Appellant preferred an appeal against the said decision of the Respondent on 15th October, 2020, before the Intellectual Property Appellate Board, which was then transferred to this Court pursuant to the abolishment of IPAB, on 12th July, 2022.

7. It was submitted by Mr. Anand that the claimed invention has been duly recognized in the corresponding patent applications in China, Europe, Japan, and USA, where the patent has been granted in each of these jurisdictions.

8. Mr. Anand further brought to the attention the set of claims presented before this Court as Auxiliary Set 2 in the written submissions filed in the appeal to overcome the objections as stated in the impugned order and the written submissions by the Respondent. The claim 1 in this auxiliary set also has the element of claim 7¹ incorporated within it. Accordingly, the Appellant

¹ 7. A composition as claimed in claim 6, wherein the cytotoxic and/or eystostatic agents are doxorubicin or vincristine.



has proposed to amend the claim 1 in the manner below, while the claim 7 has been deleted:

“Claim 1: A pharmaceutical composition for use in the therapeutic treatment of a tumour disease comprising a microvesicle (MV) derived from an adult stem cell, wherein said microvesicle inhibits tumour cell proliferation and/or induces cancer cell apoptosis and one or more cytotoxic and/or cytostatic agents, wherein the cytotoxic and/or cytostatic agents are doxorubicin or vincristine, said composition dose being between 0.1 to 200 micrograms/kg body weight of the patient, preferably 1-150 micrograms/kg body weight of the patient, even more preferably 3-120 micrograms/kg body weight of the patient.”

[Emphasis supplied]

9. The Appellant has placed on record amended claims. In view of the stand taken by the Respondent before this Court, the Appellant is proposing to amend Claim 1 to highlight the inventive feature of the invention.

10. Mr. Anand submits that it is a settled position of law that the amendments can be carried out at the appellate stage as well.

11. In *Societe Des Produits Nestle SA v. Controller of Patents and Designs and Anr.*, 2023 SCC OnLine Del 582, I have held that the High Court, while hearing an appeal against a refusal order passed by the Controller, would have the same powers as given to a Controller under Section 15 of the Act, which includes the powers to require amendment. Therefore, the Court is within its power to direct the Appellant to amend the complete specification of the patent application including claims at this stage.

12. The aforesaid observations made in *Nestle SA v. Controller of Patents* (supra) were also relied on by another Coordinate Bench of this Court in *Opentv Inc. v. Controller of Patents*, 2023 SCC OnLine Del 2771 wherein it was noted that irrespective of the amendments to the claims or complete specification of a patent application being made at the behest of the applicant



or the Court, amendments are allowed at the appellate stage before Court. The relevant paragraph of the said judgment is given below:

“54. Thus, amendments having been held to be permissible at the appellate stage, this Court is of the opinion that irrespective of whether the amendment is directed by the Court or is at the instance of Patent Applicant, so long as the requirements as laid down under Section 59 of the Act are fulfilled such that the amended claims are within the scope of original claims, is not breached, the amendment is permissible.”

“61. Therefore, though there is no embargo on permitting a Patent Applicant to amend claims even at the appellate stage, the amendment sought in this particular case intends to widen the scope of the original claims as filed. It is due to this reason that the same cannot be allowed.”

[Emphasis supplied]

13. Section 59 of the Patents Act, 1970 which deals with amendment of patent applications, has the following three requirements:

- i. An amendment to a patent application, including the complete specification, can be made only by way of ‘disclaimer’, ‘correction’ or ‘explanation’.
- ii. The amendment has to be for the purpose of incorporation of actual facts.
- iii. The amendment cannot be in respect of matters not disclosed in the specification prior to the amendment and the amended claims have to fall within the scope of claims as originally filed.

14. In my considered view, the proposed amendments are in the nature of an explanation and disclaimer. They are not broadening the scope of unamended claims in any manner and the subject matter of the amendment has also been disclosed in the specification.



15. Therefore, the proposed amendments fall within the scope of Section 58(1), 59 of the Patents Act, 1970.
16. In view of the above, the amendment is allowed. The amended claims are taken on record.
17. In light of the aforesaid, the Appellant shall file the complete amended specification including the amended claims, before the Patent office.
18. The Patent Office shall proceed to examine the matter afresh, taking into account the amended claims now taken on record.
19. In view of the above, the impugned order dated 27th February, 2020 is set aside and the matter is remanded back.
20. The Patent Office shall give a fresh hearing notice to the Appellant.
21. Taking into account that the subject patent application was filed as far back on 28th August, 2012, the Patent Office is directed to take a decision in the matter as expeditiously as possible and in any event within three months from today.
22. The appeal is accordingly disposed of.
23. Needless to state that the Court has not made any observations with regard to the merits of the amended claims, which shall be considered by the learned Controller in accordance with the law.
24. The Registry is directed to supply a copy of the present order to the office of the Controller General of Patents, Designs & Trademarks of India on the e-mail- llc-ipo@gov.in for compliance.

AMIT BANSAL, J

APRIL 16, 2025

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