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

+ **C.A.(COMM.IPD-PAT) 159/2022**

SCIPHARM SARL

.....Appellant

Through: Ms. Naina Gupta, Mr. Anshul Saurastri
and Mr. Jay Shah, Advocates.

versus

**ASSISTANT CONTROLLER OF PATENTS AND DESIGNS AND
ANR**

.....Respondents

Through: Mr. Mukul Singh, CGSC with Mr.
Aryan Dhaka and Ms. Sunidhi Tyagi,
Advocates.

CORAM:

HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

ORDER

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27.03.2026

1. The present appeal was filed against the rejection of the Indian Patent Application No. 6771/DELNP/2013 titled "*Method For Enhancing Engraftment Of Haematopoietic Stem Cells*" vide the order dated 29.05.2020 on the ground of non patentability under Section 3 (i) of the Patents Act, 1970 (hereinafter referred to as "*the Act*"). The impugned order is extracted hereunder:

"DECISION

An application for a patent bearing number 6771/DELNP/2013 was filed on 30/07/2013 entitled ""METHOD FOR ENHANCING ENGRAFTMENT OF HAEMATOPOETIC STEM CELLS". As per the provision under Section 11A of Patents Act, the said application was published on 23/01/2015. A request for examination under Section 11-B was filed on 12/01/2015.

The said application was examined under Section 12 and 13 of Patents Act and First Examination Report containing a statement of objections was forwarded on 05/07/2018 and the applicant's agent filed response to First Examination Report on 5/11/2018. As per the provisions under Section 13 (3) of Patents Act, the said amended case after reply to Examination Report, was examined and investigated in like manner as the original specification. The



applicant was offered a hearing on 11/03/2020 with the following objections.

Other Requirement(s)

1. The submissions in your letter dated November 5, 2018 have been considered carefully. However, the requirements of head Inventive step, Non-Patentability, Sufficiency of disclosure and clarity and conciseness of First Examination Report dated 05/07/2018 have not been met.

Invention u/s 2(1)(j)

1. The amended claims 1-7 cannot be acknowledged with an inventive step u/s 2(1)(j)(a) of the Patents Act, 1970 in view of the disclosures of D4, 05-W02008070310A2 and 06 - Mubarak: A review of prostaglandin analogs in the management of patients with pulmonary arterial hypertension. Respiratory medicine, January 2010, Volume 104, Issue 1, Pages9-21

D4 discloses the enhancement of engraftment of HSCs using prostaglandin E2 (a prostacyclin analogue).

D5 discloses method/composition of promoting tissue growth or regeneration by contacting said tissue (specifically HSCs) with a modulator that up-regulates the prostaglandin signaling pathway or downstream mediators of prostaglandin signaling. Forskolin was shown to enhance the effects of dmPGE2 which creates a reaction in which the result may be increased cell proliferation.

D6 states that a "small number of preclinical studies have directly compared the effects of several prostaglandin analogs on different physiological systems." Iloprost, treprostinil, and beraprost were examined with regard to smooth muscle proliferation and cAMP generation in the human pulmonary artery. Serum-induced proliferation produced by a number of prostacyclin analogs acting on pulmonary smooth muscle cells was assessed, with intracellular cAMP being elevated by all analogs. It was determined that prostacyclin has desirable effects on pulmonary vasculature and make it effective in the treatment of PAH. Fig. 3 within D6 shows that increasing cAMP can have significant effects increasing the effect of the prostaglandin on its receptors and on G protein activities. Using forskolin to enhance PGE2 activity on EP4 receptors can assist the EP4 receptor to induce bone formation, mediate joint inflammation in collagen-induced arthritis, protect against inflammatory bowel disease and facilitate Langerhans cell migration and maturation.

It would be obvious for a person skilled in art to use the cAMP enhancer forskolin (D5), with the prostacyclin analogs (D6), in the method of D4. D5 teaches that the result would likely lead to increased cell proliferation as part of the prostaglandin pathway of which is the purpose of D4, the increase proliferation of HSCs. D6 teaches that the various prostacyclin analogs are



in active clinical use to promote the effects of prostaglandins. Person skilled in art would have a reasonable expectation of success of using the cAMP enhancer forskolin (D5) and the prostacyclin analogs as (D6) in the method of D4 as D5 and D6 teach that the result would likely lead to increased cell proliferation as part of the prostaglandin pathway of which is the purpose of 04, the increase proliferation of HSCs.

Non-Patentability u/s 3

The method claims 1 and 2 still fall within the purview of section 3(i) of the Act as the HSC used in the first step can be only obtained via surgical method.

Hearing was held on 11/03/2020 and written submission filed on 24/03/2020

My inference from the above arguments with respect to amended claims are as follows:

Regarding inventive step

The reply filed by the applicant has been considered and found persuasive. The explanation provided by the applicant with regard to prior art documents and figure 4 have been considered and found satisfactory and hence the objection is considered as met.

Regarding Non- Patentability

3(i)

The explanation given by the applicant has not been found persuasive. The applicant has amended the claims by deleting subsection (a) of the original method claims, which refers to

obtaining a sample containing haematopoietic stem cells.

This step is an essential essence for properly carrying out the invention. It should be noted that the exclusion from the surgical method cannot be avoided merely by drafting claims that omit one step of such method. Even though it is pretreatment method, it is an essential step which involves surgical method . Hence the amended claims are not allowable u/s 3(1) of the Patent Act, 1970.

3(e)

Fig 4 has been considered with regard to 3(e) and has been found persuasive. Hence the objection is considered as met.

Regarding Sufficiency of Disclosure u/s 10(4) and Clarity and Conciseness



The applicant has met the objection amendment of claims.

Since, the applicant has failed to meet the requirements of outstanding objection u/s 3(i) of the hearing letter, I refuse to proceed further with this application for patent No. 6771/DELNP/2013 under Section 15 of the Act.”

[Emphasis Supplied]

2. So far as the objection regarding the lack of inventive step under Section 2(1)(ja) of the Act is concerned, essentially the learned Controller in his inference records that the explanation provided by the appellant with regard to the prior art documents and having regard to the figure 4, have been considered, which were found satisfactory, and concluded that the objection under Section 2(1)(ja) of the Act was met. In other words, the objection regarding lack of inventive step was met with, by the appellant.

3. So far as the objection regarding Section 3(e) of the Act is concerned, the learned Controller has also found the submissions to be persuasive and has on that account, noted that the objection has been met with by the appellant. Additionally, the learned Controller also noted that the objection regarding Sufficiency of Disclosure under Section 10(4) of the Act and Clarity and Conciseness has been met by the appellant.

4. What remains for consideration is only the objection about non-patentability under Section 3(i) of the Act. The learned Controller has not found the submissions of the appellant persuasive on account of the fact that though the appellant had amended the claims by deleting sub-section (a) of the original method claims referring to “obtaining the sample containing Haematopoietic Stem Cells”, yet that step was an essential essence for properly carrying out the invention. The learned Controller had noted that the exclusion from the surgical method cannot be avoided merely by drafting claim which would emit one step of such method. The learned Controller was of the opinion that the said step is an essential one, which would involve surgical methods and



since the application pertaining to surgical method itself would be violative of the prohibition or proscription under Section 3(i) of the Act, the patent application was rejected.

5. It appears that during the subsistence of the present appeal, the appellant *vide* the e-mail letter dated 10.02.2026, through its counsel, communicated to the respondent that in order to bring quietus to the issue, the appellant would amend its claims by deleting claim 1, however, retaining claims 2 to 5. On that account, an additional affidavit has been filed on behalf of the respondents/Controller who in para 5 of the said additional affidavit has stated as under:

“5. That in light of the abovementioned letter of the Appellant dated 10.02.2026, it is most humbly submitted that the application was JB/refused because the applicant failed to meet the requirements relating to the outstanding objection under Section 3(i) of the Patents INVAct 1970, which applies only to Claim 1. As per the contents of the letter dated 10.02.2026, if Claim 1 is deleted as proposed by the Appellant, the objection may be considered as resolved. It is most humbly submitted that there are no further objections with respect to the composition claims. Accordingly, the respondent most humbly submits that the matter may be remanded back for grant of the application with the amended claims as proposed by the Appellant vide letter dated 10.02.2026.

True copy of the communication by way of Email dated 06.03.2026 is annexed hereto and marked as Document 2.”

6. In effect, the learned Controller has stated that the patent application of the appellant was refused on account of the fact that the appellant failed to meet the requirements relating to the objection under Section 3(i) of the Act which applied only to claim no.1. In such circumstances, it has been stated that if the appellant is willing to amend its claim by deleting claim no.1, the objection may be considered as resolved and further states that in case such construction is agreed to, the matter can be remanded for consideration of the application with the amended claims as proposed by the appellant *vide* the letter dated 10.02.2026.



7. This Court in ***C.A.(COMM.IPD-PAT) 20/2023 titled “M/S Coral Drugs Private Limited vs. The Assistant Controller Of Patents”*** dated 29.01.2026 and in ***C.A.(COMM.IPD-PAT) 302/2022 titled “Fresenius Medical Care Deutschland GmbH vs. Controller General of Patents”*** dated 16.04.2025 has permitted amendment of claims before this Court and further remanded the matter back to the learned Controller for consideration of the applications, which were the subject matter of the appeals therein. The relevant paras of the judgment ***Fresenius Medical Care (supra)*** are reproduced hereunder:

“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.”

8. Having regard to the aforesaid as also the additional affidavit enclosing relevant communications between the appellant and the Controller’s Office, this Court deems it appropriate to permit the appellant to amend its patent application by deleting claim no.1, however, retaining claims 2 to 5.

9. In that view of the matter, the appeal is allowed limited to the aforesaid extent, remanding the matter back to the Controller’s office for a consideration of the patent application in terms of the directions noted above.

10. The additional affidavit, enclosing all the documents dated 25.03.2026 is taken on record.

11. The learned Controller is requested to process the subject patent application after affording an opportunity to the appellant of hearing within three months from date. Notice of such hearing shall be issued to the appellant by the learned Controller.

12. It is important to note that this order is passed without going into merits of the appeal and therefore the learned Controller is directed to decide the



matter on merits uninfluenced by any observations made in this order.

13. The appeal is disposed of in above terms without any orders as to costs.

TUSHAR RAO GEDELA, J

MARCH 27, 2026/anj