IN THE HIGH COURT AT CALCUTTA
ORIGINAL SIDE
Ordinary Original Civil Jurisdiction

BEFORE:
The Hon'ble JUSTICE RAVI KRISHAN KAPUR

IPDAID/41/2024

ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE
VS
THE CONTROLLER OF PATENTS AND DESIGNS

For the appellant	: Mr. Debnath Ghosh, Sr. Adv. Mr. Biswaroop Mukherjee, Adv. Mr. Pradipta Bose, Adv. Ms. Madhumanti Chakraborty, Adv. Mr. S. Banerjee, Adv
For the Controller	: Mr. Swatarup Banerjee, Adv. Mr. Priti Jain, Adv. Mr. Shankharit Charkbaroty, Adv.
Heard on	: 22.12.2025
Judgment on	: 22.12.2025

Ravi Krishan Kapur, J.:

1. This appeal is directed against an order dated 23rd March, 2022 passed by the Assistant Controller of Patents and Designs.
2. The primary ground urged on behalf of the petitioner is that the impugned order has been passed mechanically ignoring the provisions of the amended claims and does not consider the true and correct facts of the case. It is further contended that the subject invention has been granted in several other countries.

3. Briefly, the subject invention is titled as "IMPROVED METHODS OF PRODUCING RPE CELLS AND COMPOSITIONS OF RPE CELLS" and contemplates a method of producing retinal pigment epithelial cells (RPE) cells from human pluripotent cells. The differentiated RPE cells can be used in screening assays and as therapeutics. The Retinal Pigment Epithelium (RPE), is a single layer of pigmented hexagonal cells behind the retina as the outer most layer of the retina. The RPE plays an important role in maintaining visual function and the visual cycle. RPE cells are phagocytic, with the ability to engulf and eliminate exfoliated POS and maintain the normal renewal of visual cells. The RPE plays a fundamental role in both the transport and storage of retinoids essential for maintenance of the visual cycle. RPE cell damage, in turn, causes retinal dysfunction and even blindness.
4. It is contended on behalf of the applicant that the invention provides for the first time, a method in which the embryonic stem cells are commercially exploited for the production of retinal pigment epithelial cells (RPE Cells). The embryonic stem cells recited in the claimed invention are obtained by methods which do not require the destruction of the human embryo. As stated in Example 1: "Two hES cell lines derived from single blastomeres were used-MA1 and MA09". Hence, pre-established hES cell lines were used in the claimed method. It is alleged that the claimed method could use the cell line without the need to destroy and embryo anew. It is submitted on behalf of the applicant that the instant stem cells research is purely based on obtaining the human embryo from the

umbilical cord and as such, there is no ground for rejection of the application under section 3(b) of the Act.

5. On behalf of the respondent Controller, it is submitted that the entire case made out before this Court that the umbilical cord is the only source for deriving the embryos is neither made out in the pleadings nor the amended claims nor the specifications which had been filed. In such view of the matter, there is no infirmity with the impugned order and the same has been passed after consideration of all the facts and circumstances of the case. As such, the rejection of the subject invention under section 3(b) of the Patents Act, 1970 warrants no interference whatsoever. There are sufficient and elaborate reasons provided in the impugned order. The case made out by the appellant that stem cells would be exclusively obtained from the umbilical cord is *de hors* the pleadings and specifications filed by the appellant. This case is sought to be made out for the first time from the Bar and warrants rejection.

6. The application was filed for grant of a patent bearing National Phase Patent Application Number 1547/KOLNP/2010. Pursuant to the filing of the instant application, a First Examination Report dated 25th May, 2017 was issued by the Deputy Controller of Patents. The appellant had responded to such First Examination Report by responding to all the substantive and formal objections. Subsequently, the appellant's agent received the hearing notice. Written notes of arguments were also filed and fresh hearing notice with fresh objections under section 59(1) of the Act was also issued by the authorities. Upon completion of the proceedings,

the impugned order dated 23rd March, 2022 was passed by the Assistant Controller.

7. A perusal of the impugned order would demonstrate that after considering all the submissions made on behalf of both parties and discussing the subject invention extensively, the Assistant Controller has concluded as follows:

> v. *It is observed that the process of single blastomere derivation may not kill the embryos; however, may affect the successful implantation of the embryo and may cause a detrimental effect on the survival rate of cleavage-stage embryos. Thus, the process cannot be considered as an embryo-saving strategy; and the same is ethically challenging. Evidence that the process is not an embryo-saving method can be found in Heidi ET AL, "An ethical analysis of alternative methods to obtain pluripotent stem cells without destroying embryos, Human Reproduction, Volume 21, Issue 11, Nov 2006, Pages 2749-2755, https://doi.org/10.1093/humrep/de1233.*

8. Section 3(b) of the Act of 1970 provides as follows:

> ***3.(b)*** *an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.*

9. On a plain reading of the above section, inventions which may violate public order are excluded under the given section since they are concerns about threats to environment, public security and physical integrity of individuals.

10. The impugned order is adequately reasoned and deals with all the objections. It has been held that the subject invention falls within the scope of section 3(b) of the Act of 1970 and is not patentable. The entire case made out in this appeal that the subject invention is only obtained

from biological waste and/or umbilical cord is not borne out from the specifications and the pleadings which have been filed by the appellants. In this context, the amended claim filed on behalf of the appellant titled "Improved methods of producing RPE cells and compositions of RPE cells" is to provide a method for differentiating RPE cells from human pluripotent stem cells, such as human embryonic and human induced pluripotent stem cells which appears from the amended claim does not disclose the above fact. There is nothing in the amended claims which would support the contention made by the appellant that stem cells are only to be extracted from the umbilical cord.

11. On the contrary, the specifications which have been filed in the subject invention would demonstrate that the present invention provides the corresponding feature, i.e., by parthenogenesis merely optional and has no limiting effect on the scope of the method which is used for obtaining the embryonic stem cells.

12. In this context, the decisions cited on behalf of the appellant are all distinguishable and inapposite. As stated above the contention on behalf of the appellant that the stem cells were only to be obtained from the umbilical cord does not appear from the subject application or the specifications. The finding in the impugned order that the subject invention was ethically prohibited is sufficiently reasoned and justifies no interference.

13. In this background, there are no grounds to interfere with the impugned order. There is no infirmity which the appellant has been able to

demonstrate which would warrant interference with the impugned order. There is no illegality nor contravention of law nor perversity which warrants any interference with the discretion exercised in passing the impugned order.

14. In view of the above, IPD-AID No.41 of 2024 stands dismissed.

There shall be no order as to costs.

(RAVI KRISHAN KAPUR, J.)

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