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

BEFORE:
The Hon'ble JUSTICE RAVI KRISHAN KAPUR

IPDPTA/7/2025

VIACYTE INC
Vs
DEPUTY CONTROLLER OF PATENTS AND DESIGNS

For the appellant	: Ms. Swati Mittal, Adv. Ms. Shika Singh, Adv. Mr. Abhirup Chakraborty, Adv.
For the Controller	: Mr. Rashmi Bothra, Adv. Mr. Priyanka Sarada, Adv.
Heard on	: 24.12.2025
Judgment on	: 16.01.2026

Ravi Krishan Kapur, J.:

1. This appeal is directed against an order dated 7 May 2024 passed by the respondent no.1 refusing grant of an invention described as a bioreactor.
2. Briefly, the subject application relates to a bioreactor comprising of primate pluripotent stem cell-derived cell aggregates in suspension in a physiologically acceptable culture medium, wherein the primate pluripotent stem cell-derived cell aggregates are substantially uniform in size and shape and have a diameter of 50 microns to 600 microns, and the primate pluripotent stem cell-derived cell aggregates are formed in the bioreactor by rotational culture; wherein the said bioreactor is a stirred tank bioreactor, a spinner flask bioreactor, a tissue culture dish, rotating bottle or a vessel on an orbital shaker. Such a bioreactor is specific and cannot be construed as encompassing any other bioreactor.

The bioreactor has a distinct component which essentially includes cells which are also part of the bioreactor. It is suggested that the claimed bioreactor provides an efficient system which overcomes the drawbacks of any prior arts i.e., it provides a large-scale manufacturing ("scale-up") for eukaryotic mammalian cells, and more particular, mammalian pluripotent cells such as human embryonic stem (hES) cells.

3. By the impugned order, the application for patent has been rejected on the ground that the same lacked inventive steps under section 2(1)(j) and 2(1)(ja) of the Act. The invention also fails to make disclosures under section 10 of the Act and was found to be non-patentable under section 3 of the Act.

4. On behalf of the appellant it is contended that, the impugned order is based on an incorrect understanding of the invention and the applicable law. The subject invention does not lack novelty nor inventiveness. The subject invention does not also fall within the ambit of section 3(d) or section 3(j) of the Act and was not liable to be rejected. The specifications provided by the appellant also adhered to all the requirements under section 10(4)(a) and 10(5) of the Act and did not warrant any rejection. In such circumstances, the impugned order is liable to be set aside and the matter remanded to the Controller for hearing afresh.

5. On behalf of the respondent authorities, it is submitted that the impugned order does not warrant any interference. The order is adequately reasoned. The Controller has dealt with all the submissions made on behalf of the parties. The order is justified and is based on sound technical and scientific reasoning and was passed after compliance with the mandatory requirements of invention under the Act.

The appellant has failed to disclose any infirmity or procedural irregularity or error in legal interpretation which warrants any interference with the order.

6. One of the principal objects of the Patents Act, 1970 is to promote technological innovation in public interest while ensuring that patents are not granted for subject matters excluded from patentability or which do not comply with the requirements of novelty, inventive step or sufficient disclosure.

7. Section 3(j) of the Act is as follows :

> *"3. what are not inventions - The following are not inventions within the meaning of this Act- (j) plants and animals in whole or any part thereof other than microorganisms but including seeds varieties and species and essentially biological processes for production or propagation* of plants and animals,".

8. On a plain reading of the above provision, it is essential to identify the true focus and substance of the invention. In the present case, the Controller has identified that the claims are directed substantially towards primate pluripotent stem-cell derived aggregates, including human embryonic stem cell derived aggregates and that the bioreactor functions merely as a container for maintaining such biological material in suspension. These aggregates are unequivocally parts of animals, and the invention though drafted in the form of a device or system, in effect seeks protection over animal or human biological material which cannot be patented.

9. By the impugned order, the Controller has concluded that the invention is a mere use of a known apparatus - a bioreactor including stirred tanks bioreactors, spinner flasks and rotating vessels are commonplace systems

extensively employed in the domain of culturing mammalian cells and embryonic stem cells. The alleged novelty resides only in the parameters such as rotational speed, aggregate size and biological markers of the cells, which merely reflects optimization of known operating conditions. The bioreactor functions solely as a vessel and no new technical feature, reactant or product distinct from the prior art has been disclosed. The appellant seeks protection over an end result achieved through the use of known equipment under routine variations of process conditions, which is barred under section 3(d) of the Act. A bioreactor, even if tailored for biological applications, is universally recognized as a mechanical apparatus, engineered to enable to precise control of environmental variables such as temperature, pH, agitation, oxygenation, and nutrient delivery. The present claims disclose no novel nor mechanical configuration nor distinctive material composition nor any structural adaptation which would distinguish the claimed bioreactor from known designs.

10. Section 2(1) (j) of the Patents Act, 1970 defines "invention" as a new product or process involving an inventive step and capable of industrial application. The Controller has found that the appellant's invention is wholly based on the desired outcome and process parameters and lacks constructional features. The process parameters which the appellant has specified for aggregate size (50-600 microns) and agitation speed (60-140 rpm) are not novel and any person skilled in the art could routinely optimize to balance factors like stress and oxygen pressure. There exists no structural advancement nor novel apparatus configuration which distinguishes the claimed bio-reactor from existing or known systems. The

reliance on the prior art documents (D1-D6) in the impugned order has been elaborately dealt with. D1 discloses the cultivation of human embryoid bodies using bioreactors operated at rotational speeds between 13 rpm and 30 rpm to control aggregate size. D2 to D4 further describe shear-controlled stirred suspension cultures of mouse embryonic stem cells at higher agitation speeds, such as 100 rpm, establishing the viability of manipulating shear forces to regulate cell aggregation. D5 details the formation of floating human embryonic stem cell aggregates in suspension cultures supplemented with ROCK inhibitors, while D6 discloses undifferentiated hESC aggregates maintained in suspension bioreactor systems. In summary, all these prior arts establish that the use of known bioreactor formats for suspension-based cultivation of pluripotent stem cells with defined rotational parameters and size control. This is a routine and well-documented practice. The reliance by the appellant on differences in cell types, specific size ranges, or rotational speeds fails to raise the threshold requirement of inventive contribution, particularly in the absence of any novel bioreactor structure or operational mechanism. The claimed invention does not identify any unique internal geometry, agitation system, gas exchange configuration, or other technical feature distinguishing it from the prior arts.

11. Section 2(1)(ja) of the Patents Act, 1970 states that "inventive step means feature of an invention that involves technical advancement as compared to the existing knowledge or having economic significance or both and which makes the invention not obvious to a person skilled in the art". In the present case, it has been held by the Controller that the claimed process involves rotational speed, aggregate size range, suspension

culture-are all adjustable within known margins and do not, singly or in combination, yield a non-obvious technical effect. As such, the claims represent no more than an application of routine experimentation within the knowledge of the person skilled in the art and fails to disclose any technical advancement or economic significance contemplated under section 2(1)(ja) of the Act. The impugned order has appreciated the disclosures in D1-D6 and correctly applied the test of inventive steps. It has been found that the alleged technical problem which the appellant claims to solve is large scale production of undifferentiated hESCs, and this has already been addressed in multiple prior art disclosures relied on in the impugned order.

12. Section 10(4) of the Patents, Act 1970 mandates that a complete patent specification must fully describe the invention, its operation alongwith the best method of performing it and ends with claims defining the scope, ensuring that a person skilled in the art can understand and reproduce it forming the core of the patent bargain for exclusive rights in exchange for public disclosure. The application filed by the appellant does not sufficiently describe the invention claimed and has been found to be vague and incomplete which is in contravention of section 10(4) of the Act. The amended claim 1 suffers from a fundamental defect in its claim construction in that it remains a mixed-category claim improperly combining elements of a product (bioreactor) with process-dependent features such as the formation of uniform cell aggregates under specific rotational conditions. It has been held in the impugned order that the conflation of product and process without a clear technical specification of the structural features of the claimed device violates the definiteness

requirement under sections 10(4)(a) to (c) and 10(5) of the Act. It has also been held that the so-called "novel and inventive" element which purportedly suggests rate optimization is merely a process variable, not a structural or inventive feature of the bioreactor itself, and such parameters are routinely adjusted by skilled artisans depending on variables such as cell type and scale.

13. Section 10(5) mandates that all claims shall be clear, succinct and fairly based on the matter disclosed and relates to a single invention or a group of inventions linked as to form a single inventive concept. On the contrary, the specification and claims have been found to be vague, ambiguous and did not sufficiently define the invention since it did not disclose structural features which would be necessary to achieve the claimed outcome.

14. In view of the above, the impugned order is well reasoned and is based on sound technical and scientific evidence and data. The appellant has failed to disclose any infirmity or procedural irregularity or error in legal interpretation which warrants any interference with the order. In passing the impugned order the Controller has examined the claims, the cited prior arts and has applied the statutory tests for patentability with adequate reasons. In such circumstances, there are no grounds which justify any interference with the impugned order. IPDPTA 7 of 2025 stands dismissed.

(Ravi Krishan Kapur, J.)