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

% *Judgment delivered on: 28.03.2026*

\+ **C.A.(COMM.IPD-PAT) 493/2022**

PRESIDENT AND FELLOWS OF HARVARD COLLEGE .....Appellant

versus

CONTROLLER GENERAL OF PATENTS DESIGNS AND TRADEMARKS .....Respondent

Advocates who appeared in this case

For the Appellant : Dr. Satyapal Arora, Mr. Ashish Sharma, Mr. Kuldeep Kumar Singh & Mr. Nitin Sharma, Advocates.

For the Respondent : Mr. Balendu Shekhar, CGSC with Mr. Krishna Chaitanya, Mr. Rajkumar Maurya, Mr. Divyansh Singh Dev and Ms. Tanisha Samanta, Advocates.
Dr. Bhanumathi R, Assistant Controller of Patents & Designs (through VC).

CORAM:
HON'BLE MR. JUSTICE TEJAS KARIA

JUDGMENT

TEJAS KARIA, J

INTRODUCTION

1. This is an Appeal under Section 117 of the Patents Act, 1970 ("**Act**") read with Section 151 of the Code of Civil Procedure, 1908 filed against the

order dated 25.08.2022 ("**Impugned Order**") passed by the Controller General of Patents, Designs and Trademarks ("**Respondent / Controller**") whereby the learned Controller refused the grant of patent *vide* Patent Application No. 201617000758 titled as "*SC-β CELLS AND COMPOSITIONS AND METHODS FOR GENERATING THE SAME*" dated 08.01.2016 ("**Subject Application**").

FACTUAL MATRIX

2. On 11.06.2013, the Appellant filed the First Priority Application corresponding to the Subject Application *vide* Application No. US 61/833,898. On 28.03.2014, the Appellant filed the Second Priority Application corresponding to the Subject Application *vide* Application No. US 61/972,272. On 11.06.2014, the Appellant filed the Patent Cooperation Treaty Application corresponding to the Subject Application *vide* Application No. PCT/US2014/041992 ("**PCT Application**"). On 08.01.2026, the Appellant filed the Subject Application.

3. On 08.01.2016, the Appellant filed Form No. 13 for amendments in the claims as PCT Application had 1 claim, while the Subject Application is filed with 29 claims. On 01.06.2017, the Appellant filed a request for examination and voluntarily amended the claims. Thereafter, the Respondent issued the First Examination Report dated 28.02.2020 ("**FER**"). The Appellant filed the response to the FER along with the amended claims and Form No. 13 for voluntary amendment in claims with respect to the PCT Application on 28.08.2020 ("**Reply**").

4. The Respondent issued a hearing notice dated 24.11.2020 scheduling the hearing for 08.01.2021. A request for adjournment under Rule 129 of the Patent Rules, 2003 was filed for the hearing scheduled on 08.01.2021. An

extended hearing notice was issued on 09.06.2021 for a hearing scheduled for 08.07.2021. Subsequently, an extended hearing notice was issued on 25.06.2021 ("**Hearing Notice**") for a hearing scheduled for 06.08.2021 ("**Hearing**"). On 21.08.2021, written submissions were filed on the basis of the oral arguments submitted in the Hearing by the Appellant along with the amended claims ("**Written Submissions**").

5. *Vide* the Impugned Order, the Respondent refused the Subject Application under Section 15 of the Act stating that the Subject Application does not meet the requirement under Sections 3(j), 3(e), 10(4) and 10(5) of the Act.

SUBMISSIONS ON BEHALF OF THE APPELLANT

6. The learned Counsel for the Appellant made the following submissions:

6.1. The Respondent has refused the Subject Application on the following grounds for the objections raised in the Hearing Notice: (i) definitiveness under Section 10(4) and Section 10(5) of the Act; (ii) non-patentability under Sections 3(j) and 3(e) of the Act; and (iii) sufficiency of disclosure under Section 10 (4) of the Act.

6.2. The Respondent acknowledges that claim no. 1 recites a composition comprising a non-native pancreatic beta ("**β**") cell and one or more pharmaceutically acceptable carriers, additives, and / or diluents. The Respondent has refused the Subject Application on the ground that the cells allegedly are defined by a broad generic gene expression profile and that the phrase 'non-native', 'native', and 'gene expression profile' are unclear. Thus, the claims

allegedly are not definitive as required under Section 10(4)(a) of the Act.

6.3. For interpretation of words in claims, first priority is to take help of intrinsic evidence, i.e., from patent documents, specifications etc. Therefore, for true meaning of words in the claim, first of all specifications are to be looked into. The word 'non-native' cells are well defined in the specifications. The relevant paragraphs from the Complete Specification of the PCT Application are reproduced hereunder:

> *"[193] The SC-β cells disclosed herein share many distinguishing features of native β cells, but are different in certain aspects (e.g., gene expression profiles). In some embodiments, the SC-β cell is non-native. As used herein, "non-native" means that the SC-β cells are markedly different in certain aspects from β cells which exist in nature, i.e., native β cells. It should be appreciated, however, that these marked differences typically pertain to structural features which may result in the SC-β cells exhibiting certain functional differences, e.g., although the gene expression patterns of SC-β cells differs from native β cells, the SC-β cells behave in a similar manner to native β cells but certain functions may be altered (e.g., improved) compared to native β cells.*
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> *** *** ***
>
> *[329] Aspects of the disclosure involve generating SC-β cells which resemble endogenous mature β cells in form and function, but nevertheless are distinct from native β cells.*
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> *** *** ***
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> *[597] The generation of insulin-producing pancreatic β cells from stem cells in vitro would provide an unprecedented cell source for drug discovery and cell transplantation therapy in diabetes."*

6.4. These ‘non-native’ cells are novel and inventive and do not occur in nature. However, the native pancreatic β cells are obtained from natural sources and cannot be reliably grown *in vitro*. In contrast, non-native pancreatic β cells can be reliably generated *in vitro* from stem cells or precursors to the non-native pancreatic β cells using protocols such as those described in the Subject Application.

6.5. Regarding input source for generating ‘non-native’ cells, the Subject Application describes numerous examples of cells that could be used to make non-native pancreatic β cells and do not necessarily involve the destruction of embryo cells. In some embodiments, the source of human stem cells or pluripotent stem cells used for chemically induced differentiation into mature, insulin positive cells did not involve destroying a human embryo.

6.6. The pending claims recite a composition comprising a non-native pancreatic β cell and one or more pharmaceutically acceptable carriers, additives, and / or diluents and the relevant paragraphs from the Complete Specification is reproduced hereunder:

> *“[511] For administration to a subject, a cell population produced by the methods as disclosed herein, e.g. a population of SC-β cells (produced by contacting at least one insulin-positive endocrine cell with at least one p cell maturation factor (e.g., any one, two, three, four, five, or more p cell maturation factors as described herein) can be administered to a subject, for example in pharmaceutically acceptable compositions. These pharmaceutically acceptable compositions comprise a therapeutically-effective amount a population of SC-β cells as described above, formulated together with one or more pharmaceutically acceptable carriers (additives) and/or diluents.*
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> *** *** ***

[563] Pharmaceutical compositions comprising effective amounts of a population of SC-β cells are also contemplated by the present invention. These compositions comprise an effective number of SC-β cells, optionally, in combination with a pharmaceutically acceptable carrier, additive or excipient. In certain aspects of the present invention, a population of SC-β cells are administered to the subject in need of a transplant in sterile saline. In other aspects of the present invention, a population of SC-β cells are administered in Hanks Balanced Salt Solution (HBSS) or Isolyte S, pH 7.4. Other approaches may also be used, including the use of serum free cellular media. In one embodiment, a population of SC-β cells are administered in plasma or fetal bovine serum, and DMSO. Systemic administration of a population of SC-β cells to the subject may be preferred in certain indications, whereas direct administration at the site of or in proximity to the diseased and/or damaged tissue may be preferred in other indications."

6.7. The carrier is selected so as to be compatible with other aspects of the composition, including the delivery of the non-native pancreatic β cells to a subject. This claimed 'non-native' cells composition does not fall under non-patentable subject matter under Section 3(j) of the Act. The relevant paragraphs from the Complete Specification of the PCT Application is reproduced hereunder:

"[514] As used here, the term "pharmaceutically-acceptable carrier" means a pharmaceutically-acceptable material, composition or vehicle, such as a liquid or solid filler, diluent, excipient, manufacturing aid (e.g., lubricant, talc magnesium, calcium or zinc stearate, or steric acid), or solvent encapsulating material, involved in carrying or transporting the subject compound from one organ, or portion of the body, to another organ, or portion of the body. Each carrier must be "acceptable" in the sense of being compatible with the other ingredients of the formulation and not injurious to the patient. Some

examples of materials which can serve as pharmaceutically-acceptable carriers include: (1) sugars, such as lactose, glucose and sucrose; (2) starches, such as corn starch and potato starch; (3) cellulose, and its derivatives, such as sodium carboxymethyl cellulose, methylcellulose, ethyl cellulose, microcrystalline cellulose and cellulose acetate; (4) powdered tragacanth; (5) malt; (6) gelatin; (7) lubricating agents, such as magnesium stearate, sodium lauryl sulfate and talc; (8) excipients, such as cocoa butter and suppository waxes; (9) oils, such as peanut oil, cottonseed oil, safflower oil , sesame oil, olive oil, corn oil and soybean oil; (10) glycols, such as propylene glycol; (11) polyols, such as glycerin, sorbitol, mannitol and polyethylene glycol (PEG); (12) esters, such as ethyl oleate and ethyl laurate; (13) agar; (14) buffering agents, such as magnesium hydroxide and aluminum hydroxide; (15) alginic acid; (16) pyrogen-free water; (17) isotonic saline; (18) Ringer's solution; (19) ethyl alcohol; (20) pH buffered solutions; (21) polyesters, polycarbonates and/or polyanhydrides; (22) bulking agents, such as polypeptides and amino acids (23) serum component, such as serum albumin, HDL and LDL; (22) C2-C12 alcohols, such as ethanol; and (23) other non-toxic compatible substances employed in pharmaceutical formulations. Wetting agents, coloring agents, release agents, coating agents, sweetening agents, flavoring agents, perfuming agents, preservative and antioxidants can also be present in the formulation. The terms such as "excipient", "carrier", "pharmaceutically acceptable carrier" or the like are used interchangeably herein.

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[551] In some embodiments, a population of SC-β cells as disclosed herein can be supplied in the form of a pharmaceutical composition, comprising an isotonic excipient prepared under sufficiently sterile conditions for human administration. For general principles in medicinal formulation, the reader is referred to Cell Therapy: Stem Cell Transplantation, Gene Therapy, and Cellular Immunotherapy, by G. Morstyn & W. Sheridan eds, Cambridge University Press, 1996; and Hematopoietic Stem Cell Therapy, E. D. Ball, J. Lister & P. Law, Churchill

Livingstone, 2000. Choice of the cellular excipient and any accompanying elements of the composition comprising a population of SC-β cells as disclosed herein will be adapted in accordance with the route and device used for administration. In some embodiments, a composition comprising a population of SC-β cells can also comprise or be accompanied with one or more other ingredients that facilitate the engraftment or functional mobilization of the SC-β cells. Suitable ingredients include matrix proteins that support or promote adhesion of the SC-β cells, or complementary cell types, especially endothelial cells. In another embodiment, the composition may comprise resorbable or biodegradable matrix scaffolds."

6.8. There may be a number of such cases, where such type of cells or their compositions have been granted patent in India. One example is the grant of Patent No. 404415 granted on 24.08.2022 in Indian Patent Application No. 1616/DELNP/2015. The applicant as referred to the principal claim no. 1 of the aforesaid patent.

6.9. On further observing the prosecution history in the Indian Patent Office, it is found that the patentee has indicated that in the written submissions on Page No. 1 that cell preparation means a composition. The relevant paragraph of the written submissions is reproduced hereunder:

> *"claim 1 has been amended to claim a cell preparation which is a composition comprising of pluripotent stem cells and DMSO and/or serum albumin, as supported by paragraph [0026] of English specification."*

On further analysis of the source of stem cells, as claimed in claim no. 1, the specification states that the English translation on Page No. 16 of specification describes about the said pluripotent stem cells called Multilineage differentiating Stress Enduring ("**MUSE**") cells.

6.10. The abovementioned example draws similarity with the Subject Application of the Appellant as: (i) the source of stem cells is plant or animal in whole or part thereof; and (ii) the claims relate to cell preparation or cell composition. The Subject Application has further characteristics that though the source was cells from human / animal body, these cells were processed and generated to get non-native β cell. These non-native β cell are not occurring in nature and are distinct from natural occurring native β cells. The non-native β cell of the present invention have been novel and inventive and the claimed composition of involving non-native β cells has synergic effect, and have pharmaceutical efficacy and solves the long-standing problem of the prior art. The present invention solves the technical problem of the prior art and relates to a patentable subject matter and is not hit by Section 3(j) of the Act.

6.11. The stem cell derived β ("**SC-β**") cells were generated by engineering an elaborate process and cannot be said to be a part of an animal in whole or part thereof and the claims are not hit by Section 3(j) of the Act. Reliance was placed upon the decision in ***Imclone LLC v. Assistant Controller of Patents and Designs, Government of India***, 2024 SCC OnLine Mad 8397 wherein the Court held that the antibody was generated by deleting murine genetic material from mice and replacing the same with human genetic material in the mice and, thereafter, injecting an engineered antigen into the mice. After doing so, material extracted from the spleen of the mice was fused with myeloma cells by the hybridoma

process. This resulted in the antibody over which the patent claim is made.

6.12. Non-native SC-β cells, like tri-hybrid cells, involve technical human intervention and are, therefore, patentable. SC-β cells are novel and inventive and do not form part of animal or plant and are not hit by Section 3(i) of the Act. Non-native SC-β cells are novel and inventive comparable to tri-hybrid cells; both are man-made, not naturally occurring, not plant / animal parts, and not from an essentially biological process. Reliance was placed upon the decision in ***BTS Research International Pty. Ltd. (SR/55/2020/PT/KOL) v. The Controller General of Patents & Designs, Mumbai & Ors.***, 2025 SCC OnLine Cal 2943 wherein the Court held that Section 3(j) of the Act exclusion must be narrowly construed; inventions involving genetic engineering or non-natural cell creation are not hit by Section 3(j) of the Act. The Court recognized tri-hybrid cells as outside Section 3(j) of the Act, setting a precedent that applies similarly to SC-β cells.

6.13. In the decision of ***Natural Alternatives International, Inc. v. Creative Compounds LLC***, 918 F.3d 1338 (2019) wherein the Court held that compositions comprising a component of natural origin are patentable, so long as the composition demonstrates different characteristics when compared to the component found in nature.

6.14. There are corresponding applications, main, divisional or continuation in part applications have been granted patent in the United States of America, Great Britain, Australia, Germany,

Japan, Korea, Russia etc. The Appellant filed 29 identical claims for examination, which were granted patent in the United Kingdom.

6.15. Accordingly, the present Appeal shall be allowed, and the Impugned Order is liable to be set aside.

SUBMISSIONS ON BEHALF OF THE RESPONDENT

7. The learned Counsel for the Respondent made the following submissions:

7.1. Section 3(j) of the Act based on Article 27.3(b) of the Trade-Related Aspects of Intellectual Property Rights Agreement states "*Plants and animals in whole or any parts thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production and propagation of plants and animals.*" are not patentable.

7.2. The only exception appears to be microorganisms which may be granted a patent. However, when a microorganism which has been just isolated from nature, is not considered to be patentable under Section 3(c) of the Act. Section 3(c) of the Act prohibits patentability of "*the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature*". Hence, the microorganism, which are patentable are limited to those that are genetically modified organisms only.

7.3. Section 3(j) under the Act, expressly excludes "*plants and animals in whole or any part thereof*" irrespective of whether those parts are cultured, maintained, or differentiated *in vitro*. Accepting the

Appellant's contention that such cells are 'synthetic' would create a loophole whereby any naturally derived biological material could be rebranded as synthetic simply by laboratory handling. The distinction between isolation or differentiation of natural material and genuine synthetic constructs has also been recognized internationally in the decision of ***Association for Molecular Pathology et al. v. Myriad Genetics Inc. et al.***, 2013 SCC OnLine US SC 47 wherein the Court held that where naturally occurring deoxyribonucleic acid ("**DNA**") was held unpatentable, while truly synthetic complementary DNA ("**cDNA**") was treated differently. Applying that principle, the claimed SC-β cells, however cultured, remain natural derivatives and fall squarely within the exclusion of Section 3(j) of the Act.

7.4. Microbes are single-celled organisms. Animal is a name reserved for a multicellular eukaryote that is heterotrophic, so organisms that are bigger than a single cell and almost all their cells have a nucleus. A genetically modified human or plant cell cannot be equated to a genetically modified microbe because it falls under Section 3(j) of the Act. Section 3(j) of the Act prohibits patentability of an animal and plant in whole.

7.5. 'Native' cell means a cell that is found in a natural setting, which includes multicellular organism cells *in vivo* i.e., part of an organism, and unicellular organisms 'in environment' i.e., part of a natural environment. In biology, native cells are usually considered to be cells that are naturally found in an organism or environment, as opposed to cells that have been introduced artificially.

7.6. In the Subject Application ‘non-native’ cells are cells isolated from the human body for use in human itself. They, however, do not have a comparison of non-nativeness. In the Subject Application, the definition of “non-native pancreatic β cell” fails to define what is ‘native’. Without a tangible identity of either ‘non-native’ or ‘native’, it remains unclear what the terms mean with respect to the present claim of the Appellant. The Appellant to substantiate their claim has stated that the “gene expression profile” of the claimed (non-native) SC-β cell is different from native human cells.

7.7. Taken together, the terminology ‘native’, ‘non-native’ and ‘gene expression profile that is different’ is unclear because:

a. no standard for ‘native’ or a ‘gene expression profile’ is defined;

b. there is no such thing as a standard gene expression profile for a ‘native’ cell, i.e., the standard itself is a variable;

c. it would be an undue burden to test a cell for the ‘non-native’ feature if all ‘native’ gene expression profile variations have to be taken into account for a comparison; and

d. the gene expression profile of a pancreatic cell to be ‘different’ from a reference cell is also unclear as there is no support data for such an interpretation.

7.8. The Subject Application is silent with regard to the specific cell type, the specific phase when the genes and insulin crystals as claimed are present or the gene expression level necessary to obtain the composition.

7.9. The "*Summary of the Invention*" in the Complete Specification of the PCT Application also states non-native pancreatic β "*cell is not genetically modified*", meaning it can be natural cell isolated from human. The Appellant has placed reliance upon Paragraph Nos. [4], [201] and [202] of the Complete Specification of the PCT Application. The reliance on foreign grants or international practice is misplaced as Indian patent jurisprudence has consistently applied a stricter construction of Section 3(j) of the Act, particularly in relation to human embryonic stem cells, on grounds of both express statutory exclusion and the legislative intent which was to categorically exclude human/animal parts and embryonic material from patentability, irrespective of their potential utility in regenerative medicine.

7.10. The Appellant's reliance on ***BTS Research International*** (*supra*) is misplaced as in the said case, the Court considered tri-hybrid chimeric cells produced through fusion of three distinct somatic cells (human and mouse), a construct that does not and cannot exist in nature. It was held that such a creation involved a level of artificial genetic manipulation that took it outside the scope of Section 3(j) of the Act. The Subject Application concerns SC-β cells. It is true that *in vitro* differentiation relies on specialized culture media and laboratory conditions, which are not a direct 'replication' of what occurs within the body. However, the critical point is that despite differences in the environment that induces differentiation, the ultimate product is biologically identical to the β cells that naturally arise *in vivo* and, thereby, are biological

derivatives of natural origin (human or animal material). The laboratory process merely triggers a natural developmental pathway inherent in stem cells; it does not give rise to a novel product unknown to nature.

7.11. Accordingly, the Impugned Order is liable to be upheld, and the present Appeal be dismissed.

REJOINDER SUBMISSIONS ON BEHALF OF THE APPELLANT

8. The learned Counsel for the Appellant made the following rejoinder submissions:

8.1. The Respondent seeks to equate the Appellant's SC-β cells with naturally occurring pancreatic β cells. This characterization is erroneous. The non-native SC-β cells claimed are structurally, functionally, and genetically distinct from native β cells. They exhibit altered gene expression profiles, enhanced glucose responsiveness, and mono-hormonal features that are not found in nature. Thus, the present invention is not a mere product of nature but the outcome of deliberate human technical intervention.

8.2. The Respondent attempts to distinguish the ***BTS Research International*** (*supra*) on grounds that tri-hybrid cells were wholly unnatural, whereas SC-β cells are 'natural derivatives'. This distinction is artificial. Both tri-hybrid cells and SC-β cells are created through controlled laboratory interventions that cannot and do not occur in nature. The Court held that Section 3(j) of the Act exclusion must be narrowly construed, and man-made cellular constructs fall outside its scope. The same reasoning squarely applies here.

8.3. The Respondent misreads Section 3(j) of the Act. The exclusion applies to "*plants and animals in whole or any part thereof... and essentially biological processes.*" The claimed SC-β cells are not whole animals, nor natural parts thereof, nor are they generated by essentially biological processes. Instead, they are the product of a multi-step laboratory-directed differentiation process.

8.4. The Respondent invokes the decision in ***Association for Molecular Pathology*** (*supra*) to argue that isolated natural material is not patentable. However, in the said case, itself drew a distinction between isolated DNA (unpatentable) and cDNA (patentable) because cDNA is man-made. SC-β cells are analogous to cDNA; they do not exist in nature and are generated only through human intervention.

8.5. The Respondent incorrectly asserts that derivation from pluripotent stem cells renders the claimed cells 'natural'. On the contrary, the process of re-programming and differentiating stem cells into β cells is an artificial, multi-stage laboratory protocol involving growth factors, culture conditions, and gene regulation. This process is neither essentially biological nor a natural developmental event. The mere use of a natural starting material does not bar patentability of a novel, non-naturally occurring product obtained therefrom.

8.6. The SC-β cells developed by the Appellant are not the same as natural β cells. They show special features that natural β cells do not have such as different gene activity, better response to glucose, and consistent production of only insulin. Something that has new

and different characteristics created by human effort is considered an invention and not just a natural product. Reliance was placed upon the decision in ***Sidney A. Diamond, Commissioner of Patents and Trademarks v. Ananda M. Chakrabarty et al.***, 1980 SCC OnLine US SC 128 while making the above submission.

8.7. The Respondent's emphasis on use of embryonic / foetal material is misplaced. The claims encompass derivation from induced pluripotent stem cells, adult stem cells, and cadaveric sources, which do not involve embryo destruction. The specification itself clarifies that embryos were not destroyed.

8.8. The Respondent relies upon the Department for Promotion of Industry and Internal Trade notes regarding exclusion of 'plants and seeds' to extend the exclusion to SC-β cells. Section 3(j) of the Act primarily addresses plant / animal varieties and biological propagation. Synthetic, engineered cellular products such as SC-β cells are outside its ambit, consistent with international patent practice where identical claims have been granted.

8.9. The Respondent dismisses international grants as irrelevant, however, Indian Courts, including in ***BTS Research International*** (*supra*), have recognized that while foreign practice is not binding, it is persuasive, especially when consistent across multiple major jurisdictions. The uniform recognition of such inventions as patentable supports the Appellant's position.

8.10. The Respondent's attempt to characterize non-native SC-β cells as 'natural parts of animals' is legally and scientifically untenable. The claimed SC-β cells consistently show stable and distinct gene

expression patterns, superior insulin secretion, and glucose responsiveness, distinguishing them from any naturally occurring β cells. These reproducible differences demonstrate that the SC-β cells are not mere natural variants, but a new and distinct cellular construct created through human technical intervention. The present invention represents a man-made construct (non-native), not an essentially biological process or natural material. Thus, the claims fall outside Section 3(j) of the Act and are patent-eligible.

ANALYSIS AND FINDINGS

9. The present invention of Subject Application relates to "*SC-β Cells, Compositions and Methods for Generating the same.*" As per the Abstract of the Complete Specification, it discloses methods, compositions, kits, and agents useful for inducing β cell maturation as well as isolated populations of SC-β cells for use in various applications like cell therapy.

10. The Complete Specification notes that the research to-date has generated only abnormally functioning insulin-expressing cells that fails to secrete appropriate amounts of insulin in response to sequentially varied glucose levels / pancreatic progenitor cells which can only mature into functioning insulin-expressing cells after three months of transplantation into a mouse host. Contrary to normal islets / dispersed adult β cells, which release high levels of insulin in response to high levels of glucose in the glucose stimulated insulin secretion ("**GSIS**") assay and can do so repeatedly, human pluripotent stem cell derived insulin-expressing cells which are generated by existing methods does not secrete insulin appropriately in response to the addition of various concentrations of glucose. Therefore, as per the Complete Specification of the Subject

Application, there is a need for a method of deriving cells from human pluripotent stem cells which exhibit a phenotype of normal islets or mature adult β cells.

11. The present invention claims a non-native pancreatic β cell that comprises one or more crystalline insulin granules. Claim no. 1 also claims the non-native pancreatic β cell expressing the genes INS, PDX1, NKX6-1, and ZNT8. This claim further claims the non-native pancreatic β cell which exhibits an *in vitro* GSIS response to a first glucose challenge as well as non-native pancreatic β cell that does not express one or both of somatostatin and glucagon. The claims of the Subject Application are reproduced hereunder:

> *"We Claim;*
> *1. A composition comprising a non-native pancreatic β cell, and one or more pharmaceutically acceptable carriers, additives, and/or diluents, wherein:*
> *(a) the non-native pancreatic β cell comprises one or more crystalline insulin granules;*
> *(b) the non-native pancreatic β cell expresses the following genes: INS, PDX1, NKX6-1, and ZNT8;*
> *(c) the non-native pancreatic β cell exhibits an in vitro glucose stimulated insulin secretion (GSIS) response to a first glucose challenge; and*
> *(d) the non-native pancreatic β cell does not express one or both of somatostatin and glucagon; and wherein said composition is in the form of an in vitro cell cluster.*
> *2. The composition as claimed in claim 1, wherein the non-native pancreatic β cell exhibits an in vitro glucose-stimulated insulin secretion response to a first glucose challenge, a second glucose challenge, and a third glucose challenge, when the first glucose challenge, the second glucose challenge and the third glucose challenge are applied sequentially.*
> *3. The composition as claimed in claim 1, wherein the non-native pancreatic β cell further expresses at least one gene selected from the group consisting of MAFA, PAX6, NEUROD1, GCK, SLC2A1, PCSK1, KCNJ11, ABCC8, SNAP25, RAB3A, GAD2, PTPRN,*

NKX2-2, and PAX4.

4. The composition as claimed in claim 1, wherein the non-native pancreatic β cell secretes insulin in response to a first glucose concentration compared to a second glucose concentration in a ratio of at least 1.1 wherein the first glucose concentration is higher than the second glucose concentration.

5. The composition as claimed in claim 1, wherein the non-native pancreatic β cell is monohormonal.

6. The composition as claimed in claim 1, wherein the insulin secreted by the nonnative pancreatic β cell is at least 0.5 μIU per 1000 cells per 30minute incubation when the non-native pancreatic β cell is exposed to at least 20mM of glucose.

7. The composition as claimed in claim 1, wherein insulin secretion from the nonnative pancreatic β cell is enhanced in response to an anti-diabetic agent.

8. The composition as claimed in claim 1, wherein the non-native pancreatic β cell exhibits cytokine-induced apoptosis in response to a cytokine.

9. The composition as claimed in claim 1, wherein the non-native pancreatic β cell has a gene expression profile that is different from the gene expression profile of a native β cell.

10. An isolated population of cells comprising one or more non-native pancreatic β cells as claimed in claim 1, wherein at least 10% of the cells in the population of cells are the non-native pancreatic β cells.

11. The population of cells as claimed in claim 10, further comprising insulin positive endocrine cells.

12. The population of cells as claimed in claim 10, wherein the population of cells comprises one of the following:

a. a C-peptide-negative/glucagon-positive cell;
b. a C-peptide -negative/somatostatin-positive cell;
c. a glucagon-positive/somatostatin-negative cell;
d. a glucagon-negative/somatostatin-positive cell; or
e. any combination thereof.

13. The population of cells as claimed in claim 10, wherein at least 3% of the population of cells are C-peptide –negative/glucagon-positive cells or glucagon positive/ somatostatin-negative cells.

14. An artificial islet comprising the population of cells as claimed in claim 10.

15. An artificial pancreas comprising the population of cells as claimed in claim 10.

12. The learned Counsel for the Appellant filed the following amended claims with the post-hearing Written Submissions to the learned Controller. The claims are reproduced hereunder:

> *"**We Claim,***
> *1. A non-native pancreatic β cell, wherein:*
> *(a) the non-native pancreatic β cell comprises one or more crystalline insulin granules;*
> *(b) the non-native pancreatic β cell expresses the following genes: INS, PDX1, NKX6-1, and ZNT8;*
> *(c) the non-native pancreatic β cell exhibits an in vitro glucose stimulated insulin secretion (GSIS) response to a first glucose challenge; and the non-native pancreatic β cell does not express one or both of somatostatin and glucagon.*
> *2. The non-native pancreatic β cell as claimed in claim 1, wherein the non-native pancreatic β cell exhibits an in vitro glucose-stimulated insulin secretion response to a first glucose challenge, a second glucose challenge, and a third glucose challenge, when the first glucose challenge, the second glucose challenge and the third glucose challenge are applied sequentially.*
> *3. The non-native pancreatic β cell as claimed in claim 1, wherein the non-native pancreatic β cell further expresses at least one gene selected from the group consisting of MAFA, PAX6, NEUROD1, GCK, SLC2A1, PCSK1, KCNJ11, ABCC8, SNAP25, RAB3A, GAD2, PTPRN, NKX2-2, and PAX4.*
> *4. The non-native pancreatic β cell as claimed in claim 1, wherein the non-native pancreatic β cell secretes insulin in response to a first glucose concentration compared to a second glucose concentration in a ratio of at least 1.1 wherein the first glucose concentration is higher than the second glucose concentration.*
> *5. The non-native pancreatic β cell as claimed in claim 1, wherein the non-native pancreatic β cell is monohormonal.*
> *6.The non-native pancreatic β cell as claimed in claim 1, wherein the insulin secreted by the non-native pancreatic β cell is at least 0.5 μIU per 1000 cells per 30 minute incubation when the non-native pancreatic β cell is exposed to at least 20mM of glucose.*
> *7. The non-native pancreatic β cell as claimed claim 1, wherein insulin secretion from the non-native pancreatic β cell is enhanced in response to an antidiabetic agent.*
> *8. The non-native pancreatic β cell as claimed in claim 1, wherein the non-native pancreatic β cell exhibits cytokine-induced apoptosis*

in response to a cytokine.
9. The non-native pancreatic β cell as claimed in claim 1, wherein the non-native pancreatic β cell has a gene expression profile that is different from the gene expression profile of a native β cell.
10. An isolated population of cells comprising one or more non-native pancreatic β cells as claimed in claim 1, wherein at least 10% of the cells in the population of cells are the non-native pancreatic β cells.
11. The population of cells as claimed in claim 10, further comprising insulin positive endocrine cells.
12. The population of cells as claimed in claim 10, wherein the population of cells comprises one of the following:
a. a C-peptide-negative/glucagon-positive cell;
b. a C-peptide -negative/somatostatin-positive cell;
c. a glucagon-positive/somatostatin-negative cell;
d. a glucagon-negative/somatostatin-positive cell; or
e. any combination thereof.
13. The population of cells as claimed in claim 10, wherein at least 3% of the population of cells are C-peptide –negative/glucagon-positive cells or glucagon positive/ somatostatin-negative cells.
14. An artificial islet comprising the population of cells as claimed in claim 10.
15. An artificial pancreas comprising the population of cells as claimed in claim 10."

13. A perusal of the Impugned Order reveals that the learned Controller has based the finding while considering the original claims. Although the Impugned Order has mentioned the amended claims placed on record through the post-hearing Written Submissions as "***Alternative set of Claims***", the same are not considered while passing the Impugned Order.

14. It is clear from the amended claims that they are not composition claims as evident from the comparison of original claim no. 1 and amended claim no. 1, which are reproduced hereunder:

Original claim no. 1	***Amended claim no. 1***
1. ***A composition comprising a non-native pancreatic β cell, and one or more pharmaceutically acceptable carriers, additives, and/or diluents, wherein:*** *(a) the non-native pancreatic P cell comprises one or more crystalline insulin granules; (b) the non-native pancreatic p cell expresses the following genes: INS, PDX 1, NKX6-1, and ZNT8; (c) the non-native pancreatic P cell exhibits an in vitro glucose stimulated insulin secretion (GSIS) response to a first glucose challenge; and (d) the non-native pancreatic p cell does not express one or both of somatostatin and glucagon; and wherein said composition is in the form of an in vitro cell cluster"*	*1.* ***A non-native pancreatic β cell, wherein:*** *(a) the non-native pancreatic β cell comprises one or more crystalline insulin granules; (b) the non-native pancreatic β cell expresses the following genes: INS, PDX1, NKX6-1, and ZNT8; (c) the non-native pancreatic β cell exhibits an in vitro glucose stimulated insulin secretion (GSIS) response to a first glucose challenge; and the non-native pancreatic β cell does not express one or both of somatostatin and glucagon.*

15. As the Impugned Order has only considered the original claims and not the amended claims filed along the post-hearing Written Submissions, it would be imperative to examine the impact of the amended claims on the Subject Application. The Impugned Order has, under Objection Nos. 1 and 5, considered the original claims and held that the technical disclosure is missing in the claimed composition and, therefore, the objections under Sections 10(4) and 10(5) of Act continued to subsist.

16. As regards the objections under Sections 3(j) and 3(e) of the Act, the Impugned Order again considers the original claims and it is concluded that the Complete Specification neither discloses a composition *per se*, nor does it disclose all the components or their amounts or synergy data. However, if

the amended claims are considered, they claim a non-native pancreatic β cell instead of the composition in the original claims. Therefore, the entire basis of the Impugned Order may undergo change if the amended claims are considered by the learned Controller.

17. In ***Jitendra Kohli v. The Controller of Patents***, Neutral Citation: 2022:DHC:1904, the Court held that not considering the amended claims is clearly a glaring error. The relevant paragraphs are reproduced hereunder:

> *"8. The Court has perused the entire order which clearly shows that the Assistant Controller has considered the invention to be a computer based realization of a conventional bidding process method of doing business. The Assistant Controller has come to the conclusion that the technical advance proposed in the invention is simply a method of doing business, even if it is a technically smarter way of doing business and has rejected the application under Section 3(k) of the Act. The amended claims have not been taken into consideration by the Assistant Controller at the time of deciding the fate of Appellant's application. This is clearly a glaring error.*
>
> *** *** ***
>
> *10. Under these circumstances, the impugned order is set aside. The matter shall be reconsidered by the office of Controller General of Patents, Designs, & Trade Marks (CGPDTM) afresh. A fresh order shall be passed after duly considering the amended claims on all counts including novelty, inventive step and patentability."*

18. Further, in ***Akebia Therapeutics INC v. The Controller of Patents and Designs***, CMA(PT)/64/2024 dated 20.03.2025, the Court held that the amended claims change the nature of the claims from method to composition claims and, therefore, it becomes crucial for the controller to address the same. The relevant paragraphs are reproduced hereunder:

> *"9. In effect, the respondent has rejected the claim substantially, if not entirely, on the ground that the appellant has amended the claim from a claim for a method of treating anaemia to a claim for a pharmaceutical composition which may be used for treating anaemia. As held in Allergan and concurred by me in an earlier decision in Commonwealth Scientific & Industrial Research*

Organization and Anr. v. The Assistant Controller of Patents & Designs 2023/MHC/4501, the rejection substantially or solely on such ground is not tenable. On comparing the original claims with the amended claims, I find that the scope of the claims remains the same, but the nature of the claims have changed from method to composition claims. Since objections were also raised on grounds of lack of inventive step and with reference to Sections 3(i) and 3(e), and those aspects were not discussed or determined in the impugned order, a remand is necessary.

10. Therefore, impugned order dated 26.11.2021 is set aside and the matter is remanded for re-consideration on the following terms:

(i) In order to preclude the possibility of pre determination, an officer other than the officer who issued the impugned order shall undertake re-consideration.

(ii) After providing a reasonable opportunity to the appellant, a reasoned decision shall be issued within a period of four months from the date of receipt of a copy of this order.

(iii) For the avoidance of doubt, it is made clear that no observation has been made on the merits of the patent application."

19. Consequently, amended claims that significantly alter the original claims transitioning from a composition to a non-native pancreatic β cell must be duly considered by the learned Controller independently without being influenced from prior conclusions regarding the original claims in the Impugned Order. Accordingly, the Impugned Order is hereby set aside, and the matter is remanded back to the learned Controller for fresh consideration of the Subject Application in view of the amended claims submitted along with post-hearing Written Submissions. This learned Controller shall pass a detailed order on the Subject Application after considering the amended Claims within six months from the date of communication of this Judgment after giving opportunity of hearing to the Appellant.

20. It is clarified that this Court has not considered the merits of the respective cases, and the Subject Application shall be decided in accordance

with law without being influenced by any observations made in this Judgement. Accordingly, the Appeal is disposed of with the aforesaid directions.

21. A copy of this Judgement be sent to the learned Controller General of Patents, Designs and Trademarks at the e-mail address llc-ipo@gov.in for the necessary compliance.

TEJAS KARIA, J

MARCH 28, 2026
'KC' / 'N'