(2020) 12 IPAB CK 0006

In the Intellectual Property Appellate Board

Case No : Original Application No. 9 Of 2020/PT/CHN

Kyoto University — APPELLANT

Vs

Assistant Controller Of Patents And Designs — RESPONDENT

Date of Decision : 21-12-2020

Acts Referred:
Indian Patents Act, 1970 — Section 2(1)(j), 3(d), 3(3(b), 3(3)(j), 3(i), 3(3)(i), 15, 57, 59, 117A

Citation : (2020) 12 IPAB CK 0006

Hon'ble Judges : Manmohan Singh, J;Dr. B.P. Singh, Technical Member

Bench : Division Bench

Advocate : Bharathi Viswanathan

Final Decision : Allowed

Judgement

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1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 03/01/2020, passed by the Respondent,",

being the Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, 1970, refusing to grant the Appellantsâ?? Indian",

patent application no. 1636/CHENP/2009.,

2. It is the case if the appellant that 2.1 During First Examination stage no objection regarding novelty and non-patentability under Section 3(d) in,

respect of the original claims were raised. Also the documents relied upon for inventive step were completely different.,

2.2 The objections regarding novelty and inventiveness in view of new documents and in view of Section 3(d) were raised for the first time in the,

hearing notice.,

2.3 The appellant further submits that despite the Appellantâ??s pleading to offer another opportunity in case of any outstanding objection, the",

Respondent has refused the application, on the new grounds raised for the first time only in the hearing notice.",

2.4 Further, the respondent has failed to provide any reasoning whatsoever in respect of the alleged ground for refusal.",

2.5 The impugned order is a non-speaking one, devoid of proper deliberation, coherent reasoning and justification to the stance adopted by the",

Respondent.,

2.6 Hence, the Appellants submit that natural justice has been denied to the appellant by the impugned decision.",

3. The Present Invention as explained by the appellant is as under:,

3.1 The present invention is based on the revolutionary finding that a small number of defined factors can reprogram a somatic cell nucleus to a less,

differentiated state. These factors are called ""nuclear reprogramming factors"". The present invention addresses and fulfills a significant need for",

providing a process for generating induced pluripotent stem cells by reprogramming differentiated somatic cells. Particularly, the present invention",

address the need to provide a process for generating safe induced pluripotent stem cells having no fear of tumorigenesis in the cells or tissues obtained,

by differentiation-inducing the induced pluripotent stem cells.,

3.2 It may be noted that one of the inventors, Prof. Yamanaka, has been awarded with the Nobel prize in Physiology and Medicine 2012, in",

recognition of his outstanding achievement in this field.,

3.3 The independent claims presented to the Respondent during the Hearing held on 24 October 2019 and filed at IPO on 06 November 2019 along,

with written submission are as below:,

3.1.1 Claim 1 is directed to A process for generating induced pluripotent stem cells from somatic cells, comprising the step of introducing the following",

five genes: Oct family gene, Klf family gene, Sox family gene, Lin28 gene, and L-Myc gene into somatic cells.",

3.1.2 Claim 6 is directed to A process for generating induced pluripotent stem cells from somatic cells, comprising the step of introducing a",

combination of the following two genes: Oct family gene and Sox family gene or a combination of the following two genes: Oct family gene and Klf,

family gene, and Lin28 gene and L-Myc gene, and at least one of genes selected from the following two genes: Sall1 and Sall4 into somatic cells.",

3.1.3 Claim 8 is directed to A process for generating induced pluripotent stem cells from somatic cells, comprising the step of introducing a",

combination of the following five genes: Oct family gene, Sox family gene, Klf family gene, Lin28 gene, and L-Myc gene, and at least one kind of",

genes selected from the following two genes: Sall1 and Sall4 into somatic cells.,

3.1.4 Claim 12 is directed to A process for generating induced pluripotent stem cells from somatic cells, comprising the step of introducing the",

following six genes: Oct family gene, Klf family gene, Sox family gene, L-Myc gene, Lin28 and Nanog into somatic cells.",

3.4 The objective technical problem addressed by the present invention is that of provision of means for production of iPS cells with improved,

efficiency.,

4. The learned counsel of the appellant submitted the distinguishing features of the present invention over cited prior art D1: CA2632142A1 as follows:,

4.1 D1: CA2632142A1 belongs to the patent family of WO2007/069666, which has been relied upon in Background of the present application as",

Patent Publication 1.,

4.2 D1 describes preparation of iPS cells that are ES-like cells using nuclear reprogramming factors such as Oct3/4, Sox2, Klf4, and c-Myc. D1",

discusses using alternate members of the Oct, Myc and Klf4 families, in particular c-Myc, for inducing iPS. D1 does not teach the use of Lin28 to",

induce iPS. Further, D1 does not provide any pointers that Sall1 or Sall4 in combination with Lin28 and the other factors would result in effective and",

safe production of iPS cells.,

4.3 Thus D1 does not disclose generating iPS using a combination of reprogramming genes which comprises an Oct family gene, a Sox family gene, a",

Klf family gene, Lin28 and L- Myc.",

4.4 Accordingly, the claimed process is novel over the disclosure of D1.",

4.5 Further, D1 does not provide any pointers that the use of a combination of L-Myc and Lin28 would improve iPS cell production efficiencies",

compared to the use of c-Myc and Lin28.,

4.6 In fact, regarding L-Myc, Example 6 of D1 states ""Further, each of N-Myc

and L-Myc (each wild type) was almost the same as c-Myc in both of",

the number of G418-resistant colonies formed and iPS cell establishment efficiency.""",

4.7 Moreover, in working examples of D1, C-Myc or its variant is consistently used, except example 6. It is understood that that N-Myc and L-Myc",

are just comparisons or references.,

4.8 Thus, D1 teaches that L-Myc is almost the same a c-myc and hence a skilled person would have had no motivation, let alone any reasonable",

expectation of success for using the factor combination of the present claim in order to provide means for production of iPS cells with improved,

efficiency. Hence, D1 can only be construed to teach away from the present invention.",

4.9 On the other hand, as demonstrated in Table 14, the use of Lin28 in combination with L-myc instead of c-Myc resulted in approximately a 3.7",

times higher number of iPS colonies (366 Vs 98 hiPS colonies). Thus, the use of L-Myc is critical to successful generation of safe induced pluripotent",

stem cells.,

4.10 Additionally, Table 14 also demonstrates that use of Lin28 in combination with L-Myc improvise the efficiency of iPS cell production compared to",

the respective use of c-Myc.,

4.11 Thus use of L-myc, as employed by the claimed process is a non-obvious departure from use of c-Myc in the prior art.",

4.12 In this regard, it may be noted that c-Myc is NOT ideal for generation of iPS because c-Myc is a cancer associated transcription factor, which",

when introduced to somatic cells for reprogramming along with other factors gives rise to the possibility that the cells or tissue differentiation-induced,

from the obtained iPS have tumorigenicity cannot be denied.,

4.13 Therefore, the presently claimed invention embodies a significant technical advancement over the results achieved in prior art which could not be",

realised heretofore the priority date of the present invention.,

5. The learned counsel of the appellant has submitted distinguishing features of the present invention over cited prior art D2: Golan- Mashiach M et al;,

Design principle of gene expression used by human stem cells: implication for pluripotency""; Federation of American Societies for Experimental",

Biology; Vol19(1); Jan 2005.,

5.1 D2 merely analyses the expression profile of human ESC line 9.2 and compares it to the expression profiles of adult tissuesâ?"differentiated cells,

(blood and keratinocytes) as well as their progenitor cells.,

5.2 Further, D2 only hypothesizes a strategy of expressing genes that represent various differentiation pathways. It lists only 9 genes as candidate",

ESC signature genes. It may be noted that Myc family in itself, let alone L_myc, is not listed as one of the signature gene. Also, Lin28 is simply listed",

in parallel with other genes. Therefore, a skilled person in the art reading D2 is not motivated to particularly select Lin28 from other genes.",

Furthermore, D2 does not provide any working examples and thus only merely indicates a selection of few genes for continuous expression upon",

differentiation to a particular target.,

5.3 For the above reasons, it is humbly submitted that the invention claimed in the present application is not obvious over D1 & D2.",

5.4 The Respondent has failed to analyze the teaching of D1 and D2 and provide the reasoning how a person skilled in the art can arrive at the,

claimed invention in an obvious manner.,

6. The learned counsel of the appellant has submitted his arguments in respect of non-patentability of claims under section 3(d) of the Patents Act,",

1970 as follows:,

6.1 The restraints of Section 3(d) of the Indian Patents Act is clearly and specifically targeted to a â??processâ? directed to mere use of a known,

process which does not results in a new product or employ at least one new reactant.,

6.2 For reasons elaborated above, the claimed process is novel.",

6.3 Also Table 14 provides a direct comparison between the use of Sox2, Oct4, Klf4, Lin28 and either c-Myc or L-Myc. The table clearly shows that",

the use of Lin28 in combination with L- myc instead of c-Myc resulted in approximately a 3.7 times higher number of iPS colonies.,

6.4 Hence, it is submitted that the claimed â??processâ?? cannot be construed as a â??known processâ?? under Section 3(d).",

7. The appellant also submitted the details of corresponding foreign patent applications:,

Country Application No. Status Patent No. Date of Grant,

Australia 2008297024 Granted 2008297024 11/12/2014,

Canada 2660123 Granted 2660123 09/05/2017,

China 200880000834,

.5 Granted 20088000083,

4.5 12/03/2014,

Europe 08832782.0 In order for grant,

Japan 2009-508036 Granted 5349294 30/08/2013,

Korea 2009-7006480 Granted 1564044 22/10/2015,

Singapore 2009018037 Granted 153139 15/06/2011,

7.1 In this regard, the Appellants wish to bring to the notice of the Honâ??ble Board that claims on record are similar in scope with claims found in",

order for grant in corresponding European Application No: 08832782.0 and also been allowed as JP5349294B2. The have attached herewith a copy of,

the claims found to be in order for grant, the decision to allow the application in Europe and machine translated claims of JP5349294B2.",

7.2 It may be noted that while EPO has relied upon D1: WO2007/069666/D1a: EP 1970446, the JPO has relied upon D1: WO2007/069666, which",

belong to the same family as D1: CA 2632142, that has been relied upon by the Respondent in the hearing notice.",

Document,genes introduced

D1,"Oct family, Klf family, and Sox family

D2,"Oct4, Lin28, TDGF1, LeftB, and Sox2

The present invention,"Oct family, Klf family, Sox family, L-Myc,

and Lin28

obvious for a person skilled in art to generate induced pluripotent cells from somatic cell by introducing Oct family gene Sox family gene and k1f,

family gene into somatic cells. Therefore claims 1-19 of the instant application lack inventive step under section 2(1)(j) of The Patents Act, 1970.",

9.1.2 Claim(s) (1-19) are statutorily non-patentable under the provision of clause (3(b), 3(j), 3(i)) of Section 3 for the following reasons:",

9.1.2.1 The claims 1-19 relate to ""method of generating induced pluripotent cells from somatic cell by introducing Oct family gene Sox family gene and",

k1f family gene into somatic cells"". The said claims fall within the scope of section 3(b) of The Patents Act, 1970 as the said claims are directed",

towards an invention the primary or intended use or commercial exploitaion of which could be contrary public order or morality.,

9.1.2.2 Claims 1-19 recites ""method of generating induced pluripotent cells from somatic cell by introducing Oct family gene Sox family gene and k1f",

family gene into somatic cells"". Claims 1-19 fall within the scope of section 3(j) of The Patents Act, 1970, as the said claims are directed towards",

essential biological processes for the production of plants/animals; and use of animal in whole or any pary thereof.,

9.1.2.3 The claims 1-16 of the instant application relate to ""method of generating induced pluripotent cells from somatic cell by introducing Oct family",

gene Sox family gene and k1f family gene into somatic cells"", therefore fall within the scope of section 3(i) of The Patents act, 1970.",

9.1.3 As per the requirement u/s. 10(4) (ii) (D) you have to disclose the source and geographical origin of ALL THE BIOLOGICAL MATERIALS,

used in the invention (even if not from India). The same may be provided in a tabular format. (Source means the exact source from where the,

applicants procured the biological material(s) and Geographical origin means the actual geographical origin of the biological material(s). The source,

and geographical origin can be same or different.),

9.1.4 The subject matter of claims 1-19 recite terms such as ""induced pluripotent cell, somatic cell, oct family gene, sox family gene and klf family",

gene, tissue, organ, body fluis or individual, human somatic cell etc."" said terms are very broad and do not define the scope of invention. Hence these",

terms shall be clearly specified.,

10. The hearing notice issued on 02/09/2019 contained mainly the following objections:,

10.1 In view of applicant's submission dated 20/08/2019, claims 1- 13 of the instant application lack novelty in view of the document cited below D1:",

CA2632142A1; June 21, 2007: Discloses nuclear reprogramming factor for a somatic cell, which comprises a gene product of each of the following",

three kinds of genes: an Oct family gene, a Klf family gene, and a Myc family gene, wherein said factor further comprises a gene product or gene",

products of one or more kinds of genes selected from the group consisting of

Fbx15, Nanog, ERas, ECAT15-2, Tcl1, and beta.- catenin. D1 also",

discloses method for preparing an induced pluripotent stem cell by nuclear reprogramming of a somatic cell, which comprises a step of contacting the",

said nuclear reprogramming factor with the somatic cell. D1 further discloses method for improving differentiation ability and/or growth ability of a,

cell, which comprises the step of contacting the nuclear reprogramming factor with a somatic cell, wherein the cell is a human cell.",

All the essential technical features of claims 1-13 have been disclosed in D1, hence claims 1-19 of the instant application lack novelty in view of D1.",

Inventive step: Claims 1-19 of the instant application lack inventive step in view of the document cited below,

D1: CA2632142A1; June 21, 2007",

D2: Golan-Mashiach M et al; ""Design principle of gene expression used by human stem cells: implication for pluripotency""; Federation of American",

Societies for Experimental Biology; Vol19(1); Jan 2005: Discloses that genes that were analyzed in various ESC systems and shown to be essential,

for pluripotency and self-renewal include OCT4, LIN28, TDGF1, LeftB, SOX2, and others.",

D1 discloses process for generating induced pluripotent stem cells from somatic cells by a method, comprising the step of introducing the following",

three genes: Oct family gene, Klf family gene, and Sox family gene into somatic cells. D2 discloses that LIN28 gene is essential for the pluripotency",

and selfrenewal. Therefore in view of disclosure of D1 and D2, it is obvious for a person skilled in art to generate induced pluripotent stem cells from",

somatic cells, comprising the step of introducing the following six genes: Oct family gene, Klf family gene, Sox family gene, Myc family gene, Lin28",

and Nanog into somatic cells. Therefore claims 1-19 of the instant application lack inventive step under section 2(1)(j) of The Patents Act, 1970.",

Non-Patentability u/s 3 Claims 1-19 of the instant application relate to ""process for generating induced pluripotent stem cells from somatic cells,",

comprising the step of introducing the following three genes: Oct family gene, Klf family gene, and Sox family gene into somatic cells"". The document",

D1 already discloses method for preparing an induced pluripotent stem cell by nuclear reprogramming of a somatic cell which comprises a gene,

product of each of the following three kinds of genes: an Oct family gene, a Klf

family gene, and a Myc family gene. Therefore the claims 1-19 of the",

instant application fall within the scope of section 3(d) of The Patents Act, 1970 as the said claims are directed towards mere use of a known",

process/new for a known product.,

11. A look on the order of the respondent reveals that he has just narrated the objections of hearing notice and held in operating portion of his order as:,

â??The post-hearing proposed amendment is not allowed under section 57 read with section 59 of the Patent Act.,

After carefully reading through the FER response, while hearing oral and post-hearing written submissions and in light of the specification and",

amended claims, it is understood that the requirements of clarity and conciseness and along with formal requirements stand complied/waived off.",

The oral & written submission placed before me could not justify the objections u/s 2(1)(j) & 2(1)(ja), and 3(d).",

Therefore, in view of the above discussion, this application is refused patent u/s 15 of â??The Patent Act 1970â? for want of compliance",

requirements u/s 2(1)(j) & 2(1)(ja), and 3(d). The application stands disposed off.â??",

12. The order of the respondent is a classic example of non-speaking order. Issuance of such orders is against the principal of natural justice and at,

this stage, we only express our displeasure on such orders. We expect that the respondent will be very cautious herein after and will be issuing",

speaking order(s) in all future cases.,

13. We have reviewed the post-hearing amendments of claims, submitted by the applicants/appellant and found that they have introduced the features",

of Lin28 in combination with L-Myc into each claim which appears an essential amendment to bring out the inventive feature(s) not only in the,

principal claim but in all the subsidiary claims as well. Claims 10 and 11 were consequentially amended or deleted accordingly. Further, claims 17-19",

which were relating to either to â??product by processâ?? or â??productâ?? claims have been deleted; which were otherwise not relating to,

patentable subject matter. The amendments bring clarity and definitiveness to the claims and are restricting the scope of the claims. Further, the",

amendments are incorporating the actual facts and based on the matter disclosed in the specification prior to the amendment. Hence the amended,

claims 1-15 are well within the scope of section 57 read with section 59 of the Patents Act, 1970 and we allow such amendments.",

14. We have also analyzed the cited documents D1 and D2 and are inclined to accept the arguments of the appellant that the invention is,

â??novelâ?? and â??inventiveâ?? with respect to both the citations. The lone citation for novelty i.e. CA2632142A1 belongs to same family of ISA,

citation WO2007069666 a common citation in the other entire jurisdictions, where the patent stands granted.",

15. Letâ??s have a look on provisions of section 3(d) (d) the mere discovery of a new form of a known substance which does not result in the,

enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere,

use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.",

Explanation.â?"For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers,",

complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in",

properties with regard to efficacy; [Emphasis added],

16. The application of section 3(d) appears totally misplaced as Section 3(d) is applicable only if the claimed process is a mere use of a known,

process. In the instant case, the claimed process is held to be novel in its entirety and therefore falls outside the purview of â??knownâ? process and",

hence does not attract the provision of section 3(d) of the Patents Act, 1970.",

17. We, therefore, set aside the impugned order dated 03/01/2020 issued by the respondent, and direct the respondent to grant the patent within 3",

weeks from the issuance of this order.,

18. Keeping in view the above facts and circumstances, the instant appeal is allowed. No cost.",

