IN THE HIGH COURT AT CALCUTTA
INTELLECTUAL PROPERTY RIGHTS DIVISION
ORIGINAL SIDE

BEFORE:
The Hon'ble Justice Ravi Krishan Kapur

IPDPTA 56 OF 2023

IN THE MATTER OF

BTS Research International Pty Ltd (SR/55/2020/PT/KOL)
Vs.
The Controller General of Patents & Designs, Mumbai & Ors.

For the petitioner : Mr. Mr. S. Majumdar, Adv.
Mr. ParitoshSinha, Adv.
Mr. K.K. Pandey, Adv.
Ms. Mitul Dasgupta, Adv.
Ms. Amrita Majumdar, Adv.
Mr. SoumyaSen, Adv.
Mr. T. Das, Adv.

For the respondents : Mr. Swatarup Banerjee, Adv.
Mr. Sukanta Ghosh, Adv.
Mr. Sariful Haque, Adv.

Judgment on : 03.04.2025

RAVI KRISHAN KAPUR, J.:

1. This is an appeal under section 117 of the Patents Act, 1970 against an order dated 16 June 2020 passed in Patent Application no.0041/KOLMP/2012.

2. The title of the subject invention is "Method of generating hybrid/chimeric cells and uses thereof". The invention relates to a tri-hybrid cell and the method for preparing the same. It is contended that a tri-hybrid cell is produced by an artificial process of fusion of three somatic cells of which at least two are of different types and can be cells of humans and a mouse. Such a hybrid cell is formed by using genetic engineering techniques and is not an organism or part of a plant and animal nor does it involve any

essentially biological process for production or propagation of plants and animals. In brief, the formation of a trihybrid cell essentially requires human intervention so as to prepare it artificially and the same is not produced by an essentially biological process *for* production or propagation of plants and animals.

3. By the impugned order, the subject application has been rejected on the ground that the same falls within the scope section 3(j) of the Act and is not patentable. The impugned order proceeds on the basis that because the cells for hybridization are taken from certain cell line (human or non-human cell) and have attributes of naturally occurring parent cells, the same falls within the definition of section 3(j) of the Act. The impugned order records that the resultant hybrid cell is a structural and functional unit of that organism from which cells are taken and which fall under the first part of section 3(j) of the Act which excludes plants and animals in whole or in part from the category of inventions. Thus, it is concluded that the method of preparation tri-hybrid cells from a stem cell is a biological process and such tri-hybrid cells cannot be said to be artificially produced. It has also been held that the subject invention falls under section 3(c) of the Act i.e. "discovery of any living thing or non-living substance occurring in nature".

4. On behalf of the appellant it is contended that, the impugned order is erroneous and based on a misinterpretation of the Act. In addition, though after the filing of a response to the First Examination Report (FER), the application was re-examined, there was no Second Examination Report (SER) which the law necessarily mandates. The prior arts cited in the

examination report had also been cited in the European proceedings and also formed part of the European Search Report. This fact has also been ignored in the impugned order though the subject patent had been granted in other jurisdictions. It is also contended that section 3(j) of the Act is inapplicable and of no relevance. In such circumstances, the impugned order is contrary to law and is liable to be set aside.

5. On behalf of the respondents, it is submitted that there is no infirmity with the impugned order. It is submitted that myeloid progenitor cell and lymphoid progenitor cell appearing in the subject claim are stem cells and capable of developing into an organism. In any event, the applicability of section 3(j) of the Act has been adequately reasoned and elaborately explained. In support of such contention, the respondents rely on the decision in *Nuziveedu Seeds Ltd. & Ors. vs. Monsanto Technology LLC & Ors. 2018 SCC OnLine Del 8326.*

6. At the outset, it appears that, though pursuant to objections filed to the First Examination Report (FER) the subject application was re-examined, no Second Examination Report (SER) was issued in terms of the mandate of section 13(3) of the Act. In *Oyster Point Pharma Inc vs. The Controller of Patents and Designs Anr. MANU/WB/1544/2023,* it has been held as follows:

> *"14. There is also no merit in the contention that the Second Examination Report (SER) was not necessary to be issued and that non-issuance could not prejudice the rights of the appellant. The statutory mandate of section 13(3) must be followed regardless of the consequences and the ultimate result thereof. Hence, the Assistant Controller also erred in not issuing the SER in compliance with section 13(3) of the Act."*

7. Significantly, though the respondent while issuing the FER had cited prior art documents. Each of the prior arts had been examined and formed part of

the Report filed by the European Patent Office. This fact would also be evident from the European Search Report. Despite the five prior art documents being cited as prior arts in the European proceedings, the respondent authorities failed to even consider the outcome of the European proceedings or refer to the same which had granted the subject patent. On the contrary, the respondents proceeded mechanically and rejected the subject invention without giving any weightage whatsoever to the European proceedings. It is true that the findings of the European Patent Office are not binding on the respondent authorities. Nevertheless, in view of the fact that all the similar prior arts had been cited and taken into consideration and all the records were before the authority, the same at least ought to have been considered before passing the impugned order.

8. Section 3(j) of the Act deals with non-patentable subject matters i.e. biotechnology and agriculture and reads as follows:

> *'3. What are not inventions*
>
> *The following are not inventions within the meaning of this Act,—*
>
> *(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;*
>
> *(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;*
>
> *(c) 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;*
>
> *(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.—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;

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

(g)..(omitted)

(h) a method of agriculture or horticulture;

(i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(k) a mathematical or business method or a computer programme per se or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.'

9. The Chapter has the Heading "Inventions Not Patentable" and section 3 has the marginal heading "What are not inventions. "As suggested by the

Chapter heading and the marginal heading of section 3, and as may be seen on a perusal of the same, it puts at one place provisions of two different kinds: one that declares that certain things shall not be deemed to be "inventions" [for instance clauses (d) & (e)]; and the other that provides that, though resulting from invention, something may yet not be granted patent for other considerations. (for instance clause (b) [*Novartis AG v. Union of India, (2013) 6 SCC 1*]

10. Section 3(j) was introduced by way of the Patents (Amendment) Act, 2002. The final provision is very similar to what was in the original Bill, barring a change recommended by the Joint Parliamentary Committee. The *Statement of Objects and Reasons* of the 2002 Amendment express the Parliamentary intent that the 2002 Amendment was, in general, intended to bring India into compliance with The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, and that section 3 was amended to exclude items permitted to be excluded under the TRIPS Agreement. The relevant provision under Article 27.3 of the TRIPS Agreement is set out below:

> *3. Members may also exclude from patentability:*
> *…*
> *(b) plants and animals other than micro-organism, and essentially biological processes for the production of plants or animals other than non-biological and microbiological process. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreements.'*

11. In the TRIPS provision, member countries were permitted to exclude plants, animals, and essentially biological processes from patent protection.

However, the TRIPS provision does not allow members to exclude microorganisms and non-biological and microbiological processes from patent protection. In this context, the Indian provision differs from the TRIPS provision in two critical ways:

(i) Over and above plants and animals, 'parts thereof are also declared inherently unpatentable in India; and.

(ii) No reference is made to the patent eligibility of 'non-biological and microbiological processes'.

12. Article 53(b) of the European Patent Commission which came into force in 1978 is as follows:

> *'Article 53 Exception to patentability*
> *…*
> *(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological process or the products thereof.'*

13. The first category of the cases which are excluded from protection comprise of those things which qualify as "animal varieties". The second category of the matter excluded from protection are "plant varieties". The third type of subject matter excluded from protection are inventions which are regarded as "essentially biological process for the production or propagation of plants and animals". It is important to note that the exclusion only applies where an essentially biological process is *for* the production or propagation of animals and plants. Accordingly, the exclusion will not apply if the process results in the death or destruction of animals or plants. It would also not apply where the invention merely produces information which is used to manage plants or animals. The section excludes essentially biological

processes or the production of plants and animals and not plants and animal varieties. As such, the section is not limited to the process for the production of plants and animal varieties but extends to the more abstract and open categories of "plants" and "animals".

14. A process is *"essentially biological"* if it consists entirely of natural phenomena such as of crossing or the like. The crucial question is how much of human intervention is necessary for a process which involves biological steps not to be classified as an *essentially biological process*? This can only be judged on the basis of the *essence* of the invention after taking into account the totality of human intervention and its impact on the result achieved *[Plant Bioscience/Broccoli, T 83/05 (2007) OJ EPO 644; G 2/07 (2012) OJ EPO 130 (EBA); Plant Bioscience/Broccoli II, T 83/05 (2014) OJ EPO A39; G 2/13 (2016) OJ EPO A28 (EBA)]*. Hence, while each step of an invention might be characterized as biological, the arrangement of steps *as a whole* should also represent an essential modification of a known biological process. In order to fall within the category of *"essentially biological"*, what requires to be ascertained is the extent to which a process should be non-biological before it loses the status of *"essentially biological"*. The overall degree of *human intervention* in the process has to be taken into consideration. As such, the totality of human intervention and its impact or the results achieved is what is required to be determined. Thus, an invention has to be judged as a *whole*. *(Sakata Seed Corporation vs. The Controller of Patents and Design, Order dated 19.7.2024 in CMA (PT) No.30/2023, Madras High Court, Speaking Roses International Inc. vs Controller-General of Patents*

& Ors MANU/MH/0194/2007 and Monsanto Technology LLC vs The Controller of Patents & Designs & Anr. 2013 SCC Online IPAB 106).

15. In someways, the question can also be answered by focusing on the role played of the *technical step* in the breeding of the plant or animal. There are a myraid of situations which may arise, including the process by which a gene or trait is inserted in a plant by genetic engineering which appears to be potentially patentable. In other words, to be excluded from the mischief of section 3(j) there has to be a *technical step* or *human intervention* which by *itself* introduces or modifies a trait in the genome *[State of Israel/Tomatoes II, T 1242/06 (2013) OJ EPO 42]*. Thus, given that genetic manipulation is a technical process, a genetically modified plant or animal, not being an essentially biological process, would fall outside the mischief of section 3(j) of the Act. As such, the exclusion is to be narrowly and strictly construed only limited to the scope of the section (*Terrell on the Law of Patents, 19th Edition, paras 2-142 to 2-151*).

16. The impugned order does not deal with how the subject invention is by nature an essentially biological process *for* propagation or production of any plant or animal. The contention of the appellant that the subject invention was not produced from an essentially biological process but rather through advanced genetic engineering techniques where three somatic cells are fused of at least two are of different types which could be cells of humans or of a mouse has not been considered in the impugned order. There is no reasoning in the impugned order as to why a hybrid cell is considered to be a part of the human/animal body. The impugned order does not also deal with the artificial process involved in the subject invention. There is a serious flaw

in the impugned order inasmuch as the subject invention including specifications and descriptions have neither been discussed nor the specification details of hybridization enumerated in the invention been adverted to. The pre-conception with which the Controller has proceeded with in passing the impugned order is evident from the fact that despite amendments being carried out by the appellant, the impugned order proceeds on the basis as if the subject invention deals with stem cells alone. The impugned order also ignores that trihybrid cells being synthetic and not naturally occurring do not fit into the description of "plants" or "animals" as contemplated under the sub-section. This also does not reflect a correct and proper understanding of the invention. The impugned order fails to deal with the basic contention that the tri-hybrid cell is by nature not an essentially biological process *for* propagation or production of any plant or animal. In view of the above, the conclusion that the subject invention is prohibited under section 3(j) of the Act is unsubstantiated and is based on a fundamental misinterpretation of the section. Similarly, the conclusion of applicability under section 3(c) of the Act is without basis and ignores the technical intervention or human step in the subject application. The section operates independently and declares naturally occurring living and non-living things as inherently unpatentable. [*ImClone LLC vs. Assistant Controller of Patents & Designs, Government of India MANU/TN/1032/2024 (Madras)]*. To this extent, the impugned order does not deal and ignores the role of artificial and human intervention in the subject invention.

17. The decision cited in *Monsanto Technology LLC (Supra)* is also distinguishable and inapposite. The said decision dealt with seeds.

Monsanto has specifically claimed a manmade DNA construct which did not exist in nature but by virtue of such DNA being inserted into plants, the same could form a trait of insect tolerance and continue into future generations. The extent of human intervention as enumerated in the subject invention is of a different extent and the two cannot be equated.

18. For the above reasons, the impugned order is unsustainable and set aside. The matter is remanded to the Controller for adjudication afresh. In view of the pre-determined approach of the Hearing Officer in passing the impugned order it would be appropriate that the matter be heard by a different Hearing Officer. Liberty is granted to the appellant to make amendments and to rely upon additional documents, if any, in accordance with law. The Hearing Officer is requested to dispose of the subject application within a period of 12 weeks from the date of communication of this order. It is made clear that there has been no final adjudication on the merits of the case and all issues are left open to be decided afresh and in accordance with law.

19. To the above extent, IPDPTA 56 of 2023 stands allowed.

(Ravi Krishan Kapur, J.)