IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **26.09.2024**

CORAM:

THE HON'BLE **MR. JUSTICE SENTHILKUMAR RAMAMOORTHY**

(T) CMA(PT).No.200 of 2023

[OA/SR.118/2020/PT/CHN]

KYMAB LIMITED,
Meditrina (B260), Babraham Research Campus,
Cambridge, Cambridgeshire CB22 3AT,
United Kingdom. ... Appellant

Vs.

The Assistant Controller of Patents & Designs,
The Patent Office,
IPR Building, SIDCO Plot,
GST Road, Guindy,
Chennai 600 032. ... Respondent

PRAYER : This Transfer Civil Miscellaneous Appeal (Patents) filed under Section 117-A of the Patents Act, 1970 and the Patent Rules, 2003, (i) to allow the present appeal and set aside/quash the impugned order dated May 29, 2020 passed by the respondent in Indian Patent Application No.10716/CHENP/2012; (ii) allow said Indian Patent Application No.10716/CHENP/2012 and direct

grant of patent in respect thereof.

For Appellant : Mr.Shatadal Ghosh
for Mr.K.Muthu Selvam

For Respondent : Mr.S.Janarthanam, SPC
Mr.VG.Saravana Ram Prasad, Controller

JUDGMENT

Background

This appeal is directed against an order dated 29.05.2020 by which Indian Patent Application No.10716/CHENP/2012 was rejected. The appellant filed the above mentioned application for grant of patent in respect of an invention titled "ANIMAL MODELS AND THERAPEUTIC MOLECULES". Such application was derived from the PCT application bearing PCT/GB2011/050019. Consequently, it was filed with the 103 claims that were submitted with the PCT application. Upon a request from the appellant, the First Examination Report (FER) dated 14.05.2018 was issued. In the FER, objections were raised on grounds of novelty, inventive step and patent-ineligibility under Section 3(e), 3(j) and 3(d) of the Patents Act, 1970 (the Patents Act). These objections were in respect of specific claims from and out of

the original claims. Objections on other grounds such as sufficiency of disclosure, clarity & conciseness and definitiveness were also raised. The appellant responded to the FER on 12.02.2019. Such reply dealt with each objection raised in the FER. The appellant also deleted several claims and submitted amended claims 1 to 7 in response. This was followed by hearing notice dated 19.12.2019. In such hearing notice, objections were raised under Section 10(4), Section 59, Section 3(i) and Section 2(1)(ja). The appellant responded to the hearing notice on 06.03.2020. By this reply, each objection was dealt with and amended claims 1-6 (the current claims) were submitted.

2. The order impugned herein was issued in these facts and circumstances. Such order rejects the patent application on the ground that the claims are patent ineligible under Section 3(i) of the Patents Act.

Counsel and their contentions

3. Oral arguments on behalf of the appellant were advanced by Mr.Shatadal Ghosh, learned counsel, and on behalf of the respondent by Mr.S.Janarthanam, learned SPC, assisted by Mr.VG.Saravana Ram Prasad, learned Assistant Controller.

4. Learned counsel for the appellant invited my attention to the complete specification. With reference to the background of the invention, he pointed out that the claimed invention provides, *inter alia*, a process for the generation in non-human mammals of antibodies that comprise a human immunoglobulin variable region and further provides non-human animal models for the generation of such antibodies. In this connection, he referred to and relied upon the recitals in internal pages 28 and 29 of the complete specification (pages 53 & 54 of the paper book). After taking me through the relevant documents pertaining to the prosecution of the patent, including the manner in which the appellant dealt with each objection, learned counsel focused on the impugned order. After submitting that such order concludes that

the patent application is liable to be rejected under Section 3(i), learned counsel contended that the claimed invention does not fall within the scope of Section 3(i), as applicable to the treatment of animals. In support of this contention, learned counsel relies upon the judgment dated 12.10.2023 of this Court in *The Chinese University of Hong Kong and another v. The Assistant Controller of Patents & Designs, 2023:MHC:4617 (The Chinese University of Hong Kong),* particularly paragraph 21 thereof. By also relying on the Guidelines for Examination of Biotechnology Applications for Patents (the Biotechnology Applications' Guidelines) and the examples provided therein, he contended that the claimed invention is not a method of treatment of animals for the purpose of rendering such animals free of disease or to increase their economic value or that of their products. Hence, learned counsel contends that the impugned order cannot be sustained. As a corollary, he submits in conclusion that the application should be directed to proceed to grant.

5. In response to these contentions, it is submitted on behalf

of the respondent that the claimed invention is not in respect of specific antibodies. Instead, it is submitted that it is merely in respect of a method of administering antigens in transgenic mice. Consequently, it is contended that it qualifies as a method of treatment of animals, which is patent ineligible under Section 3(i). As regards objections raised earlier on grounds such as lack of novelty, inventive step and sufficiency of disclosure, it is submitted that the appellant amended its claims by deleting the objectionable claims.

Discussion, analysis and conclusion

6. Since the patent application was eventually rejected only with reference to Section 3(i), the question that arises for consideration is whether the claimed invention is patent ineligible under the said provision. In order to determine this issue, it is necessary to first set out independent claim 1, which is as under:

> *"1. A method for producing an antibody or antibody heavy or light chain specific to a desired antigen, the method comprising immunizing a*

non-human mammal with the desired antigen and:

(i) recovering the antibody or antibody chain; or

(ii) recovering a cell producing the antibody or heavy or light chain; or

(iii) providing: a nucleic acid encoding the antibody, or part thereof; or sequence information from which a nucleic acid encoding the antibody, or part thereof, can be expressed to allow the antibody to be produced;

wherein the non-human mammal genome comprises:

(a) a plurality of human IgH V regions, one or more human D regions and one or more human J regions upstream of the constant region of the host non-human mammal;

such that the non-human mammal is able to produce a repertoire of chimaeric antibodies or heavy antibody chains having a non-human mammal constant region and a human variable region, wherein the non-human mammal is made by a method comprising:

i. insertion of DNA forming an initiation cassette into the genome of a cell;

ii. insertion of a first DNA fragment into

the insertion site, the first DNA fragment comprising a first portion of a human VDJ DNA region and a first vector portion containing a first selectable marker or generating a selectable marker upon insertion;

iii. optionally removal of part of the vector DNA;

iv. insertion of a second DNA fragment into the vector portion of the first DNA fragment, the second DNA fragment containing a second portion of human VDJ DNA and a second vector portion, the second vector portion containing a second selectable marker, or generating a second selectable marker upon insertion;

v. removal of any vector DNA to allow the first and second human DNA fragments to form a contiguous sequence; and

vi. iteration of the steps of insertion of a part of the human VDJ DNA and vector DNA removal, as necessary, to produce a cell with all of the human VDJ region sufficient to be capable of generating a chimaeric antibody in conjunction with a host constant region

and wherein the non-human mammal genome

optionally comprises

(b) one or more human Ig light chain kappa V regions and one or more human Ig light chain kappa J regions upstream of the host non-human mammal kappa constant region and/or one or more human Ig light chain lambda V regions and one or more human Ig light chain lambda J regions upstream of the host non-human mammal lambda constant region; respectively,

wherein the non-human mammal is made by a method comprising

i. insertion of DNA forming an initiation cassette into the genome of a cell;

ii. insertion of a first DNA fragment into the insertion site, the first DNA fragment comprising a first portion of a human VJ DNA region and a first vector portion containing a first selectable marker or generating a selectable marker upon insertion;

iii. optionally removal of part of the vector DNA;

iv. insertion of a second DNA fragment

into the vector portion of the first DNA fragment, the second DNA fragment containing a second portion of human VJ DNA and a second vector portion, the second vector portion containing a second selectable marker, or generating a second selectable marker upon insertion;

v. removal of any vector DNA to allow the first and second human DNA fragments to form a contiguous sequence; and

vi. iteration of the steps of insertion of a part of the human VJ DNA and vector DNA removal, as necessary, to produce a cell with all of the human VJ region sufficient to be capable of generating a chimaeric antibody in conjunction with a host constant region."

7. The operative portion of the impugned order rejecting the monopoly claims of the appellant, including the above extracted independent claim 1, is as under:

"2. The objections of the said hearing notice were discussed during the hearing. Regarding objection to amended claims 1-6, applicant has made submission which was found not persuasive in view of following observations.

The present invention pertains to a method for producing an antibody or antibody heavy or light chain specific to a desired antigen that essentially involves the treatment of immunizing a non-human mammal i.e., mouse with the desired antigen. Hence. the amended claims are not allowed u/s 3(i) of The Patents Act.

Consequently, the outstanding objection of the said hearing notice is maintained and claims 1-6 are not allowed. This application for grant of patent is refused under Section 15, The Patents Act, 1970."

8. Given the reason for rejection, it is necessary to set out Section 3(i) of the Patents Act:

"(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."

In *The Chinese University of Hong Kong*, I discussed Section 3(i) primarily from the perspective of a claimed invention relating to

human beings. In paragraph 21 thereof, Section 3(i) was analysed as follows:

> *"21. Section 3(i) contains the following two limbs:*
>
> *(a) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings; or*
>
> *(b) 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.*
>
> *In my view, each limb of Section 3(i) is distinct and self-contained. I draw this conclusion for the following reasons. First, the first limb deals with human beings and the second with animals. Secondly, the disjunctive 'or' separates the two limbs. Thirdly, the second limb opens with the expression " any process for a similar treatment of animals" and proceeds to set out three purposes of treatment: to render them free of disease or increase their economic value or that of their products. Of these, the latter two purposes are clearly inappropriate and inapplicable to human beings because treatment of human beings is never intended to*

increase their economic value or that of products produced by them. Thus, it is clear that the second part of Section 3(i) deals only with the treatment of animals and thereafter sets out three objects and purposes of treatment. When viewed in isolation, the first purpose "to render them free of disease" could apply to human beings. However, keeping in mind that the first and the second limbs deal with distinct subjects; they are separated by the disjunctive "or"; and the pronoun "them" is used after the antecedent "animals", I conclude that said pronoun is referable only to the last antecedent "animals" and not to human beings. Apart from the above reasons, it bears mention that treatment is provided not only to free/cure a person of disease but also for prophylactic purposes, to alleviate pain, prevent aggravation of or to better manage a condition or disorder. Hence, I reject the contention that the word "diagnostic" in Section 3(i) should be confined to treatment of human beings to render them free from disease."

9. From the above analysis, it follows that Section 3(i) would be attracted in relation to a process for the treatment of animals provided such treatment is for any of the following three

purposes:

(i) To render them free of disease;

(ii) To increase their economic value; or

(iii) To increase the economic value of their products;

The use of the adjective "similar" to qualify the noun "treatment" in the second limb of Section 3(i) indicates that the form of treatment could be analogous to forms such as medicinal, surgical, curative, prophylactic, diagnostic or therapeutic, which are enumerated in the first limb of Section 3(i) in the context of treatment of human beings. In order to better appreciate the scope of Section 3(i) in relation to animals, it is profitable to consider illustrations. If cattle were to be subjected to treatment to cure such animals of foot and mouth disease, it would clearly qualify as a method of treatment to free such animals of disease and, therefore, patent ineligible under Section 3(i). If cows were subjected to treatment for purposes of improving the quality of milk or for purposes of increasing the quantity of milk that such cows are capable of producing, both the economic value of such

cows and that of its products would increase, thereby bringing it within the scope of the exclusion. Similarly, if sheep were to be subjected to some form of treatment to improve the quality of wool or to increase wool output from the fleece, it could result both in an increase in the economic value of the sheep and its produce. Substantially similar illustrations are set out in the Biotechnology Applications' Guidelines and, in all these cases, the method of treatment would fall within the ambit of Section 3(i).

10. By bearing in mind these illustrations, I turn to the background of the complete specification, wherein the claimed invention is described as under:

> *"The present invention provides, inter alia, a process for the generation in non-human mammals of antibodies that comprise a human Ig variable region, and further provides non-human animal models for the generation of such antibodies."*

When the object and scope of the claimed invention, as gleaned from the complete specification and the current claims, is

examined for the purpose of determining whether it is aimed at fulfilling any of the three purposes specified at paragraph 9 above, it is abundantly clear that the method described by the claimed invention is not targeted at treating the mice so as to render them free of disease. Equally, it is not intended to increase the economic value of such mice so as to sell such transgenic mice at higher prices. The only aspect remaining for consideration is whether these antibodies may be construed as products of such mice, whose economic value is enhanced by the method described by the invention. Meat, hair, skin, milk and the like are clearly intrinsic parts of or secretions of an animal and, therefore, qualify as products of such animal. Antibodies, by contrast, are typically produced in response to antigens. In this case, the antigens were administered to the mice after substantially modifying the genome of the mice so as to generate non-murine antibodies. Such non-murine antibodies clearly do not qualify as products of mice. Consequently, the ground on which the claimed invention was rejected in the impugned order is completely unsustainable. Since

this was the only ground on which the patent application was rejected, the appellant is entitled to a grant.

11. For reasons set out above, (T) CMA (PT) No.200 of 2023 is allowed on the following terms:

(i) Impugned order dated 29.05.2020 is set aside.

(ii) Indian Patent Application No.10716/CHENP/2012 shall proceed to grant on the basis of current claims 1 to 6.

(iii) There will be no order as to costs.

26.09.2024

Index : Yes/No
Internet : Yes/No
Neutral Citation : Yes/No

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