2024:MHC:1149

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

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| Judgment reserved on | 15.12.2023 |
| Judgment pronounced on | 06.03.2024 |

CORAM

The Hon'ble Mr. Justice **SENTHILKUMAR RAMAMOORTHY**

**(T) CMA (PT) No.134 of 2023**
**(OA/01/2017/PT/CHN)**

Genmab A/S
Bredgade 34 P.O. Box 9068 DK-1260
Copenhagen
K Denmark ... Appellant

v.

Assistant Controller of Patents and Designs,
Government of India, Patent Office,
Intellectual Property Building,
G.S.T. Road, Guindy,
Chennai – 600032. ...Respondent

**PRAYER:** This Civil Miscellaneous Appeal is filed under Section 117-A of the Patents Act, 1970, praying to set aside the order dated 30 May 2016 and issued by the Respondent in Indian Patent Application No.4718/CHENP/2007 for patent be allowed to proceed to grant.

For Appellant : Mr.Rahul Balaji,
Mr.Vijay Anand and
Dr.Meera Venugopal
For M/s De Penning and De Penning

For Respondent : Mr.M.Karthikeyan, SPC

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**JUDGMENT**

**Background**

The appellant assails an order dated 30 May 2016 by which Indian Patent Application No.4718/CHENP/2007, which is the national phase application derived from PCT Application No. PCT/DK06/00166, was rejected.

2. The appellant filed the above mentioned application dated 23 October 2007 for grant of patent in respect of an invention titled "Antibodies against CD38 for Treatment of Multiple Myeloma" by claiming its priority date from US Application No.60/667,579 dated 01 April 2005. Originally, the appellant had made 84 claims. Upon a request being made, the respondent issued the first examination report (FER) on 27 February 2013. In the FER, objections were raised *inter alia* on the grounds that the claimed invention is obvious in view of prior arts D1-D7; patent ineligible under Section 3(j), 3(e), 3(i) and 3(c) of the Patents Act, 1970 (the Patents Act) in respect of specific claims; and does not comply with Section 10(4) thereof. By response dated 17 January 2014, the appellant dealt with each objection in the FER, revised its claims and submitted a set of 63 amended claims.

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3. In the hearing notice issued on 09 April 2014, the respondent maintained many of the objections set out in the FER and, in particular, raised the objection that amended claims 1-44 fall within the scope of Section 3(c) of the Patents Act. Pursuant to a hearing on 28 April 2014, written submissions were filed as an enclosure to communication dated 17 July 2014, and the claims were amended further to a set of 29 claims. Eventually, by order dated 30 May 2016, the application was rejected.

4. In the impugned order, the respondent recorded that the appellant met objections 1, 2(a), 3,4, 6-11 and 13-27 of the hearing notice, but that objections 2(b) [lack of inventive step], 5 [non-compliance with Section 10(4)(c)] and 12[ineligibility under Section 3(c)] were not met. In particular, the respondent concluded that the DNA and protein of claims 1-24 and 25, respectively, were from *homo sapiens* as per the sequence listing. Hence, it was held that the antibody claimed is the discovery of a naturally existing molecule/substance and, therefore, not patent eligible under section 3(c) of the Patents Act. The present appeal arises in the above facts and circumstances.

**Counsel and their contentions**

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5. Oral arguments on behalf of the appellant were advanced by Mr.Rahul Balaji, learned counsel, assisted by Mr. Vijay Anand and Dr. Meera Venugopal; and on behalf of the respondent by Mr.M.Karthikeyan, learned SPC.

6. Learned counsel for the appellant contended that the appellant's invention is a monoclonal antibody that binds to human CD38, which is a protein antigen expressed on cancerous cells. After providing an overview of the terms necessary to understand the invention by submitting a glossary, he submitted that the antibody comprises light chain and heavy chain variable regions. By pointing out that these regions are referred to as complementarity determining regions (CDRs), he submitted that it is these regions that contain the antigen binding sites. Such antigen binding sites in the CDRs bind to the epitope, which is the specific site of the antigen to which the antibody binds. He next submitted that the patent claim over the antibody is in respect of three light chain variable regions described as VL CDR1, VL CDR2 and VL CDR3 and three heavy chain variable regions described as VH CDR1, VH CDR2 and VH CDR3.

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7. With this introduction, learned counsel turned to the impugned order and contended that all three grounds of refusal are untenable. He first dealt with the rejection under Section 3(c) of the Patents Act. After pointing out that this objection was originally raised only in respect of claims 51-56 in the FER, which claims were either deleted or modified as a consequence, he submitted that the scope of this objection was expanded in the hearing notice to cover claims 1-44. Learned counsel then contended that there are four reasons to reject the conclusion of the respondent. The four reasons are as follows: the claimed antibody was produced by substantial human intervention and was not directly isolated from nature; numerous patents were granted by the Indian Patent Office for monoclonal antibodies; the Intellectual Property Appellate Board (the IPAB) overturned a decision of the Controller in *Biogaia AB v. Controller of Patents and Designs, MANU/IC/0044/2021* in respect of monoclonal antibodies; and the claimed invention was granted a patent in all major jurisdictions. As regards the first reason set out above, learned counsel submitted that the antibody production process involved immunizing transgenic mice (HCo12) with two immunogens, both of which were artificially produced by modifying the human CD38 antigen. By further submitting that the antibody was produced by fusing the extract from the transgenic mice with an immortal myeloma

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cell, i.e. the hybridoma process, learned counsel submitted that such antibody was certainly neither discovered nor naturally occurring.

8. On the interpretation of Section 3(c) of the Patents Act, learned counsel relied on the judgment of the IPAB in *Biogaia,* particularly paragraph 8 thereof, for the proposition that non-living substances occurring in nature or isolated from nature are not patent eligible, whereas any genetically modified microorganism or nucleic acid sequence is not excluded if other criteria such as novelty, inventive step and industrial applicability are satisfied. He also relied on the judgment of the IPAB in *The University of British Columbia v. Controller of Patents, order dated 31 December 2020,* particularly paragraph 9 thereof, for the principle that a non-human monoclonal antibody does not attract Section 3(c) of the Patents Act. For the proposition that a substance created with human intervention does not fall within the scope of Section 3(c), he relied on the judgment of the IPAB in *Health Protection Agency v. The Controller General of Patents and another,* especially paragraph 12 thereof. By relying on the Indian Patent Office's Guidelines for Examination of Biotechnology Applications for Patents (the Biotechnology Application Guidelines), he contended that said

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Guidelines provide that only products directly isolated from nature are patent ineligible.

9. Dr. Meera Venugopal supplemented these submissions. By relying on the affidavit of Dr.Tom Vink, molecular biologist, who was part of the CD38 project from July 2002, she pointed out that the antibody of the claimed invention is also referred to as Daratumubab. She further pointed out that naturally produced antibodies are so diverse that each individual contains a unique repertoire of diverse antibodies. After pointing out from the affidavit that the transgenic mouse enzymes play a role in determining the final composition of the antibody by the introduction of somatic hyper mutations, she pointed out that there are differences between the sequence of Daratumubab and the closest human germline sequence, as indicated at internal pages 7-10 of Dr. Vink's affidavit. By further referring to internal page 11 of said affidavit, she relied on the categorical statement therein that isolating this class of antibodies from the human population is impossible. She next relied on the affidavit of Michel de Weers, immunologist, to contend that Daratumubab inhibited ADP-ribosyl cyclase reaction of CD38 or cellular CD38 and that the mouse CD38 antibody CKT-10 or isotype control antibody HuMab-KLH (antibodies disclosed in the prior art) did not

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perform this function. She concluded her submissions by contending that the CDR sequence of the claimed antibody is different and that the hearing notice did not mention the objection regarding non-compliance with Section 10(4)(c).

10. In response to these submissions, at the outset, the respondent contended that the affidavits of the experts, such as Dr.Vink and de Weers, were not placed before the Assistant Controller. The second contention was that the sequences do not indicate that mouse enzymes played a role in the generation of novel antibodies. The last contention was that the claims are based on the sequence listing, which sets out the structure of the antibody. In the sequence listing, the organism of origin is specified as *homo sapiens*. On the interpretation of Section 3(c), it was contended that the qualifier "mere" does not extend to the third limb dealing with "discovery of any living thing or non-living substance occurring in nature" and that Parliament's intention, in this regard, is clear upon comparing and contrasting Section Section 3(c) with Section 3(d), which contains the qualifier "mere" before every limb. Hence, in conclusion, it was further contended that the claimed invention is in respect of antibodies that occur in

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nature, and that such claims are not patent eligible under Section 3(c) of the Patents Act.

**Discussion, analysis and conclusions**

11. Before grappling with the legal and factual issues that the determination of this dispute entails, it is necessary to summarize the scientific terms, concepts and principles that are germane for an understanding of the dispute. Since antibodies are naturally or synthetically produced to defend the organism (such as human beings) against antigens, a good place to start is with antigens. An antigen is a molecule, often foreign to the organism, that an antibody binds to and attacks. Typical examples of antigens are bacteria, viruses, fungi, toxins or even allergens. The antigenic site to which the antibody binds is called an epitope. Antibodies are immunoglobulin molecules, i.e. proteins consisting of about four polypeptides. Naturally occurring antibodies are produced in the human body by B cells, which are specialized white blood cells.

12. Most, if not all, naturally occurring antibodies are polyclonal, i.e. they are produced by many distinct B cells/lymphocytes and each polyclonal antibody typically has different specificity. Therefore, different

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polyclonal antibodies for the same antigen may bind to different epitopes of the antigen. Polyclonal antibodies are, consequently, polyvalent and their affinity to a particular epitope, i.e. the extent to which an antibody is drawn to and binds to an epitope, is low. There could also be variation in avidity, which is a measure of the strength of interaction between antibody and antigen, as between monoclonal and polyclonal antibodies. In contrast to polyclonal antibodies, monoclonal antibodies have monovalent affinity, i.e. they bind to the same epitope of the antigen. Monoclonal antibodies are broadly of four categories: non-human, i.e. produced in a non-human host such as a mouse; chimeric, i.e. containing parts or regions from different organisms; humanized, i.e. derived from non-human species and, thereafter, grafted into a human framework so as to minimize risk of immunological reactions; or human, i.e. produced in transgenic animals based on human germline sequences. Each antibody molecule comprises two heavy chains and two light chains, which roughly form a structure like the alphabet 'Y'. Each heavy (H) and light (L) chain has a variable (V) region and a constant (C) region. The constant regions form the trunk of the Y and do not come into contact with the epitope of the antigen. Each antibody has six chains: three in the heavy and three in the light chain. The amino acids constituting the tips of the variable regions form loops while folding, which are referred

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to as complementarity determining regions (CDRs). The claim of inventiveness generally centres around the sequences relating to the CDRs.

13. Against this backdrop, the first issue that requires determination pertains to the interpretation of clause (c) of Section 3. The said provision is set out below:

> *"What are not inventions – The following are not inventions within the meaning of this Act, –*
>
> *"(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****"(emphasis added).*

Prior to its amendment by Act 38 of 2002, the provision was as under:

> *"(c) the mere discovery of a scientific principle or the formulation of an abstract theory"*

The Patents Act was enacted pursuant to a report of the Iyyangar Committee. In the said report, at paragraph 328 thereof, the Committee was of the view that discoveries are universally not patentable. The rationale appears to be that a discovery is a process by which something already in existence is found, whereas an invention is the creation of something that was not in existence previously. Given that the Patents Act was intended to

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foster inventiveness and not to reward discovery of things that already exist, the basis for the exclusion is clearly discernible.

14. As is evident from the pre-amended text, this provision was originally limited to the mere discovery of scientific principles or the formulation of abstract theories. The first limb dealt with discovery and the second with the intellectual exercise of formulating an abstract theory. The qualifier "mere", which is an adjective, was added before the noun "discovery" in the first limb to underscore that something more than a discovery of a scientific principle, such as, perhaps, the production of a novel device that operates on such scientific principle, may fall outside the scope of patent exclusion. Because the second limb does not deal with discovery but to the formulation of an abstract theory, if the intention were to apply the adjective "mere" to the second limb, it should have been placed before the noun "formulation" in such limb. After the introduction of the third limb: "discovery of any living thing or non-living substance occurring in nature" by the amendment, can the adjective "mere" be construed as reaching and qualifying such limb? To begin with, it would be a strained construction to conclude that the adjective "mere" does not reach and qualify the second limb but qualifies the third. The ordinary rule of grammar and,

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therefore, one of the principles of statutory construction is that a modifier, such as the word "mere", would qualify the entire series of nouns or verbs if such series is a straightforward parallel construction, whereas, it would be restricted to the nearest reasonable referent otherwise. For instance, if the second limb did not exist and Section 3(c) had been framed as follows: *the mere discovery of a scientific principle or of any living thing or non-living substance occurring in nature,* both the adjective "mere" and the noun "discovery" would have applied to both limbs as the phrase would not make sense otherwise. Reference may be made to *Reading Law, The Interpretation of Legal Texts, Antonin Scalia and Bryan Garner*, *2012 Edition, Thomson/West,* for an illuminating discussion on these principles of interpretation.

15. Another aspect to be noticed, in this regard, is that the noun "discovery" in the third limb is intended to apply both to living things and non-living substances occurring in nature. This is a pointer, albeit not conclusive, that the adjective "mere" does not extend to this limb as otherwise even a "living thing" could fall outside the scope of patent exclusion if there were to be something more than mere discovery. As

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discussed earlier, the amendment to this clause was effected by Act 38 of 2002, which was enacted pursuant to the Patents (Second Amendment) Bill 1999 (Bill No.49). In the Statement of Objects and Reasons, in relevant part, it is stated as under with regard to the amendment of Section 3:

> *"(b) to modify section 3 of the present act to include exclusions permitted by TRIPS Agreement and also subject matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable invention"*

Clause 4 of the bill provides as under:

> *"sub-clause (b) seeks to amend clause (c) of Section 3 so as to include discoveries of any living thing or non-living substance occurring in nature as not inventions patentable."*

It is noticeable that the qualifier "mere" was not used in the Statement of Objects and Reasons for Bill No.49 or in clause 4. If Parliament intended to apply the qualifier, it is likely that the word "mere" would have found place before the word "discovery". It should also be noticed that clause (d) of Section 3, which also uses the qualifier "mere" uses it in each limb of the

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provision. Hence, the text, interpreted as per the ordinary rules of grammar, the immediate statutory context, and the legislative history of amended clause (c) of section 3 point to the same conclusion, i.e. that the qualifier "mere" is confined to the nearest reasonable referent "discovery of a scientific principle" and does not extend to "the discovery of any living thing or non-living substance occurring in nature." For reasons set out above, I deviate from the interpretation of the Delhi High Court, in this regard, in *Diamond Star Global Sdn. Bhd. v. Joint Controller of Patents and Designs, 2023 SCC OnLine Del 1879.*

16. The next aspect to which I turn my attention is the impact of the phrase "occurring in nature". Does it also apply to the expression "living thing"? The ordinary rules of syntax would indicate the following structure if the intention were to extend "occurring in nature" to "living thing": *'the discovery of any living or non-living thing occurring in nature'.* Even otherwise, given the current state of science, the extension of "occurring in nature" to "living thing" would create a redundancy that cannot ordinarily be imputed to Parliament. Thus, I conclude that the expression "occurring in nature" in the third limb of Section 3(c) only qualifies the nearest reasonable referent "non-living substance".

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17. Before answering questions relating to the scope of Section 3(c) in the Indian statutory context, it is instructive to examine judgments of the US Supreme Court in this regard, and I discuss the same next. Section 101 of the US Patent Act prescribes as under:

> "*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*"

Two aspects are conspicuous: no express patent exclusions are prescribed; and even discovery appears to fall literally within the scope of patent protection. In this statutory context, in paragraph 14 of the SCC OnLine Report, the US Supreme Court in *Sidney A. Diamond v. Ananda M. Chakrabarty (Chakrabarty), 1980 SCC OnLine US SC 128,* held, in relevant part, as under:

> "*This is not to suggest that Section 101 has no limits or that it embraces every discovery. The laws of nature,physical phenomena, and abstract ideas have been held not patentable....Thus a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could*

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*not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of nature, free to all men and reserved exclusively to none..."*

*On noticing that the bacterium, in that case, was man-made, the US Supreme Court held in Chakrabarty that it was patent-eligible.*

18. In *Mayo Collaborative Services, dba Mayo Medical Laboratories v. Promotheus Laboratories Inc.(Mayo), 2012 SCC OnLine US SC 28,* in the context of process claims regarding the dosage level of thioprine drugs, it was held that the claims apply natural laws describing the relationships between the concentration in the blood of certain thioprine metabolites and the likelihood that the drug dosage would be ineffective or induce harmful side effects. Therefore, the claims were held to be patent-ineligible. In *Association for Molecular Pathology et al v. Myriad Genetics et al, 133 S.Ct. 2107 (2013),* the US Supreme Court concluded that a claimed invention for discovery of the precise location and sequence of two human genes was patent-ineligible, whereas a synthetically created complementary deoxyribonucleic acid (cDNA) was held to be patent eligible.

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19. Reverting to Indian law, as noticed earlier, Section 3(c) uses the expression "occurring in nature" to qualify "discovery of a non-living substance." While it could be argued that this qualifier is only intended to underscore that the exclusion would not apply to a non-living substance that is man-made, in my view, said explanation does not withstand close scrutiny because such non-living substance, if man-made and novel, would not be discovered; it would be created or invented. If man-made but not novel, it would be produced and not discovered. It would also not surmount the Section 2(1)(j) hurdle and the Section 3(c) exclusion is clearly not intended for such non-living substances. What is the sequitur of the use of the expression "occurring in nature": would a synthetic version of a substance that rarely occurs in nature but is required to be produced in large quantities for the treatment of serious illnesses qualify for or be excluded from patent protection? Should a patent applicant establish that such non-living substance never occurs in nature? The text of clause (c) of Section 3 contains guidance.

20. The statutory prescription is "discovery of any ... non-living substance occurring in nature". Both the use of the noun "discovery"- which

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implies finding something which already exists and not producing, engineering or making something - and the use of the present continuous form “occurring in nature” indicate that the exclusion will only apply to the process of finding a hitherto undiscovered non-living substance by identifying and isolating it from nature. While reaching this conclusion, I take on board the presumption in statutory construction that redundancy should not be imputed to Parliament, and that the expression “occurring in nature” should not be robbed off all meaning and purpose. Ultimately, it should not be lost sight of that Section 3(c) is confined to patent exclusions or ineligibility and passing through such filter does not guarantee the grant of patent.

21. The real challenge with regard to a patent application in respect of a synthesized non-living substance, especially a monoclonal antibody, is establishing novelty or technical advance and not patent eligibility. For such purpose, the sequence of the antibody, especially the CDRs, may need to be compared with known antibody sequences. The patent applicant may also be required to establish that it does not fall within other exclusions in Section 3, such as sub-section (d) thereof, and further satisfy the requirements of Section 2(1)(j) of the Patents Act. The judgments

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of the IPAB, such as *Biogaia, The University of British Columbia* and *Health Protection Agency* record substantially similar conclusions. Although not a concern in this case because of the nature of claims, the other legitimate concern from the Indian Patent Office perspective, in the context of monoclonal antibodies, could be to closely examine the width of claims so as to ensure that very broad claims focused entirely or largely on functionality are not allowed because that could impede instead of fostering inventiveness in future.

22. The conclusion of the respondent that the antibodies claimed in the appellant's invention occur in nature was strongly refuted by learned counsel and agent by contending that the antibody was engineered by an elaborate process. In order to substantiate such contention, the appellant relied on both structural and functional attributes of the claimed invention. With regard to the method of production, the examples in the complete specification were relied on. As regards structural novelty and non-obviousness, the sequence listing was relied on and it was contended that the sequences relating to the CDRs referred to in the claims are novel and non-obvious in comparison to prior art. In order to understand the nature of the monopoly claim of the appellant, it is instructive to set out independent claims 1 and 2, which read as under:

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*"We claim:*

*An antibody binding to human CD38 comprising human light chain and human heavy chain regions, wherein the light chain variable region comprises a VL CDR1 having the sequence as set forth in SEQ ID No:13, a VL CDR2 having the sequence as set forth in SEQ ID No:14 and a VL CDR3 having the sequence as set forth in SEQ ID No: 15, and the heavy chain variable region comprises a VH CDR1 having the sequence as set forth in SEQ ID No: 18, a VH CDR2 having the sequence as set forth in SEQ ID No:19 and a VH CDR3 having the sequence as set forth in SEQ ID No:20, and wherein said antibody is encoded by (i) human light chain and heavy chain nucleic acids comprising nucleotide sequences in their variable regions as set forth in SEQ ID No:16, respectively.*

*2. An antibody binding to human CD38 comprising human light chain and human variable regions, wherein the light chain variable region comprises a VL CDR1 having the sequence as set forth in SEQ ID No: 13, a VL CDR2 having the sequence as set forth in SEQ ID No:14 and a VL CDR3 having the sequence as set forth in SEQ ID No:15, and the heavy chain variable region comprises a VH CDR1*

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*having the sequence as set forth in SEQ ID No: 18, a VH CDR2 having the sequence as set forth in SEQ ID No: 19 and a VH CDR3 having the sequence as set forth in SEQ ID No.20."*

23. The response of the respondent was that merely because the antibody was generated synthetically through a process does not satisfy the requirements of Section 3(c) because the product, i.e. antibody and nucleic acid claimed in claims 1-25, originate from *homo sapiens*. The basis of the respondent's findings are evident from the following excerpts from internal pages 32-33 of the impugned order:

"*....As stated above the claimed SEQ ID No.11,13, 14,15,16,18,19 and 20 which are detailed as above in SEQUENCE ID refers to the DNA and protein (PRT) from Homo sapiens. Hence, the argument of agent falls short to explain that when the claim is for all natural sequences and where is the non-natural nature of the claimed antibody or DNA? Though performing the artificial or non-natural process for generation of naturally existing molecule does not prove product claimed is out of*

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*discovery and hence does not escape the clutches of Section 3(c) of the Patents Act, 1970"*

24. Since the respondent relied on the fact that the description of the organism in the sequence listing is *homo sapiens,* some explanation is necessary for the appreciation of this contention and to put it in perspective. Every patent application in respect of substances, such as antibodies, is required to be accompanied by a sequence listing. The World Intellectual Property Organisation (WIPO) has formulated standards in relation to. The currently applicable standard is Standard 26(St.26). At the relevant point of time, Standard 25 was applicable. Standard 25 prescribes the mandatory and optional information that should be provided in the sequence listing. Such mandatory information includes information relating to the organism from which the nucleotide or amino acid sequence originates and setting out the sequence. Standard 25 also prescribes that such information is required to be provided against the numerical identifier [213] and [400], respectively.

25. The appellant does not dispute that the organism of origin was listed as *homo sapiens* with regard to the SEQ ID's regarding which claims were made. Instead, the explanation of the appellant is that only three

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options are available as regards numeric identifier [213], namely, organism, artificial and unknown. Because the antibody was developed from the transgenic HuMab Mouse platform based on human germline sequence, the appellant states that the annotation '*homo sapiens'* was specified in numerical identifier [213] as the most similar or homologous. Significantly, the appellant contends that this does not establish that the monopoly claim is over a naturally occurring antibody. The appellant also contends that numeric identifier [400], which contains the sequence, should determine inventiveness and not numeric identifier [213].

26. In light of the conclusions drawn on the interpretation of Section 3(c) of the Patents Act, the contention of the respondent that the claims are in respect of the discovery of an antibody/non-living substance occurring in nature cannot be countenanced merely because the organism specified in the sequence listing is *homo sapiens*. As discussed earlier, such conclusion would be justified only if the appellant had discovered/found a hitherto unknown antibody and isolated it from nature. This objection may, however, have some bearing as regards the conclusion that there was no inventive step, and I deal with this aspect next.

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27. The conclusion with regard to lack of inventive step was reached by citing prior arts D1-D7. The appellant contended that the six CDR sequences in respect of which claims are made are structurally novel.

The appellant also claims functional advances over the cited prior art by referring to the ability of the antibody to induce effector functions, such as antibody-dependent cellular cytotoxicity (ADCC) (Example 5) and complement dependent cytotoxicity (CDC)(Example 6). With reference to Example 13, inhibition of tumour growth is asserted and with reference to Example 23, inhibition of CD38 cyclase activity is asserted.

28. As regards D1, it was contended that it discloses two engineered forms of murine monoclonal antibody, which are either humanized or chimeric and not human. By referring to the CDR sequences of D1, the appellant contended that they are different from the claimed invention. The appellant also contended that the CDC inducing ability of the claimed invention is superior to D1 by citing Example 6. As regards prior art D2, it was contended that the sequence of the single-chain fragment variable (scFv) was not disclosed and, consequently, the same cannot be made on the basis of the complete specification. D3 was distinguished by

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pointing out that it is substantially similar to D1. As regards D4 and D5, it was contended that they were only used for scientific investigations and not for therapeutic purposes. As regards D6 and D7, it was contended that they are not anti-CD38 antibodies. The affidavit of Marije Overdijk was relied on to contend that mouse antibodies (the antibodies of D1 and D3) have a shorter half-life and mouse IgG1 does not induce ADCC and that IgG2 does so only to a limited extent. The affidavit of Michel de Weers was relied to contend that Daratumubab inhibited the ADP-ribosyl cyclase reaction of CD38, whereas such effect was not seen in the prior art antibodies.

29. In support of the conclusion that the claimed invention lacks an inventive step, apart from stating that the organism of origin of the CDR sequences is natural, the respondent also concluded that no comparative data was provided. On perusal of the complete specification, the affidavits discussed above and the cited prior arts, I find that there is no basis to the conclusion that the claimed invention either lacks technical advancement over the cited prior art or that it would have been obvious to a person skilled in the art. In this connection, it should also be noticed that the prior art cited herein was also cited either in the International Search Report (ISR) or in proceedings before the European Patent Office(the EPO) or the United

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States Patent Office (the USPTO). While this is not dispositive, it is a material consideration. All that remains is to consider the objection relating to non-compliance with Section 10(4)(c).

30. Without acquiescing in the validity of this objection, in the written submissions, the appellant has agreed to delete claims 4,7,10-15,18 and 19, which are the only claims in respect of which these objections were raised. With the deletion of these claims, this objection is rendered moot.

31. For reasons discussed above, the objections on the basis of Section 3(c) and lack of inventive step are overruled. Consequently, the impugned order cannot be sustained and is hereby set aside. Since all the other objections in the FER were subsequently dropped pursuant to the deletion of corresponding claims or on provision of a satisfactory explanation, in view of the above conclusion, I direct that the claimed invention proceed to grant on the basis of the claims submitted with the written submissions before the respondent, i.e. claims 1-29, subject to the deletion of claims 4,7,10-15,18 and 19. The claims shall be refiled after renumbering for such purpose.

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32. (T)CMA(PT)No.134 of 2023 is disposed on the above terms without any order as to costs.

**06.03.2024**

Index : Yes/No

Internet : Yes/No

Neutral Citation : Yes/No
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To

The Assistant Controller of Patents and Designs,
Government of India, Patent Office,
Intellectual Property Building,
G.S.T. Road, Guindy,
Chennai – 600032.

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**SENTHILKUMAR RAMAMOORTHY J.**

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**Pre-Delivery Judgment in**

**(T) CMA (PT) No.134 of 2023**
**(OA/01/2017/PT/CHN)**

**06.03.2024**

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