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IN THE HIGH COURT OF JUDICATURE AT MADRAS

Judgment reserved on	15.12.2023
Judgment pronounced on	06.03.2024

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

(T) CMA (PT) No.126 of 2023
(OA/08/2019/PT/CHN)

Imclone LLC
160, Greentree Drive, Suite 101
Dover, Delaware 19904
United States of America ...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 31 January 2018 and issued by the Respondent in Indian Patent Application No.6334/CHENP/2009 for patent be allowed to proceed to grant.

For Appellant : Mr.Shatadal Ghosh,
Mr.Muthuselvam,
for M/s.K&S Partners

For Respondent : Mr.Subbu Ranga Bharathi, CGSC

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JUDGMENT

Background

The appellant assails an order dated 31 January 2019 by which Indian Patent Application No.5808/CHENP/2007, which is the national phase application derived from PCT Application No. PCT/US2006/023856, was rejected.

2. The appellant filed the above mentioned application dated 17 December 2007 for grant of patent in respect of an invention titled "Receptor Antagonists for Treatment of Metastatic Bone Cancer" by claiming its priority date from US Application No.60/691,920 dated 17 June 2005. Originally, the appellant had made 80 claims. Upon a request being made, the respondent issued the first examination report (FER) on 10 March 2014. In the FER, objections were raised in respect of claims 1 to 43 and 64 to 80 on the ground that they are not patent-eligible under Section 3 (i) of the Patents Act, 1970 (the Patents Act). As regards claims 44 to 59, the respondent raised objections by relying on the exclusion in Section 3(c) of the Patents Act. With regard to claim 60 to 63, objections were raised under Section 3 (j) of the Patents Act. In addition, other objections were also

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raised. By response dated 13 February 2015, the appellant revised its claims by deleting claims 1 to 43 and 64 to 80, and submitting a set of amended claims.

3. Apart from submitting amended claims, the appellant responded to the objections. The objection under Section 3(c) was refuted by contending that the antibody in respect of which claims 44 to 59 were made was not isolated from nature. The appellant asserted that paragraphs [00153] and [00154] of the complete specification clearly recite that the antibody was generated by immunising transgenic mice (engineered mice) that express human gamma heavy and kappa light immunoglobulin (Ig) chains with porcine aortic endothelial (PAE) cells expressing platelet-derived growth factor receptor alpha(PGDFR alpha), which were subsequently boosted with PGDFR alpha extracellular domain (ECD). The appellant further asserted that the material generated in response by such transgenic mice was extracted from the cells of the spleen of the mice, fused with immortal myeloma cells by using hybridoma technology so as to produce the antibody therefrom through the processes of cloning and chromatography. Thus, the appellant asserted that the antibody was not isolated from nature and that the above-mentioned chain of events does not

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occur in nature. On the above basis, the appellant called upon the respondent to withdraw the objection.

4. In the hearing notice issued on 20 November 2017, the respondent maintained all the objections set out in paragraphs 2 to 7 of the FER. The hearing notice was responded to on 10 January 2018. In the said reply, the appellant asserted that the amended claims annexed thereto are in respect of a recombinant antibody or antibody fragment specific for human PDGFR alpha. It was also submitted that immunisation, somatic recombination and selection were all absolutely necessary to engineer the claimed antibody. The appellant further asserted that engineered PAE cells expressing human PDGFR alpha and recombinant PDGFR alpha ECD were used as antigens during immunisation of the mice, and that these antigens do not normally exist in nature. By pointing out that three different species are involved in the process, it was reiterated that the antibody was neither naturally occurring nor isolated from a human being. The appellant further submitted that the antibody does not freely occur in nature because PDGFR alpha is necessary for embryonic development and, consequently, the natural production of an antibody by the human body to the PGDFR alpha would impede and arrest embryonic development.

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5. In the impugned order, the respondent recorded that the appellant met objections 2 and 4 to 7 by deleting the relevant claims. As regards objection 3, the respondent noticed the addition of the word 'recombinant' and concluded that the use of the word 'recombinant' is not supported by the specification. The respondent further concluded that the antibodies of the application are produced by standard methods and known techniques. Therefore, it was held that the antibody claimed in claims 1 to 4 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

6. Oral arguments on behalf of the appellant were advanced by Mr.Shatadal Ghosh, learned counsel, assisted by Mr. Muthuselvam; and on behalf of the respondent by Mr.Subbu Ranga Bharathi, learned CGSC.

7. Learned counsel for the appellant contended that PGDFR alpha plays a significant role in bone cancer, especially metastatic cancer. Therefore, he submitted that the appellant produced an antibody (IMC-3G

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3) which targets the specific epitope and prevents ligand binding at the receptor site. By referring to paragraphs [00153] and [00154] of the complete specification, he contended that the recitals therein make it abundantly clear that human anti-PGDFR alpha antibodies were not isolated from nature but were generated by adopting the following process using a standard hybridoma technology. The process involved the engineering of transgenic mice which express human gamma heavy and kappa light Ig chains. Thereafter, the mice were immunised subcutaneously with PAE cells expressing PGDFR alpha. The splenocytes of the mice were then isolated and fused with myeloma cells; the hybridoma cultures exhibiting blocking activity were cloned; and antibodies from the hybridoma were purified by protein G chromatography.

8. Learned counsel next submitted that the antibodies produced by the appellant have complementarity determining heavy and light regions(CDHR and CDLR). By referring to paragraphs [00172] and [00173] of the complete specification, he submitted that the antibody was produced by using recombinant technology. He next contended that the human body does not produce an antibody to the PGDFR alpha because the same is necessary for human embryonic development. Put differently, his contention

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was that any naturally occurring antibody would have arrested embryonic development. In support of the submission, he referred to an article regarding the role of PGDFR in embryonic development.

9. On the interpretation of Section 3(c) of the Patents Act, learned counsel relied on the judgments of the Intellectual Property Appellate Board(the IPAB) in *Biogaia AB v. Controller of Patents and Designs, order dated 13 February 2021,* 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. In conclusion, he pointed out that the

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Patent Office had granted patents to monoclonal antibodies in the past and that the rejection, in this case, violates the principle of equality.

10. In response to these submissions, the respondent contended that the antibodies of the claimed invention were isolated from human beings. By referring to paragraph [0075] of the complete specification, the respondent submitted that the appellant admitted therein that antibodies and antibody fragments of the present invention can be obtained from naturally occurring antibodies. By turning to the sequence listing, the respondent pointed out that sequence(SEQ) ID numbers 2, 4, 6, 10, 12 and 14 specify the organism of origin of the sequence as *homo sapiens*. With reference to Section 3(c) of the Patents Act, the respondent contended that the appellant generated already known and naturally occurring antibodies using standard hybridoma technology, which is not novel. The respondent further submitted that no recombination was seen in the sequence listing. As regards previous orders of the IPAB and decisions of the Patent Office, it was submitted that the IPAB order in *Health Protection Agency* was in respect of a biological process indicator which does not occur in nature and that the order of the Patent Office in Patent Application No.5057/CHENP/2007 was in respect of a mutated antibody. A similar contention was raised in respect of Patent

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Application No.2569/MUMNP/2008. Therefore, the respondent submitted, in conclusion, that the claimed invention falls squarely within the ambit of section 3(c) of the Patents Act.

11. By way of rejoinder, learned counsel for the appellant submitted that transgenic mice were produced by knocking out the murine immune system and inserting human genes. Such mice were immunised subcutaneously with PAE cells that express PGDFR alpha. Splenocytes from mice were then isolated and fused with myeloma cells. By this process, the antibodies were produced. Therefore, he contended that it cannot be said that these antibodies were isolated from human beings. Since the antibodies were not isolated from human beings, he further contended that the claimed invention does not fall within the scope of Section 3(c) of the Patents Act. As regards the interpretation of the above provision, he referred to the Patents (Second Amendment) Bill, 1999 (Bill No.49) and the speech relating thereto in Parliament. He also pointed out that Section 3(c) was amended to introduce the third limb thereof by Patents (Amendment) Act, 2002, and that Section 3(c) cannot, therefore, be interpreted with reference to Section 3(d), which was amended by the Patents (Amendment) Act, 2005. By relying on the judgment of the Delhi High Court in *Diamond Star*

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Global Sdn. Bhd. v. Joint Controller of Patents and Designs (Diamond Star) 2023 SCC OnLine Del 1879, he contended that the qualifier "mere" in Section 3(c) also applies to "discovery of any living thing or non-living substance occurring in nature".

Discussion, analysis and conclusions

12. 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 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. Naturally occurring antibodies are produced in the human body by B cells, which are specialized white blood cells. Antibodies are proteins consisting of about four polypeptides.

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13. 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 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

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

14. 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

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

15. 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 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 a 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. What about the third limb: "discovery of any living thing or non-living substance occurring in nature"? To begin

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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, 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.

16. 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

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otherwise even a "living thing" could fall outside the scope of patent exclusion if there is something more than mere discovery. As 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."*

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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 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.*

17. 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

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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".

18. 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:

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> *"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 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.

19. 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

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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.

20. 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

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substance never occurs in nature? The text of clause (c) of Section 3 contains guidance.

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

22. The real challenge with regard to a patent application in respect of a synthesized non-living substance, especially a monoclonal antibody, is establishing novelty, technical advancement and not patent

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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 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.

23. The conclusion of the respondent that the antibodies claimed in the appellant's invention occur in nature was strongly refuted by learned counsel for the appellant on the basis that the antibody was engineered by an elaborate process. In order to substantiate such contention, the appellant relied on paragraphs [00153] and [00154] of the complete specification. The said paragraphs are set out below:

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*"[00153] Isolation of human anti-PDGFR alpha antibodies. Human anti-PDGFR alpha monoclonal antibodies were generated by a standard hybridoma technology (Harlow and Lane, ed., Antibodies: a Laboratory Manual, Cold Spring Harbor, 211-213 (1998), which is incorporated by reference herein) using transgenic mice (Medarex Inc., Sunnyvale, CA) that express human gamma heavy and kappa light immunoglobulin chains. Human PDGFR alpha extracellular domain (ECD) was purchased from R&D Systems (Minneapolis, MN). KM miceWere immunised subcutaneously (s.c.) with 3 * 10 porcine aortic endothelial cells stably expressing PDGF are alpha (PAE Ra). After four weeks, mice were boosted s.c. with 50 ug PGDFR alpha ECD in complete Freund's adjuvant plus 3 * 10 PAE Ra cells given i.p. Mice were boosted two more times, 3 weeks apart, with 25 ug PDGFR alpha ECD in incomplete Freund's adjuvant.*

[00154] splenocytes from mice with high serum binding and blocking titres were isolated and fused with myeloma cells. Hybridoma cultures displaying blocking activity versus a cloned and antibodies from the hybridoma is were purified by protein G chromatography."

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24. The response of the respondent was that hybridoma technology is well known and that the use of such process cannot be construed as inventive. The findings in the impugned order, in such regard, are set out below:

> *"The applicant's argument regarding objection no.3 of the FER has been considered. The applicant has amended the claim by the addition of the word* ***recombinant,*** *which is not supported by the specification. Just by amending the claims by word "recombinant" does not make the product claimed as patentable u/s 3 (c) of the Patents Act, 1970. The antibodies of the instant application are produced by standard methods and known techniques. Neither the claims nor the specification specify any particular recombination or alteration in the structure of the antibody and in the absence of that, the antibody claimed in claims 1-4 can be treated as discovery of the naturally existing molecule/substance and are not patentable u/s 3 (c) of the Patents Act, 1970."*

The appellant does not, however, assert inventiveness in the use of hybridoma technology. Inventiveness is asserted with regard to the production of a monoclonal antibody, which targets a specific epitope at the

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receptor site of PGDFR alpha. From the description set out in the complete specification, the conclusion that follows is that the antibody of the claimed invention was undoubtedly not isolated from a human being, but was engineered in the manner described in paragraphs [00153] and [00154] of the complete specification.

25. The respondent also 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 listing the sequence. 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

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is required to be provided against the numerical identifier [213] and [400], respectively.

26. Against this background, on examining the sequence listing, I find that the respondent's contention that the organism of origin was listed as *homo sapiens* is true with regard to the majority of the 63 SEQ ID's in the sequence listing, including the SEQ IDs in respect of which claims were made. It is, however, not true with regard to SEQ IDs 17 to 29, which specify that the organism is “unidentified” or “artificial”. Therefore, as required by Standard 25, further information is specified in relation thereto against the numerical identifier 223 as “synthetic primer”. 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.

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27. In light of the disclosures in the complete specification, especially paragraphs [00153] and [00154], the conclusion that follows is that the antibody was generated by deleting murine genetic material from mice and replacing the same with human genetic material in the mice and, thereafter, injecting an engineered antigen into the mice. After doing so, material extracted from the spleen of the mice was fused with myeloma cells by the hybridoma process. This resulted in the antibody over which the patent claim is made. When all these facts and circumstances are considered cumulatively, in the context of my conclusions on the scope and ambit of Section 3(c) of the Patents Act, I conclude that the claimed invention is not excluded from patent protection under clause (c) of section 3. Consequently, the impugned order cannot be sustained and is hereby set aside.

28. As regards other objections in the FER, it was recorded as under in the impugned order:

> *"The applicant's arguments regarding objection no.1 of hearing notice is found satisfactory and have been waived. By the deletion of claims the applicant has been met objection no.2, 4-7 of the FER."*

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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 current claims, which were submitted in course of hearings before the respondent. For the avoidance of doubt, the said claims are set out below:

> "*We claim:*
>
> 1. *The recombinant antibody or antibody fragment specific for human PDGFR alpha comprising CDR H1 of the sequence SSSYY (SEQ ID No.2); CDRH2 of the sequence SFFYTGSTYYNPSLRS (SEQ ID No.4); CDRH3 of the sequence QSTYYYGSGNYYGWFDR (SEQ ID No.6) in the heavy chain variable region; CDRLR1 of the sequence RASQSSYLA (SEQ ID No.10); CDRL2 of the sequence DASNRAT (SEQ ID No.12); and CDRL3 of the sequence QQRSNWPPA(SEQ ID No. 14) in the light chain variable region.*
> 2. *The recombinant antibody or antibody fragment of Claim 1, which comprises a heavy chain variable region having SEQ ID*

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No.8 or a light chain variable region having SEQ ID No.16.

3. *The recombinant antibody or antibody fragment of Claim 1, which comprises a heavy chain variable region having SEQ ID No.8 and a light chain variable region having SEQ ID No.16.*
4. *The antibody or antibody fragment of any one of claims 1 to 3, which inhibits binding of PDGFR alpha to a ligand of PDGFR alpha or which neutralises PDGFR alpha"*

29. (T)CMA(PT)No.126 of 2023 is allowed 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

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.126 of 2023

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