(2020) 12 IPAB CK 0014

In the Intellectual Property Appellate Board

Case No : Original Application No. 24 Of 2020/PT/CHN

University Of British Columbia — APPELLANT

Vs

Controller Of Patents — RESPONDENT

Date of Decision : 31-12-2020

Acts Referred:
Patents Act, 1970 — Section 3(c), 3(i), 15, 57, 59, 117A

Citation : (2020) 12 IPAB CK 0014

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

Bench : Division Bench

Advocate : Nupur Maithani

Final Decision : Allowed

Judgement

Immunogen,Amino Acid Sequence,"Similar

Immunogens",

Immunogen#1

AUG1-CLDK","C-LDKFLIKNSNDF

SEQ ID NO: 30","SEQ ID NO: 25; and

SEQ ID NO: 28",

Immunogen#2

AUG2-KKLE","KKLEKVKAYR-C SEQ

ID NO: 31","SEQ ID NO: 22 SEQ

ID NO: 23 SEQ ID

NO: 27",

Immunogen#3

AUG3-CKNS","C-

KNSVVEASEAAYKEA

SEQ ID NO: 32","SEQ ID NO: 3 SEQ

ID NO: 4 SEQ ID

NO: 5 SEQ ID NO:

24",

paras [00210] and [00210] on pages 109-110 of the appeal,,,

Â,,,

4. Additional data submitted during the prosecution of the application: In addition to the aforesaid data provided in the complete specification of the,,,

present application, the Applicant also submitted a report by SignalChem which characterizes two commercially available antibodies, namely, antibody",,,

cat#sc-17287 from SantaCruz Biotechnology (used in document D1 cited in the hearing notice) and antibody cat#IB18645 from Immuno-Biological,,,

Laboratories (used in documents D2 and D3 cited in the hearing notice). The report tests the cross-reactivity of the aforesaid commercially available,,,

antibodies with the seven14-3-3 protein isoforms and determines that none of the said antibodies is specific to the 14-3-3 eta isoform.,,,

Fig 1: Ab cat#sc-17287 from SantaCruz Biotechnology Fig 2: Ab cat#IB18645 from Immuno-Biological Laboratories,,,

5. Data submitted with Dr. Anthony Marottaâ??s declaration: A declaration by Dr. Anthony Marotta submitted during the prosecution of the,,,

corresponding U.S application was also filed with the hearing submissions. Said declaration establishes that the antibody of documents D4 and D5,,,

cited in the hearing notice is raised against an epitope (GCREQLLQRARZ) that is highly similar to the epitope of the polyclonal antibody,,,

commercially available from Biomol International LLP (raised against DREQLLQRARLA) and the slight difference are restricted to each peptide,,,

termini and are likely species related, but the overall sequences are identical. Dr. Marotta shows through Appendix A:",,,

(i) that the Biomol antibody does not show specificity for 14-3-3- eta over other isoforms and cross-reacts, particularly, with the gamma isoform.",,,

â?"See pageÂ 351Â of the appeal,,,

(ii) that the Biomol antibody does not bind to 14-3-3- eta in its native

configuration as it is shown useful for immune-blotting (western blot) but not,,,

immunoprecipitationÂ (paraÂ 3Â ofÂ Marottaâ??sÂ declaration on page 348 of the appeal).- See page 352 of the Appeal,,,

Dr. Marotta concludes that the results with the Biomol antibody are persuasive in demonstrating that that the cited art antibodies would not exhibit,,,

selectivity for the human 14-3-3 eta protein over the other 14-3-3 isoforms. â?" See paras 5 to 8 on pages 348 and 349 of the appeal.,,,

Dr. Marotta also concludes from Appendix A that there is a clear unmet need for monospecific anti-14-3-3 eta antibodies capable of immuno-,,,

precipitating endogenous 14-3-3 eta in its native configuration. â?" See para 3 on page 348 of the appeal,,,

6. The appellant has provided their explanation for the grounds of the refusal order as under:,,,

6.1 GROUND 1 OF REFUSAL:,,,

6.1.1 The amendments for addition of claims 9-21 and 28-30 are not allowable under section 59 of the Patents Act.,,,

RESPONDENTâ??S FINDINGS- Page 52 of the Appeal â??Explanation given to objection no 1 is not satisfactory and retained for amended,,,

claims 9-21 and 28-30. The amendments for addition of claims are not allowable as per section 59 of the Patents Act, 1970. Moreover these claims",,,

are not technically supported by the description. The specification provides only a vague speculation regarding the claimed sequences and its,,,

specificity.â??,,,

6.1.2 The Respondent erred in holding that the amended claims 9-21 and 28-30 were not in accordance with Section 59 of the Patents Act as,,,

amendments for addition of claims is not permitted under Section 59 of the Indian Patents Act, 1970 and that the said claims were not technically",,,

supported by the description which provides only a vague speculation regarding the claimed sequences and their specificity.,,,

6.1.3 The Respondent erred in deciding:,,,

a. whether the said addition of new claimsÂ isÂ by way of clarification, explanation or disclaimer or not; and",,,

b. whether the said revisions enlarge the scope of the claims and description as originally filed.,,,

6.1.4 At the outset, all claim amendments filed by the Appellant were within the

scope of the claims and specification as originally filed and no new",,,

matter was added. The new dependent claims 9-21 and 28-30 (see Pages 334-336 of the appeal) did not enlarge the scope of the original claims as,,,

originally filed, were supported by the description and claims and were meant for specific claiming by way of clarification. Support for the amended",,,

claims was provided to the Respondent in the hearing submissions (see Pages 318 to 319 of the appeal) and is again provided as follows:,,,

Rejected claim

no.","Support in PCT

claims",Support in specification,

Claim 9,Claim 6,Para [0054] and table 1 in para [0184],

Claim 10,Claim 5,Para [0086] and table 1 in para [0184],

Claim 11,Claim 5,Para [0086] and table 1 in para [0184],

Claim 12,Claim 5,Para [0086] and table 1 in para [0184],

Claim 13,Claim 5,Para [0086] and table 1 in para [0184],

Claim 14,Claim 6,Para [0088] and table 1 in para [0184],

Claim 15,Claim 5,Para [0086] and table 1 in para [0184],

Claim 16,Claim 5,Para [0086] and table 1 in para [0184],

Claim 17,Claim 5,Para [0086] and table 1 in para [0184],

Claim 18,Claim 4,Para [0083] and table 1 in para [0184],

Claim 19,Claim 6,Para [0088] and table 1 in para [0184],

Claim 20,Claim 6,Para [0088] and table 1 in para [0184],

Claim 21,Claim 6,Para [0088] and table 1 in para [0184],

Claim 28,Claim 1,"Paras [0058], [00105] and Example 1",

Claim 29,Claims 1 and 16,Paras [0058] and [00105],

Claim 30,Claims 1 and 16,Paras [0093] and [0095] and Example 1,

ii. That the law in India in relation to dependent claims is clear- dependent claims always â??NARROWâ?Â theÂ scopeÂ ofÂ theÂ claimsÂ,,,

andÂ donâ??t have the effect of enlarging the scope. Reliance is placed on the following case law and guidelines:,,,

a. Para 34(xi) of the order of Division benchÂ ofÂ theÂ Honâ??bleÂ DelhiÂ High Court in F.Â Hoffmann-LaÂ RocheÂ Ltd.Â & Anr. Vs.,,,

CIPLA Ltd. which states thatÂ â??WhereÂ claimsÂ areÂ â??dependentâ??,,,

it incorporates by reference â??everything in the parent claim, and adds some further statement, limitations or restrictionsâ??.",,,

b. Clause 05.03.16 (q) at page 43Â ofÂ the Manual of the Patent Office Practice and Procedure that clearly states that â??A dependent claim,,,

derives antecedence from an independent claim and reads into it the features of the independent claim and may contain optional features.â??-,,,

iii. That neither is the scope of the originally filed claims enlarged in view of the said addition of new dependent claims nor are the new dependent,,,

claims introducing matter in the specification which was not part ofÂ the original description.,,,

a. Reliance is placed on The Decision of the Honâ??bleÂ Â DelhiÂ Â HighÂ Â CourtÂ Â inÂ Â AGCÂ Â Flat Glass Europe SA v/s Anand,,,

Mahajan & Ors., wherein the Honâ??ble Court in para 17 clearly states that â?? the scope of enquiry in relation to amendments in the patent claim is",,,

limited to the extent as to whether it introduces any new claim which extends the scope of the monopoly rights of the patentee.â??,,,

b. Reliance is also placed on Para 23 of the orderÂ Â Â Â Â Â ofÂ Â Â Â Â Â theÂ Â Â Â Â Â Honâ??bleÂ Â Â Â Â Â,,,

IPABÂ Â Â Â Â Â in OA/7/2016/PT/MUM dated 12th October 2020:,,,

â??Now as both the amendments are not forming part of any newly introduced matter in the speciation rather they are part and parcel of the original,,,

disclosure in the complete specification, they do not attract the provisions of section 57 read withÂ section 59; as they do not go beyond the originally",,,

filed specification and were made as â??explanationâ?? fulfilling the criterion of amendments as per the teachings of section 57 read with section 59,,,

of the Patents Act, 1970.â??",,,

6.1.10 It is submitted that on a plain reading of Section 59, it is very clear that there is no bar with regard to addition of (a) new claims, (b) deletion of",,,

claims and (c) merging of claims. The only criteria that has to be looked into is whether the scope of the claims is enlarged or not by the said addition,",,,

deletion or merging of claims.,,,

6.1.11 In view of the above, it is respectfully submitted that clearly the Respondent failed toÂ appreciate and understand the purport of the expression",,,

â??scopeâ?? in Section 59.,,,

6.1.12 FromÂ claimsÂ 9-21Â andÂ 28-30,Â theÂ Honâ??bleÂ IPAB would appreciate that said claims further and specifically define the",,,

antibody referred to in claim,,,

1, and there is adequate support for said claims not just in the claims as filed but also in the complete specification of the present application.",,,

Accordingly, this ground of refusal does not apply.",,,

6.2 GROUND 2 OF REFUSAL:,,,

6.2.1 The subject matter of theÂ claims are productsÂ of nature and are not patentable under section 3(c) of the Patents Act.,,,

RESPODENTâ??S FINDING: â??the explanation and amendment of claims 1 and 31 is not found to be persuasive. The amendment to the claim 1,,,

by the addition of the word a 'non- human monoclonal' and by omitting the word ""isolated"" from in claim",,,

31 and does not makeÂ theÂ productÂ patentable under section 3 (c) of the Patents Act, 1970.",,,

These amendments makes the claimÂ broaderÂ in scope than the earlier claim, as it encompasses all non-human and isolated as well as the non-",,,

isolated ones existing anywhere. The objection 2 of hearing notice has not been met as the amended claims claiming for an anti-14-3-3 antibody which,,,

is not patentable as per the provisions of clause (c) of section 3 of the Patents Act, 1970. The claimedÂ subject matter in these claims is the",,,

discovery of the naturally existing antibody which are isolated. It is concluded that isolated anti-14-3-3 antibody was ineligible for patent protection as a,,,

product of nature.â??,,,

See page 52 of the appeal,,,

MONOCLONAL ANTIBODIES ARE NOT SUBSTANCES OCCURING IN NATURE AND DO NOT FALL WITHIN THE AMBIT OF,,,

SECTION 3(c) OF THE PATENTS ACT,,,

6.2.2 The monoclonal antibodies claimed in the present application are not substances occurring in nature but are very much products of human,,,

ingenuity.,,,

6.2.3 Firstly, the specific epitope fragments identified by the Appellant (5-20 amino acids) do not occur in nature per se but are part of a bigger protein",,,

(246 amino acids in length). Therefore, monoclonal antibodies against said

shorter peptide fragments do no occur in nature but have been created by",,,

the Appellant by identifying and designing specific antigens.,,,

6.2.4 Antibodies do not occur in nature in the monoclonal form but are present as a polyclonal pool. The claimed monoclonal antibodies have not been,,,

isolated from a pre-existing natural pool of antibodies. The Respondent has also not provided any reason or evidence to show that the claimed,,,

antibodies are derived from a natural pool. Thus, the claimed antibodies are not substance occurring in nature.",,,

6.2.5 The monoclonal antibodies claimed are produced by hybridoma technology which utilizes a man- made cell comprising a fusion of spleen cells,,,

with myeloma cells, that is, a hybridoma cell- See Page 107 of the Appeal. Hybridomas do not occur in nature. Accordingly, monoclonal antibodies",,,

produced by hybridomas cannot be substances occurring in nature.,,,

6.2.6 Moreover, the claimed antibodies have a different selectivity profile than what exists in nature, they necessarily also have different structural",,,

(e.g, different amino acid sequences and three- dimensional structures) and functionalÂ (e.g,Â bind to different antigens) characteristics. These",,,

difference rise to the level of a marked difference, and so the claimed antibodies are not â??living or non-living substances occurring in natureâ??.",,,

6.2.7 Thus even without the limitation of a â??non- humanâ? monocolonal antibody, the antibodies claimed in the present application were not",,,

products of nature. However, the limitation of â??non- humanâ? monocolonalÂ antibodyÂ as specified in the refused claims further distances the",,,

monoclonal antibodies claimed fromÂ products of nature asÂ theÂ specific human 14-3- 3? antigenic peptide does not occur naturally in non-human,,,

sources and antibodies to the same cannot and do not occur in non-human sources. As a composition resulting from a scientifically- induced cross-,,,

species immunological interaction, the antibody composition as claimed clearly cannot and does not occur in nature.",,,

6.2.8 Therefore, the Respondent very much erred in holding that â??The amendment to the claim 1 by the addition of the word a 'non- human",,,

monoclonal' and by omitting the word ""isolated"" from in claim 31 and does not make the product patentable under section 3(c) of the Patents Act,",,,

1970â??.,,,

6.2.9 The antibodies of the instant application were not known prior to the

instant application and the invention claimed in the instant application was,,,

the first to identify an anti-14-3-3 antibody exhibiting the requisite selectivity for human 14-3-3 eta over other human 14-3-3 protein isoforms and,,,

specifically binding to the disclosed amino acid sequences (see Table 1). In fact, as demonstrated by data submitted during the prosecution of the",,,

instant application, commercially available anti- 14-3-3-? antibodies were shown to be cross-reactive to other 14-3-3 isoforms due to the highly",,,

conserved nature of the 14-3-3 family of proteins and do not compare to the highly specific 14-3-3-? antibodies of the instant application.,,,

6.2.10 Even following the strict United States case law and the USPTO Eligibility Guidelines for examination of nature-based products, the antibodies",,,

of the instantÂ application are considered patentable. The U.S. case law and the USPTO guidelines expressly require an evidence that such an,,,

antibody is naturally-occurring. In particular, example 8 of the USPTO Eligibility explicitly indicates:",,,

6.2.11 Some murine antibodies to Protein S occur in nature, and it is possible that nature might randomly create a murine antibody having the CDR",,,

sequences of SEQ ID NOs: 7-12. But unless the examinerÂ canÂ showÂ thatÂ thisÂ particularÂ murine antibody exists in nature, this mere",,,

possibility does not bar the eligibility of this claim. See, e.g., Myriad, 133 S.Â Ct. atÂ 2119Â n.8Â (""The possibility that an unusual and rare",,,

phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter,,,

non-patentable"" (emphasis in original)). Because the claimed antibodies have different CDRs than what exists in nature, they have different structural",,,

(e.g., different amino acid sequences and three- dimensional structures) and functional (e.g., bind to different antigens) characteristics. TheseÂ",,,

differences rise to the level of a marked difference, and so the claimed antibodies are not ""product of nature"" exceptions. Thus, the claimÂ isÂ not",,,

directed to an exception (Step 2A: NO), and qualifies as eligible subject matter.",,,

https://www.uspto.gov/sites/default/files/docu ments/mdc_examples_nature-based_products.pdf,,,

6.2.12 Further monoclonal antibodies are considered patentable by the Indian Patent Office also.-,,,

i. See Annexure A8 at page 377 of the appeal, particularly, patent numbers 252161 and 254036 on page 378 which relate to antibodies by sequence of",,,

the epitope.,,,

ii. See also Annexure A9 starting at page 384 of the appeal which shows more than 800 patents granted in the field of antibodies.,,,

6.2.13 The Respondent has also erred in holding that â??These amendments makes the claim broader in scope than the earlier claim, as it",,,

encompasses all non-human and isolated as well as the non-isolated ones existing anywhereâ?? Emphasis added,,,

6.2.14 By amending the claims to recite non-human antibodies, the Appellant has in fact narrowed and not broadened the scope of the application as",,,

all human antibodies are excluded from the scope of patentability. In contrast the claims as filed relatedÂ Â Â toÂ Â Â â??antibodiesâ??Â Â Â,,,

whichÂ Â Â encompassÂ Â Â both human and non-human antibodies. Again the as filed claim has no restriction in relation to isolated and non-,,,

isolated antibodies. Therefore, this cannot be a concern in determining any change in claim scope. (See page 118 of the Appeal for as filed claim 1).",,,

6.3 GROUND 3 OF REFUSAL:,,,

6.3.1 Claims 32-33 are not supported by working examples and the claims are not supported by the description.,,,

RESPODENTâ??S FINDING: â??Explanation given to objection no 4 and 6 are not found be persuasive.,,,

The applicant had opined that the exemplification of the claims isÂ notÂ even mentioned as a criteriaÂ for patentabilityÂ underÂ the Indian,,,

Patents Act. So long as the claimed invention can beÂ easily understoodÂ andÂ worked by the person skilled in the art from a reading of the,,,

specificaion, the claims willÂ beÂ consideredÂ toÂ be sufficiently described by the specification.",,,

In applications directed to inventions in the unpredictable arts (biological, chemical, and pharmaceuticalÂ inventions,),Â theÂ disclosureÂ Â of a",,,

single species usually does not provide an adequate basis to support generic claims. Technology involvingÂ unpredictableÂ factors, such as most",,,

reactions andÂ physiological activity, may require more for enablement. A single example may suffice, but if theÂ claims cover a broad field,Â",,,

theÂ applicationÂ mustÂ include multiple examples extending over the entire

range of claimed subject-matter in orderÂ to satisfy 10(4)(a)Â &Â,,,

(b)Â ofÂ theÂ PatentÂ Act, 1970.",,,

The examples described inÂ theÂ instantÂ application described only the biological experimental evidences showing the antibodies against,,,

immunogen # 1 -4 (Sq ID 30, 31, 32 and 33)and not cross reactive with sixÂ other isoforms. Since none of the working examples provide ample",,,

evidence to specificity, the description is insufficient to substantiate the instant invention. No working examples are provided to prove that the anti-14-",,,

3-3 antibodies do not bind 14-3-3 eta protein in its natural configuration,,,

The amended claims 1-33 and description refers to the function of the antibodies recognizing epitopes of given sequences. The antibodies are,,,

characterized by its inherent characters not with its technicaI features.,,,

Amended claim 32 refers to making of an antibody, which is not clear with technical description and also not exemplified. Also this claim refers to",,,

introducing to a mammal with a peptide, which falls within the scope of 3(i) of the Patent Act, 1970.",,,

Amended claim 33 refers to a kit which must be characterized by its technical features. The instructions for use recited in the said claim areÂ to be,,,

considered as relating to presentation of information and therefore are not a technical feature of that kit and do not limit the scope of such claim.,,,

Amended claims 32 & 33 do not define any technical features of the invention.â??,,,

6.3.2 Sufficiency has to be looked through the eyes of a person skilled in the art who possesses common general knowledge and based on his common,,,

general knowledge and disclosure contained in the patent specification is able to carry out the claimed invention without undue experimentation. Just,,,

like India, the law in US, China, Europe and Australia requires that the disclosure should be sufficient to enable a person skilled in the art to work the",,,

invention.,,,

6.3.3 Sufficient experimental evidence is provided in the specification for a person skilled in the art to work the invention. The epitopes designed by the,,,

Applicant are identified in theÂ experimentalÂ section in table 1 in para [00184] (See pages 104 and 105 of the appeal).,,,

i. Example 1 shows that antibodies were raised against immunogens # 1-4 (SEQ ID 30, 31, 32 and 35). Of these immunogen#1 of SEQ ID NO: 30 is",,,

similar to immunogens of SEQ ID NOs: 25 and 28, immunogen#2 of SEQ ID NO: 31 is similar to immunogens of SEQ ID NOs 22, 23 and 27 and",,,

immunogen#3 of SEQ ID NO: 31 is similar to immunogens of SEQ ID NOs: 3, 4, 5 and 24. Thus the results shown in relation to immunogens# 1, 2",,,

and 3 of SEQ ID NOs: 30,",,,

31 and 32 can be reasonably extrapolated at least to SEQ ID NOs: 3, 4, 5, 22, 23, 24, 25, 27 and 28. Therefore, it is expected that antibodies said",,,

sequences shall demonstrate a similar profile as antibodies to SEQ ID NO: 30, 31, 32.",,,

ii. The method of production of the claimed antibodies using hybridomas has also been elaborated in Example 1. (See pages 106Â to 107 of the,,,

appeal),,,

iii. Example 2Â shows that the antibodies obtainedÂ in Example 1 showed specificity for the 14-3-3 eta isotype at two dilutions and did not cross-,,,

react with other 14-3-3 isotypes even at aÂ higher dilution. (See Table 4b at para [00205] on page 109 of the appeal),,,

iv. Example 4 shows that the antibodies claimed in Example 1 bind to both 14-3-3 eta protein obtained from the cell supernatants from lysed HeLA,,,

cells and human recombinant 14-3-3 eta protein. This shows that the anti-14-3-3-? antibodies obtained in Example 1 do inÂ factÂ bind the 14-3-3-?,,,

protein in its natural configuration.Â (SeeÂ ParasÂ [00209]Â toÂ [00212] on pages 109 and 110 of the appeal),,,

v. Example 3 and Figure 5, on the other hand show that commercially available antibodies raised against the N-terminus peptide of 14-3-3 eta, namely,",,,

Ac-DREQLLQRARLA, do not show specificity for 14-3-3 eta and cross-react with other 14-3-3 isoforms, particularly, 14-3-3 gamma. (See paras",,,

[00206] to [00208] on page 109 of the appeal),,,

6.3.4 TheÂ Â Respondentâ??sÂ Â observationÂ Â thatÂ Â â??noneÂ Â ofÂ Â the working examples provide ample evidence to,,,

specificityâ??Â Â Â isÂ Â Â incorrect.Â Â Â AsÂ Â Â discussedÂ Â Â above, Example 2 provides data on specificity. The RespondentÂ Â",,,

itselfÂ Â admitsÂ Â inÂ Â theÂ Â orderÂ Â thatÂ Â â??the examples described in the instant application described only the biological,,,

experimental evidences showing the antibodies against immunogen # 1-4 (SEQ ID NO: 30, 31, 32 and 35) and not cross reactive with six other",,,

isoforms.â?? Thus there is data available in the specification regarding specificity of the antibodies of the present application and there is sufficient,,,

data available to cover all aspects of the present application.,,,

6.3.5 Further, the Respondentâ??s finding that â??no working examples are provided to prove that the anti-14-3- 3 antibodies do not bind 14-3-3 eta",,,

protein in its naturalÂ configurationâ??Â isÂ absurdÂ andÂ isÂ basedÂ on an incorrect understanding of the present application.Â Â ItÂ Â,,,

hasÂ Â neverÂ Â beenÂ Â theÂ Â Appellantâ??s stand that the 14-3-3-eta antibodies of the instant application do not bind the 14-3-3 eta protein,,,

inÂ its natural configuration. In fact, the Appellant through theÂ instantÂ applicationÂ provides antibodiesÂ thatÂ bindÂ toÂ bothÂ",,,

recombinant 14-3-3 eta protein and to 14-3-3 eta protein in its natural configuration (See Example 4 on pages 109 and 110 of the appeal) but do not,,,

bind to the other isoforms of the 14-3-3 protein. Thus an expectation that the Appellant should have provided data in the complete specification to,,,

establish that the anti-14-3-3 antibodies do not bind 14-3-3 eta protein in its natural configuration is absurd and incorrect.,,,

6.3.6 Finally, so long as there is data provided in the completeÂ specificationÂ toÂ supportÂ theÂ Appellantâ??s claim, the requirement to",,,

provide data for each and every embodiment does not arise. Patent specifications are not production documents or experimental records. Therefore,",,,

an expectation that data be provided for each and every embodiment claimed is unreasonable.,,,

6.3.7 Examples are only meant to illustrate the workingÂ of the invention and, since the specification is addressed to the person skilled in the art, not",,,

everything needs to be exemplified. So long as the claimed invention can be easily understood and worked by the person skilled in the art from a,,,

reading of the specification, the claims will be considered to be sufficiently described by the specification. There is sufficient data provided in the",,,

complete specification to work the invention andÂ toÂ establishÂ theÂ Appellantâ??sÂ claim.Â Therefore, the question of lack of support in the",,,

description for want of working examples does not arise.,,,

6.3.8 The Respondent has further observed that the antibodies are characterized by the function of the antibodies recognizingÂ epitopesÂ ofÂ given,,,

sequences, that is, their inherentÂ characterÂ and not by their technical features.

This observation of the Respondent is also based on an incorrect",,,

understanding of the invention claimed in the present application.,,,

6.3.9 The ability of the antibody claimed to bind to specific epitopes is based on the antigens used for generation of the antibodies. Therefore, said",,,

ability is not inherent but has been tailored by the selection, designing and use of specific antigens/epitopes for the generation of the antibody.",,,

Therefore, the antibody is defined by its specific technical feature which is specific binding to 14-3-3 eta, lack of cross reactivity with other 14-3-3",,,

isoforms and ability to bind the specific epitopes defined. Thus the claimed antibody has not been defined by the functional features only but through a,,,

technical feature.,,,

6.3.10 There are several ways which antibodies can be claimed. The article at page 411 of the appeal provides that antibodies can be claimed by way,,,

of the epitope too.,,,

6.3.11 Further cases granted by the Indian Patent Office show that antibodies can be defined by way of their epitopes- See Annexure A11 starting at,,,

page 420 of the appeal, which shows:",,,

PatentÂ Â nos.Â Â Â Â Â 251532,,,

(1899/MUMNP/2007)Â and 230716Â Â Â Â Â Â (2592/CHENP/2005),,,

definedÂ Â Â Â Â Â Â Â Â Â Â Â throughÂ Â Â Â Â Â Â Â Â Â Â Â Â epitope sequences;,,,

PatentÂ Â nos.Â Â Â Â Â 254039,,,

(2581/KOLNP/2006) and 245214,,,

(1540/KOLNP/2006)Â Â defined through antigenic sequences; and,,,

PatentÂ Â Nos.Â Â Â Â 272873,,,

(4482/CHENP/2010),Â 235930",,,

(774/KOLNP/2006)Â and 243960,,,

(3239/CHENP/2006)Â Â defined through functional properties.,,,

6.3.12 The Respondent has further observed that claim 33 refers to a kit not defined by its technical features. It is submitted that Claim 33 is clearly,,,

defined by its technical feature which is the antibody of the specific 14-3-3 eta antibodies of the preceding claims. The novelty and inventive step of,,,

the kit is derived from the novel and inventive antibodies of the present application and not from the instructions for use objected by the Respondent.,,,

6.3.13 The Respondent also erred in holding that amended claims 32 and 33 do not define any technical features of the invention. Claim 32 recites a,,,

method for making the 14-3-3 eta antibodies of the present application by introducing a peptide selected from the group of SEQ ID NOs: 1-32 which,,,

yield the specific 14-3-3 eta antibodies of the present application. Once the epitope sequence is identified a person skilled in the art can easily produce,,,

the antibody using that particular epitope based on his common general knowledge. In fact the method of production of the antibody is provided in,,,

detail in Example 1 of the specification. Therefore, the technical feature is clearly defined. Claim 33 recites a kit comprising the novel and inventive",,,

14-3-3 eta protein specific antibodies of the present application. The novel and inventive antibodies are the primary technical feature of the kits,,,

claimed. Therefore, theÂ technical features are clearly defined. ThusÂ inÂ each of the rejected claims 32 and 33,Â the technical features are",,,

clearly defined.,,,

6.4 GROUND 4 OF REFUSAL:,,,

6.4.1 Claim 32 is not patentable under section 3(i) of the Patents Act.,,,

RESPONDENTâ??S FINDING: â??Amended claim 32 refers to making of an antibody, which is notÂ clearÂ with technical description and also",,,

notÂ exemplified. Also this claim refers to introducing to a mammal with a peptide, which falls within the scope of 3(i) of the Patent Act, 1970.",,,

CLAIM 32 IS NOT A METHOD OF TREATMENT, DIAGNOSIS, PROPHYLAXIS OR ANY OTHER METHOD RELATED TO THE",,,

TREATMENT OF HUMANS OR ANIMALS TO RENDER THEM FREE OF DISEASE OR TO INCREASE THEIR ECONOMIC VALUE,,,

6.4.2 At the outset, this objection was neither raised in the hearing notice nor during the hearing. Therefore, the rejection of claim 32 under section 3(i)",,,

is unjust as the Appellant was not given an opportunity to address said objection. This act of the Respondent is against the principles of natural justice.,,,

6.4.3 Further, the method of making the claimed monoclonal antibody is clear and exemplification for the same is provided in Example 1 of theÂ",,,

present application.,,,

6.4.4 The Respondent has erred scientifically in holding that claim 32 â??refers to introducing to a mammal with aÂ peptide,Â whichÂ fallsÂ",,,

withinÂ theÂ scopeÂ of 3(i) of the Patent Act,Â 1970.â?Â Claim 32 is directedÂ to

a method for preparing a monoclonal antibody. The said",,,

method is a â??biotechnological processâ? of preparing antibodies (recombinant biotechnology) that requires a mammal (such as laboratory bred,,,

BALB/c mice as seen from Example 1). Said step is essential in the production of monoclonal antibodies by hybridoma technology,,,

6.4.5 Since the introduction of the peptide into the mammal as required by claim 32 is not intended for diagnosis, treatment or prophylaxis of a host but",,,

is meant for production of antibodies, the method of claim 32 cannot be treated to fall within the scope of section 3(i) of the Patents Act.",,,

6.5 GROUND 5 OF REFUSAL:,,,

6.5.1 Claims 1-33Â lackÂ inventiveÂ step RESPONDENTâ??S FINDING: â?? Antibodies which specifically bind to 14-3-3 antibodies were,,,

already knownÂ Â in the art, which was evident from D1 to D5.",,,

D1 discloses an anti-14-3-3 eta polyclonalÂ antibody that specifically binds to human 14-3-3 eta protein in its natural configuration, wherein said",,,

antibody does not bind to an epitope located at the N- terminus of humanÂ 14-3-3Â eta and which further exhibits selectivity forÂ 14-3-3Â etaÂ,,,

over the other 14-3-3 protein isoforms. The anti-14 -3-3 eta antibody of D1 inherently binds to an epitope comprising either a 14-3 -3 eta helix peptide,,,

or a 14-3-3 eta non-helix peptide and further would be suitable for use in treating arthritis in a patient. D2 and D3 each disclose an anti-14- 3-3 eta,,,

polyclonal antibody that specifically bindsÂ toÂ human 14-3-3 eta protein in its natural configuration, wherein said antibody exhibit s selectivity for",,,

14-3-3Â eta over the other 14-3-3 protein isoforms. The antibody of D2 and D3 is capable of immune precipitating 14-3-3 eta fromÂ a biological,,,

solution and has utility in immunohistochemistry. Moreover, the anti-14-3 -3 eta antibody of D2 and D3 inherently binds to an epitope comprising either",,,

a 14-3-3 eta helix peptide or a 14-3-3 eta non-helix peptide and further would be suitable for use in treating arthritis in a patient.,,,

Amended claims 1-33 lackÂ anÂ inventiveÂ stepÂ inÂ view of any one of D1 -D3 when combined with D4 or D5 and common knowledge in the,,,

art. D1-D3 each discloses an anti-14-3-3 eta antibody that specifically binds to human 14-3-3 eta protein in its natural configuration. D4 andÂ D5Â,,,

each disclose that elevated levels of 14-3-3 eta protein are present in the synovial fluid and serum of patients with arthritis. The skilledÂ personÂ,,,

wouldÂ thereforeÂ beÂ motivatedÂ to use common method of the corresponding technicalÂ field and hence theÂ claimsÂ lackÂ inventiveÂ,,,

stepÂ overÂ theÂ documents D1 -D5. Since the priorÂ artÂ documentsÂ disclosesÂ the 14-3-3 isoforms and identifying isoform specific,,,

epitopes to generate isoform selective antibody, the instant invention is obvious to a person skilled in the art.â??",,,

6.5.2 The Respondent has erred in their inventive step analysis for the following reasons:,,,

i. Failure to apply the correct test of obviousness: The closest prior art was not identified by the Respondent. Further the assessment of the prior art,,,

along with the other teachings not conducted fromÂ theÂ perspective of a person skilled in the art who has to be motivated to combine teachings of,,,

the prior art and must have reasonable expectation of success. Where the prior art does not give any direction to the invention the prior art cannot be,,,

said to obviate the invention in question.,,,

Antibody,Covered by prior art,"Cross reactivity

established in",Binds to

sc-17287 of Santa

Cruz Biotechnology,

Inc.","D1 (DiFede et al.) - P.

62 of document compilation,

table, third last entry","SIGNALCHEM

document submitted

with the hearing

submissions and with

the reply to

the FER","14-3-3 beta,

epsilon, gamma

and sigma

Cat#IB18645 of

Immunobiological

Laboratories","D2 (Sato et al.)- P. 76

of the document
compilation, under
materials and
methods, 1st para, 4th
last line
D3 (Satoh et al.)- P.
81 of the document
compilation, 1st
column, 2nd para, lines
14-16","SIGNALCHEM
document
submitted with
the hearing
submissions and
with the reply to
the FER","14-3-3 epsilon,
gamma, sigma
and zeta
SA476-0100 of
Biomol","D4 and D5 (P. 114 of the
document compilation, lines
24-
30)
(Martin et al.whose Abs
are used in D5Â talk of
antibodies to a similar
epitope
(Ac.GDREQLLQRARZ)
as that used for the
generation of Biomolâ??s

SA476-0100 (Ac-

DREQLLQRARLA))","Complete specification,

page

37, Fig 4,

Example 3

Dr. Marottaâ??s US

declaration

read with Exhibit A","14-3-3 Gamma

AlsoÂ Exhibit A

o f Marottaâ??s

declaration show

that t h e Biomol

Antibody does not

bind to 14-3-3 eta

in its native

configuration

(Ac-DREQLLQRARLA-NH2) epitope from the N-terminus of 14-3-3 eta (Biomol International LP, Cat. SA476-0100). However, as stated on page",,,

37 of the application and shown in Figure 5 (Page 109 of the appeal), apparently this commercially available antibody against 14-3-3 eta cross reacted",,,

with other 14-3-3 isoforms, primarily gamma. Thus, Example 3 of the present application shows that antibodies directed against N-terminal epitope",,,

DREQLLQRARLA (polyclonal antibody preparation sold by Biomol) do not specifically bind human 14- 3-3 eta protein and are not selective for 14-3-,,,

3 eta protein over other human 14-3-3 protein isoforms as required by present claim 1.,,,

6.5.20 Further a declaration filed in corresponding U.S. application number 12/745,235 (which has been allowed) by Dr. Anthony Marotta was",,,

submitted with the reply to the first examination report as Annexure B. Said declaration confirms that the epitope targeted by the Kilani and WO,,,

2007/128132 references is the same as the commercial anti-14-3-3 eta antibodies produced by Biomol (SA476-0100) and that tests with the Biomol,,,

antibody have shown it to be cross reactive with other 14-3-3 isoforms. For example, Dr. Marotta establishes that â??[t]he sequence used by",,,

MartinÂ Â etÂ Â al.Â Â (Ac-GDREQLLQRARZ)Â Â isÂ Â highly similarÂ toÂ theÂ immunogenicÂ sequenceÂ usedÂ Â by Biomol,,,

(now Enzo) to generate its SA476-0100 antibody product (Ac-DREQLLQRARLA). The slight differences are restricted to each peptide termini and,,,

are likely species related, but overall the sequences are identical.â? (See Para 6 on Page 348 of the appeal). Appendix B and C enclosed with the",,,

declaration provide product data sheets for the Biomol SA476-0100 antibody and blocking peptide, respectively. (Marotta Declaration, para 6- Page",,,

348 of the appeal) In characterizing the commercially available antibodies for selectivity and affinity to 14-3-3eta, Dr. Marotta describes the SA476-",,,

0100 antibody used in the cited prior art reference as lacking the ability to bind 14-3-3 eta protein in its natural configuration and/or exhibit selectivity,,,

for human 14-3-3 eta protein over other human 14-3-3 protein isoforms. Further, the data presented in Appendix A accompanying the Marotta",,,

Declaration demonstrates how the SA476-0100 antibody recognizes the gamma isoform in addition to the eta isoform. (Marotta Declaration, para 7-",,,

Page 349 of the appeal).,,,

6.5.21 Considering the above, starting from any one of references D1-D5, the objective technical problem can be formulated as: How to provide 14-3-",,,

3 eta specific antibodies? The solution according to the instant application is neither disclosed, nor suggested, in any of the prior art documents, alone",,,

or in combination.,,,

6.5.22 Based on the data and disclosure in the present application as well as evidence submitted along with the reply to the first examination report,,,

and the hearing submissions it was established that one of ordinary skill in the art would reasonably conclude that D1-D5 do not teach or suggest the,,,

invention as presently claimed. Accordingly, the claims of the instant application comprise an inventive step.",,,

6.5.23 In view of the foregoing submissions it is clear that the instant application isÂ inventiveÂ andÂ clearly does not fall within the prohibitory,,,

ambit of section 3(c) or section 3(i) of the Patents Act, provides sufficientÂ workingÂ examplesÂ and sufficient and clear disclosure in the",,,

complete specification for a person skilled in the art to work the invention and

that all claim amendments are well supported by the claims as filed and,,,

the complete specification. None of the grounds of rejection raised by the Respondent is valid or applies to the claims of the instant application. In,,,

view of the same, the rejection of the instant application by the Respondent is wholly Â unjustified.",,,

7. We have considered the submissions of the learned counsel of the appellant and analyzed vis- a-vis the order of learned Controller.Â On the issue,,,

of the amendment of claims, we partially agree with the appellant that the amendments were made for defining the claims in a better way and in their",,,

opinion; it was for narrowingÂ Â Â the scope. But what made them not to consider all this aspects prior to filing PCT International application, which",,,

was filed only with 26 claims and possible widest principal claim, which could accommodate many variations.",,,

8. We still observe that the claims on record should be commensurate with the contribution made. We direct the appellants to file the amended set of,,,

claims incorporating the following amendments:,,,

The principal claim 1 shall be restricted with the feature(s) of claim 9;,,,

Claim 4 should be restricted to SEQ ID NO. 3-5,,,

Claim 5 should be restricted to SEQ ID 29 and 32,,,

Claims 3, 6, 7, 8, 13, 15-21 and 32 should be deleted.",,,

9. We are of the opinion that for the reasons as explained by the appellant a â?? non- humanâ? monocolonal antibody, do not attract the provisions of",,,

section 3(c) of the Patent Act, 1970.",,,

10. We are also inclined to accept the arguments of the learned counsel of the appellant with regard to the official requirement of lack of inventive,,,

step. With restriction of claims as shown in paraÂ Â Â 8 above this requirement will further be obviated.,,,

11. We direct the appellant to submit the amended set of claims to the respondent, within 3 weeks from the date of issuance of this order.",,,

12. We, set aside the impugned order dated 07/12/2016 issuedÂ by the respondent, and direct the respondents to grant the patent on the amended set",,,

of claims, within 3 weeks from the submissionÂ of the amended set of claims.",,,

13. Keeping in view the above facts and circumstances, the instant appeal is

allowed. No cost.",,,

