**(2021) 01 IPAB CK 0008**

**In the Intellectual Property Appellate Board**

**Case No :** Original Application No. 52 Of 2014/PT/CH

Oncotherapy Science, Inc. — APPELLANT

Vs

Assistant Controller Of Patents And Designs — RESPONDENT

**Date of Decision :** 18-01-2021

**Acts Referred:**
Indian Patents Act, 1970 — Section 3, 3(d), 10(4)(c), 15, 117A

**Citation :** (2021) 01 IPAB CK 0008

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

**Bench :** Division Bench

**Advocate :** Ujjwala GH

**Final Decision :** Allowed

## Judgement

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 02/05/2014, passed by the Respondent,

being the Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, 1970, refusing to grant the Appellantâ??s Indian

patent application no. 954/CHENP/2008.

2. It is the case of the appellant that:

In the hearing notice the Controller had raised objections 1 to

4. In refusal order, Controller has accepted that objection no.

3 - u/s 3 (d) and objection no. 4 - regarding scope of the invention u/s 10 (4) (c ) are met. In the order, the Controller records that objections 3 and 4

are complied by the applicant. The Controller refused the Application on following grounds:

Lack of novelty and inventive step in view of the cited prior art documents: D1: US 7166573

 

For falling under the scope of sec 3 (c).

3. The invention as explained by the learned counsel of the appellant is as under:

Â Claim 1 of the present invention recites a decacpetide consisting of the amino acid sequence SEQ ID NO: 7.

Â The claimed decapeptide induces cytotoxic response in vivo.

The claimed sequence exhibits significant improvement in properties in regard to therapeutic efficacy. The peptide if SEQ ID NO: 7 of the present

application has high efficacy for inducing cytotoxic T-cell response, since the claimed peptide can induce cytotoxic response without being digested in

the dendritic cells. The peptide of the present invention is effectively presented on an antigen presenting cells and can induce cytotoxic T lymphocytes

when administered into the subject.

4. The learned counsel of the appellant has also submitted the distinguishing feature(s) of the invention over the cited prior art D1: US7166573, as

follows:

Â Objection 1:

Â The claimed sequence in the present patent application is structurally and functionally distinct in regard to the sequence in the cited document.

The cited document US7166573 discloses nearly 661 amino acid sequences. SEQ ID NO: 599 is one of them. The amino acid sequence of SEQ ID

NO: 599 disclosed in US7166573 is 319 amino acids in length.

The sequence claimed in the present application is 10 amino acid sequence.

Claim 1 defines a decapeptide - 10 amino acid sequence which is structurally distinct from cited sequence SEQ ID NO: 599.

The claimed sequence exhibits significant improvement in properties in regard to therapeutic efficacy. In order for a peptide, to induce therapeutic

response in vivo, the peptide needs to be uptaken by and digested in the dendritic cells. Further, peptide needs to bind to Human Leucocyte antigen

molecule and to be presented on antigen presenting cells. In this regard, it is unclear from the cited document, whether the full length protein of SEQ

ID NO: 599 can be uptaken by and digested by the dendritic cells. Moreover, it is also unclear whether, number of potential 10 amino acid sequences

possible from the cited 319 amino acid sequence, can bind to the Human Leukocyte Antigen molecule and can be presented on antigen presenting

 

cells. Accordingly, it is not clear from the cited document whether protein of the cited sequence SEQ ID NO: 599 with 319 amino acids can induce a

cytotoxic response in vivo as by the claimed decapeptide.

The claimed SEQ ID NO: 7 demonstrates cytotoxic T- lymphocyte inducing ability as disclosed in the specification.

From SEQ ID NO: 599 with 319 amino acids, number of stretches of 10 amino acids are possible. Any peptide fragment derived from the sequence

SEQ ID NO: 599 having 319 amino acids does not necessarily have cytotoxic T cell inducibility.

The peptide of SEQ ID NO: 7 of the present application has high efficacy for inducing cytotoxic response, since the peptide can induce cytotoxic

response without being digested in the dendritic cells. The peptide of the present invention is effectively presented on an antigen presenting cells and

can induce cytotoxic T lymphocytes when administered into the subject. Therefore, the peptide of the present invention has the significant

improvement in regard to therapeutic efficacy compared to the full-length amino acid sequence of 319 amino acids.

In order for a peptide to induce cytotoxic response in vivo, the peptide needs to be uptaken by and digested in the dendritic cells.

There is no concrete data in cited prior art document whether full length amino acid sequence of 319 amino acids can induce cytotoxic response in

vivo.

Affidavit has been filed providing experimental data which demonstrates that the peptide fragments derived from the cited sequence other than SEQ

ID NO: 7 do not have CTL inducibility.

All peptide fragments derived from the cited sequence do not necessarily have CTL inducibility and the claimed peptide has significant therapeutic

improvement as admitted by the Learned Controller by waiving objection u/s 3 (d).

Â The Learned Controller has stated in her order that objection u/s 3 (d) is met admitting that the claimed sequence is not a known substance and the

claimed sequence is therapeutically effective.

Â Thus, the claimed ten amino acid sequence SEQ ID NO: 7 is structurally and functionally distinct than the 319 amino acid sequence SEQ ID NO:

599 in the cited document. Therefore, the sequence is novel.

 

Â Functionally, the sequence has significant and distinct property in regard to the property of inducing cytotoxic T- lymphocyte response. Therefore,

the claimed sequence is inventive over the cited document.

Â For the above reasons, it is humbly submitted that the invention claimed in the present application is novel and it is not obvious over D1.

Â It is further submitted that the same claim has been granted patent by the Patent Offices of Japan, EPO, USPTO, Australia, China, Korea, Mexico

and Russia. The Patent Offices of Japan, EPO, Australia, China, Korea, Mexico and Russia have not even considered the document D1: US7166573

as prior art relevant to be cited. We hereby submit that the Applicant - the Appellant herein, as bound by the obligation of his duty of disclosure of IDS

(Information Disclosure Statement) as per USPTO Patent Law, brought the document US7166573 in notice of USPTO on December 5, 2013 as the

document was cited in Indian Examination Report. The document has been considered during examination of the counterpart US application by the

charge Examiner of USPTO. The disclosure of the document before USPTO Examination board had no impact on grant of patent and the counterpart

US application has been allowed for patent in US on March 18, 2014. Subsequently, the counterpart application before EPO has been decided to grant

patent on April 28, 2016.

Â Objection 2:

Â In regard to Objection 2, claimed 10 amino acid peptide and the 319 amino acid sequence in the cited document are structurally distinct and

therefore cannot be considered as existing in nature. The claimed peptide sequence SEQ ID NO: 7 is 10 amino acids in length, however the sequence

disclosed in the cited document SEQ ID NO: 599 is 319 amino acids in length.

Â Further, the synthesized peptide defined in claim

1 has amino group (-NH2-) at N- terminus and carboxyl group (-COOR) at C-terminus of the peptide sequence, SEQ ID NO: 7. On the other hand, in

the amino acid sequence of SEQ ID NO: 599, in the cited document, amino group (-NH2) and carboxyl group (-COOH), in the region corresponding

to the amino acid sequence of SEQ ID NO: 7 of the present application are dehydrated into â?"NH and â?"CO, due to the peptide bonds formed with

the neighboring amino acids. Therefore, the peptide of SEQ ID NO: 7 is structurally distinct than the one, 319 amino acids sequence from the cited

 

document. Therefore the claimed sequence cannot be considered to be existing naturally and cannot fall in scope of sec 3 (c).

5. We have reviewed the prosecution history of the instant application at IPO. We observe that there are three examination reports issued in the

instant case, shown as herein below:

Â The First Examination Report (FER) was issued on 03/01/2013 containing the main objections as follows:

A second examination report (SER) was issued on 26/07/2013, after considering the response of the appellants on the above quoted FER, as follows:

Subsequently, on receipt of the response of the above objections from the appellant, a Third Examination Report (TER) was issued on 20/11/2013

having main objections as follows:

The response of the said Third Examination Report was considered at IPO and a hearing notice was issued on 06/01/2014 which contained the

objections as follows:

6. Letâ??s have a look on the order dated 02/05/2014 of the Respondent:

7. We have found that the appellant also filed a divisional application to this instant application as patent application no. 8618/CHENP/2013 dated

25/10/2013, which now stands abandoned, vide IPO letter dated 15/07/2019.

8. Thus, it is evident that the citation mentioned in FER was successfully countered by the appellant and hence second examination report didnâ??t

have any objection on the ground of novelty, inventive step or section 3. It carried objections on to plurality of invention, definitiveness of claims and

lack of support of claims in the description. However, the third examination report relied upon another citation D1: US7166573.

9. We have reviewed that while prosecution of the corresponding application in USA, the applicant themselves has disclosed the citation D1:

US7166573 and after due consideration; the patent was granted in that jurisdiction. All the cited references in USPTO are enlisted below and it is

evident that lone citation relied in the instant application at IPO i.e. D1: US7166573, also find itself in the category of Cited documents indicated by the

applicant.

Cited documents identified in the search

i. US000005539084A ii. US000005785973A iii. US000005840839A

 

Â Cited documents indicated by the applicant

i. US000007166573B1 ii. US000007700359B2 iii. US020040181344A1 iv. US020040265230A1 v. WO002001049310A1 vi. WO002004018667A1 vii.

WO002004061423A2

10. We have also reviewed the International Search Report (ISR) and International Preliminary Examination Report (IPER) in the instant application

at International phase and found it as follows:

It worth mentioning here that the present existing claim in the instant application corresponds to claim 29 of the PCT International application and the

appellant entered national phase at IPO as this claim at claim no. 29 itself.

11. Hence, we do not agree with the respondent that claim 1 is newly added rather it existed right from beginning. Secondly, we observe from the

order of the respondent that she has waived off objections at sl no. 3 and 4 of the hearing notice, which related to section 3(d) and scope under section

10(4)(c) of the Patents Act, 1970. Her objection with respect to section 3(d) was that:

The respondent holds that considering their submission for the requirements of objections at 3 and 4 of the hearing notice during hearing, the

requirement are treated having met. Hence, one thing is clear that she was convinced that the applicant was successful in demonstrating the

significant improvement in the properties with regard to therapeutic efficacy over the known sequence 599 of US 7166573.

12. Letâ??s have a look on the legal provisions of section 3(d)1:

The following are not inventions within the meaning of this Act,â?

â?¦.

â??(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or

the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such

known process results in a new product or employs at least one new reactant.

Explanation.â?"For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers,

complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in

 

properties with regard to efficacy;

13. On holding that the requirements of section 3(d) is met; the respondent agreed that the invention no more falls in the category of mere discovery of

new form of known substance or such new form is having distinguishable therapeutic efficacy over that known form- a requirement to negate the

applicability of section 3(d).

1 Available at https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html

14. Further, we are convinced by the affidavit or from the submission of the appellant that though the sequences of native TOM 34 protein may be

alike with that of SEQ ID No. 7; but the claimed ten amino acid sequence SEQ ID NO: 7 is structurally and functionally distinct than the 319 amino

acid sequence SEQ ID NO: 599 in the cited document and therefore, cannot be considered as not novel or existing in nature.

15. However we are of the opinion that for better clarity of the claim the claim should be slightly amended as

â??A synthesized decapeptide, having cytotoxic T cell inducibility, consisting of the amino acid sequence of SEQ ID NO:7 (KLRQEVKQNL).â??

16. Accordingly, we direct the appellant to file the amended set of claim as shown in paragraph 15 above, within 3 weeks from the issuance of this

order.

17. We set aside the impugned order of the respondent dated 02/05/2014 and direct the respondent to grant patent on the amended set of claim strictly

within 3 weeks from the submission of the amended set of claim by the appellant.

18. Keeping in view the above, the instant appeal is allowed. No cost.

 