Intellectual Property Appellate Board
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OA/12/2020/PT/CHN

MONDAY, THIS THE 1ST DAY OF FEBRUARY, 2021

HON'BLE SHRI JUSTICE MANMOHAN SINGH — **CHAIRMAN**
HON'BLE DR. B.P. SINGH — **TECHNICAL MEMBER (PATENTS)**

ALLEGRO PHARMACEUTICALS, LLC
OF 31103 RANCHO VIEJO ROAD,
#2249, SAN JUAN CAPISTRANO, CA 92675,
US **… APPELLANT**

(Represented by: Ms. Meera Venugopal Gobind)

Versus

CONTROLLER OF PATENTS AND DESIGNS
GOVERNMENT OF INDIA, PATENT OFFICE
INTELLECTUAL PROPERTY RIGHTS BUILDING
GST ROAD, GUINDY
CHENNAI – 600 032 **… RESPONDENT**

(Represented by - None)

ORDER

Hon'ble Shri Justice Manmohan Singh, Chairman

Hon'ble Dr. B.P. Singh, Technical Member (Patents)

1. The present appeal is filed under Section 117A of the Indian Patents Act, 1970, against the order dated 31/12/2019, passed by the Respondent, being the Assistant Controller of Patents & Designs, under Section 15 of the Indian Patents Act, 1970, refusing to grant the Appellant's Indian patent application no. 4931/CHENP/2012.
2. The invention as explained by the appellant:

   2.1 The present invention relates to peptides for inhibiting cellular adhesion to Arg-Gly-Asp (the "RGD" tripeptide)

binding sites and related treatments for disorders involving cellular adhesion to "RGD" tripeptide. The present invention provides novel compounds (peptides) comprising R-G-Cysteic Acid (i.e., R-G-NH-CH(CH_2-SO_3H)COOH or Arg-Gly-NH-CH(CH_2-SO_3H)COOH) peptides. Specific examples of R-G-Cysteic Acid peptide of this invention include a linear form of Arg-Gly-NH-CH(CH_2-SO_3H)COOH (example referred to as Compound 1) and a cyclic form of Arg-Gly-NH-CH(CH_2-$S0_3H$)COOH) (example referred to as Compound 2). The invention discloses compounds having General Formulas I – VII, all of which were encompassed by the claims as originally filed. However in the final amended claims, compounds were restricted so that all claimed compounds are within the scope of general formula VII.

3. The case of the appellant is that:

3.1 The application was refused under a single ground, i.e., Section 59 of the Act. Even though various objections were raised in the hearing notice, which the appellant had addressed by amendments and arguments, there is no comment on any of those in the refusal order.

3.2 During the hearing, in view of the objection related to novelty, inventive step and clarity, the appellant proposed to restrict claim 1 to specific peptide compounds within the scope of the pending claims, which compounds were believed was novel and inventive, as proved by the grant of the same in at least about 26 corresponding applications including major jurisdictions such as USA, Europe, Japan, Australia, New Zealand, Russia and Israel.

3.3 Accordingly an amended set of claims 1 to 5 was filed on 03 December 2019 along with the written submission after the hearing.

3.4 Claims of the application: The following claim sets were filed through the entire prosecution of the application.

- Original claims filed with the PCT application and entered India.
- Claims as amended on 07 August 2018 with reply to FER
- Claims as amended on 03 December 2019 with written submission based on hearing.

Original claims:

3.5 The original claims of the international application PCT/US2010/056277 included totally 31 claims.

3.6 Claim 1 was directed to *'A method for inhibiting adhesion to RGD binding sites in a human or animal subject, said method comprising the step of: administering to the subject an effective amount of an RGCysteic Acid Peptide or derivative thereof'.*

3.7 Claims 2 to 19 were dependent on claim 1.

3.8 Claim 20 was related to *'A composition of matter comprising an RGCysteic Acid Peptide or derivative thereof'.*

3.9 Claims 21 to 30 were dependent on claim 20.

3.10 Claim 31 was related to a *'A method for filling, scaffolding or promoting tissue growth at a desired location in the body of a human or animal subject comprising the step of: introducing, into the subject's body at the desired location, a composition according to either of claims 29 or 30'.*

Claims as amended on 07 August 2018 with reply to FER

3.11 Claims were amended in view of the objections of the FER. Claims 1 to 19 and 31 were deleted in view of objection under Section 3(i) of the Act.

3.12 Original Claims 20 to 30 (revised claims 1 to 11) were retained with amendments.

Claims as amended on 03 December 2019 with written submission based on hearing.

3.13 Claims were amended in view of the objections of the Hearing Notice.

3.14 Previous claim 11 was made as claim 1. Claims 2 to 5 were included based on the pending claims, the basis for which was clearly provided in the written submission.

3.15 The basis of all the amended claims was clearly given in the written submission filed after the hearing.

3.16 We submit that all amended claims are within the scope of the claims before amendment, original claims and supported by the description this is explained below.

3.17 As indicated above, the amended claim 1 is based on previous claim 11 and within the scope of previous claims 1, and 7; and original claims 20 and 27. This is a specific example of General formula VII claimed in previous claim 7 and original claim 27; and supported by the description Page 4 (last 3 paras), page 5 paragraph 3 [page 55- 56 of the appeal]).

3.18 Previous Claim 11 which forms the basis of the amended claim 1, was related to a composition of matter comprising an RGCysteic Acid Peptide or derivative thereof. By the amendment, this was restricted to a compound comprising a peptide, wherein the peptide comprises Glycine-Arginine-Glycine-Cysteic(Acid)-Threonine-Proline.

3.19 The peptide Glycine-Arginine-Glycine-Cysteic(Acid)-Threonine-Proline of the amended claim 1 is a specific peptide within the scope of the RGCysteic Acid Peptide of previous claim 11 which is of much restricted scope.

3.20 Claim 2 relates to compound 1 which recites the structural formula of the peptide claimed in claim 1, and is supported on page 5 paragraph 3 and on page 14 line 5 and examples 1

to 4; which is within the general formula VII (page 4-5). This is within the scope of previous claims 1, 7 and 11 and original claims 20 and 27.

3.21 Claim 3 is based on original claims 20, 27 and 28 & previous claims 1, 7 and 8, which is the cyclic form of general formula VII [shown as structural formula] of formula C (example - compound 2) on page 12 para 1; page 15 and page 20 of the specification. This is within the scope of previous claims 1, 7 and 8.

3.22 Claim 4 relates to compound 3 which is based on original claims 15 and 20 which is based on Example 5 on page 42-43 of the specification. This compound is within the scope of previous claim 1.

3.23 Claim 5 is related to a pharmaceutical composition comprising the compound as claimed in claims 1 to 4 as above, and is within the scope of all previous claims and supported by the examples of the specification.

THE ISSUE OF SECTION 59

3.24 The amended claim 1 (refused claim 1) is as follows:

A compound comprising a peptide, wherein the peptide comprises Glycine-Arginine-Glycine-Cysteic(Acid)-Threonine-Proline.

3.25 Before amendment this was claim 11 which was as follows:

A composition of matter comprising an RGCysteic Acid Peptide comprising Glycine-Arginine-Glycine-Cysteic(Acid)-Threonine-Proline.

3.26 The above amendment was necessitated in view of Controller's maintenance of objection from the FER and Hearing notice regarding the clarity and conciseness as below:

Clarity and Conciseness

The composition (amended claims 1-11) should be made definite by replacing the term "comprising" with "consisting" and including all the essential constituents of the composition. 3. Claims 1-8 recites to composition, but these claims define the features of a compound. The composition should be defined with its technical features (having at least 2 components, should also demonstrate synergistic mechanism of action in order to be patentable)

3.27 The only change made in the claim is that the phrase 'composition of matter' was changed to 'compound'.

3.28 This is the reason for refusal stated in the order, that the amendment from 'composition of matter' was changed to 'compound' is not allowable under Section 59 of the Act.

3.29 Appellant however disagrees and submits that there is no Section 59 violation – because 'Compound' is within the scope of 'Composition of matter'.

3.30 Appellant respectfully submits that the present application is a national phase application of PCT/US2010/056277. Therefore claims have been drafted in compliance with the US patent practice. As per US patent Law, 'composition of matter' is one of the four principle categories of things that may be patented. A newly synthesised chemical compound or molecule can be patented as 'composition of matter'. Examples of composition of matter includes chemical compounds, compositions etc.

4. As rightly submitted by the learned counsel of the appellant, the instant application entered into National Phase at IPO, with originally filed 31 claims with PCT International Application no. PCT/US2010/056277 and claim number 20 thereof defined "*A composition of matter comprising an RGCysteic Acid Peptide or*

derivative thereof." The claims dependent on it, upto claim number 28, defined the said composition with different general formulae.

5. The First Examination Report (FER) objected claims 1-8, 20-24 and 29-31on the ground of lack of novelty. It held as under:

D1-D5 discloses peptides comprising RGC sequence bound to radioactive metal and use thereof for imaging or treating cancer. The claims 1-8, 20-24 and 29-31 are not novel over D1. The claim 20 is directed to composition comprising RGCysteic acid peptide or derivative thereof. It appears that when X is H in the formula of claim 22 is H in the formula of claim 22 cysteine is claimed. When X and Z are H in the formula of claim 23 serine falls within the scope of said claim. Therefore, it appears that the claims 20-24 are anticipated by D1-D5. Claim 29 lacks novelty over D3 insofar as albumin particles would fall in the scope of terms 'filler' or 'bioengineering material'. Claims 30 and 31 also lack novelty over D3.

6. In response to the said FER, the appellant submitted the amended set of claims wherein they deleted claims 1-19 and 31. Claims 21-30 was renumbered as claims 1-10 and claim 20 was amended and placed as claim 11.

7. The hearing notice issued on 18/10/2019 contained the following objections:

Other Requirement(s)

The submissions in your letter dated 07 August 2018 have been considered carefully. However, the requirements of head 2(1)(j), Non-Patentability, Sufficiency of disclosure and clarity and conciseness of First Examination Report dated 08/01/2018 have not been met.

Invention u/s 2(1)(j)

Amended claim 1 is directed to a composition comprising an RGCysteic Acid Peptide with a general formula. However, the compounds of claims 2-7 do not have a cysteic acid residue. This

inconsistency cast a doubt on the meaning given to the term cysteic acid in claim 1. Due to the lack of clarity, it appears not clear whether the amended claim 1 is delimited from the prior arts D1-D4. D5 discloses a peptide comprising a RGC(SO2H)GGGDG sequence which seems to fall in the scope of claims 1 and 4.

Non-Patentability u/s 3

The composition claims 9 and 10 with multiple components attract section 3(e) of the Patents Act,1970.

Sufficiency of Disclosure u/s 10 (4)

Source and geographical origin of the biological material used should be given in the specification in accordance with section 10(4)(d).

Clarity and Conciseness

The composition (amended claims 1-11) should be made definite by replacing the term "comprising" with "consisting" and including all the essential constituents of the composition. Claims 1-8 recites to composition, but these claims define the features of a compound. The composition should be defined with its technical features (having at least 2 components, should also demonstrate synergistic mechanism of action in order to be patentable).

8. The appellant submitted other amendments of claims wherein they deleted claims 1-10 to meet the objections. Claim 1 (earlier claim 11) was amended to orient towards "A compound…" in place of earlier "Composition of matter…". Further, claims 2-4 were added afresh in the body of the claims. These amendments were objected to by the respondent as not allowable under the provisions of the Patents Act, 1970.

9. The above discussions reveal that at no point of time the appellant claimed "A compound…" though we see there was ample ground for doing so. But the appellant arguments that they drafted some country specific claims, is not convincing as the drafting of a PCT International phase application should be always done keeping in

view the designations and not based on the practice prevailing in a single country.

10. We also notice that the respondent had not taken any objection on to earlier claim 11 other than that on the ground of definitiveness. The deletions of the claims on both the occasions i.e. at FER Stage and again after hearing, is partly to meet the official requirements and partly done voluntarily.

11. At the stage when the hearing was completed and the order was reserved, amendments of the claims to the extent which would again require special attention of the examiner to check their patentability criterion afresh should be avoided.

12. We notice that the complete specification under the heading "summary of invention" describes the invention as under:

    The present invention provides **novel compounds** comprising R-G-Cysteic Acid (i.e., R-G-NH-CH(CH2-SO3H)COOH or Arg-Gly-NH-CH(CH2-S03H)COOH) and derivatives thereof (including pharmaceutically acceptable salts, hydrates, stereoisomers, multimers, cyclic forms, linear forms, drug-conjugates, pro-drugs and their derivatives).

    The present invention also provides **compositions and methods** for inhibiting cellular adhesion to RGD binding sites or delivering other diagnostic or therapeutic agents to RGD binding sites in human or animal subjects by administering to the subject an effective amount of a composition comprising an R-G-Cysteic Acid peptide or a derivative thereof (including pharmaceutically acceptable salts, hydrates, stereoisomers, multimers, cyclic forms, linear forms, drug-conjugates, pro-drugs and their derivatives). [**Emphasis added**]

13. Further under the heading *Detailed Description and Examples* the invention has been described as under:

The present invention **provides novel compounds**, including those of General Formulas I through VII above. Specific examples include linear form of Arg-Gly-NH-CH(CH_2-SO_3H)COOH (example referred to herein as Compound 1) and cyclic form of Arg-Gly-NH-CH(CH_2-SO_3H)COOH) (example referred to herein as Compound 2) as well as derivatives thereof, including pharmaceutically acceptable salts, hydrates, stereoisomers, multimers, cyclic forms, linear forms, multimeric forms, drug conjugates, prodrugs and their derivatives. {Emphasis added}

14. Therefore, it is evident that though there was sufficient room for the appellant to draft claims based on "compound", right from beginning, but they chose not to pursue that and went on with either 'methods' or 'compositions' or 'composition of matters'. Hence, we find that the respondent's objection to the amendment was not without reasons.

15. We also notice that the learned counsel of the appellant argues that "*A decision to refuse was issued merely based on the change in the wording of the preamble of the claim.'* If this is correct, then why they claimed, claims 1-4 on "compound" and the fifth claim on 'composition'. It clearly indicates that both the terms cannot be used interchangeably, at least in this case.

16. While we hold that "what is not claimed is disclaimed". But looking at this case specifically, it is evident that the amendments are aimed at incorporating actual facts as shown above.

17. Further, we also hold that for the error in initial drafting of the claims, no applicant should suffer and therefore, considering as a special case, we are inclined to partially allow the claims.

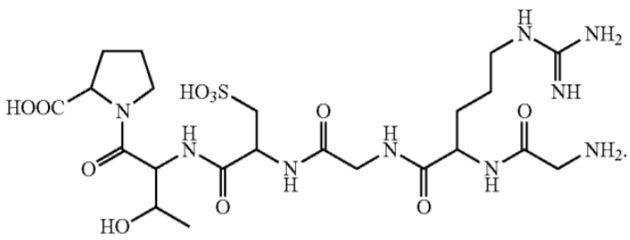
18. We have reviewed the hearing notice and found that the objection under section 2(1)(j) i.e. on 'novelty' and 'inventive step' was taken on then existing claim 1 which stands deleted now making such

objection infructuous. Further no such objection was taken on the existing claim 11 then, which now stands as claim 1.

19. Keeping in view the above facts, we are inclined to allow claims 1 and 2; of course with certain amendments, as shown below:

"1. A peptide comprising Glycine-Arginine-Glycine-Cysteic Acid)-Threonine-Proline.'

2. A peptide as claimed in claim 1 having the structural formula:



"

The reason for doing so, is that no new matter is brought either in claim 1 or 2. The peptide was already defined in erstwhile claim 11 amended as claim 1. No new matter has been brought in claim 2 either; as the feature as claimed in claim 1 is being further defined, based on the description and it specifies the scope, as well.

20. The appellant is directed to file the amended set of claims deleting claims 1-5 to the respondent and submit claims 1 and 2 as allowed above, within 3 weeks from the issuance of this order.

21. Considering the above facts, we set aside the order of the Respondent dated 31/12/2019 and direct the respondent to grant the patent on the amended set of claims, within 3 weeks from the date of filing the amended set of claims.

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

-Sd-

(Dr. B.P. Singh)
Technical Member (Patents)

-Sd-

(Justice Manmohan Singh)
Chairman