* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% Reserved on :15th January, 2024

Pronounced on:05th February, 2024

\+ **C.A.(COMM.IPD-PAT) 143/2022**

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ADDRESS FOR SERVICE IN INDIA LEXORBIS ..... Appellant

Through: Ms. Manisha Singh, Mr. Abhai Pandey, Mr. Varun Sharma, Mr. Manish Aryan, Ms. Swati Mittal, Mr. Gautam Kumar, Ms. Priyanka Anand, Ms. Shivani Singh & Mr. Dhruv Tandan, Advocates.

versus

CONTROLLER GENERAL OF PATENTS, DESIGNS &TRADEMARKS & ANR. ..... Respondents

Through: Mr. Harish Vaidyanathan Shankar, CGSC, Mr. Srish Kumar Mishra, Mr. Alexander Mathai Paikaday and Mr. Krishnan V., Advocates.

CORAM:
HON'BLE MR. JUSTICE ANISH DAYAL

JUDGMENT

ANISH DAYAL, J.

1. This appeal under Section 117A of the Patents Act, 1970 ("**the Act**") assails order dated 18th February, 2021 passed by the Assistant Controller of Patents and Designs ("**respondent No.2**") in Patent Application No.10336/DELNP/2013 dated 29th November, 2013 ("**impugned order**"). By the said impugned order, the patent application of the appellant was rejected primarily under Section 15 read with Section 59(1) of the Act. The background facts are as under:-

(i) The appellant has its principal place of business in Oakland, USA. They filed an International Application No.PCT/US2012/040455 on 01st June, 2012 titled "***Blockade of Inflammatory Proteases with Theta Defensins***". The PCT Application claimed priority to US Patent Application No.61/492,753 filed on 02nd June, 2011. Based on the PCT Application, the appellant filed a National Phase application (NP) in India with the Patent Office in Delhi on 29th November, 2013, and the said application was assigned number 10336/DELNP/2013 ("**impugned application**").

(ii) The impugned application was examined under Sections 12 and 13 of the Act and the First Examination Report ("**FER**") was issued on 04th June, 2019. In the FER, objections *inter alia* on grounds of lack of novelty under Section 2(1)(j) and lack of inventive step under Section 2(1)(j)(a) of the Act were raised in view of prior arts. Objections under Section 3(i) and Section 3(k) of the Act were also raised alleging that the subject matter claimed in the Application for a patent was not permitted.

(iii) To address these objections, the appellant amended the claims to be more definitive and restrictive in its scope by incorporating technical features implicitly covered under the dependent claims and submitted them along with the detailed reply to the FER on 31st October, 2019.

(iv) After considering the reply to the FER, appellant received a hearing notice dated 26th June, 2020 scheduling the hearing for 27th July, 2020. Respondent No.2 maintained all objections of the FER except a few related only to certain formal requirements.

(v) After considering the submissions of the appellant, the impugned order was passed primarily on the ground that amended claims submitted along with the reply to the FER could not be allowed under Section 59(1) of the Act. In order to meet the objections in the hearing notice, the written submissions were filed by the appellant along with amendments to their claim.

Submissions of the Appellant

2. Subject application at the time of National Phase entry in India was filed with 33 claims of which Claims No. 1 and 24 were independent claims, Claims No. 2 to 23 were dependent on Claim No. 1, and Claims No. 25 to 33 were dependent on Claim No. 24.

3. The claims of subject application were then amended while filing reply to FER on October 31, 2019 (*"first amendment"*), wherein preamble of Claim 1 was restricted by substituting expression *"marketing"* with *"testing"*.

Collectively technical features disclosed in Claims No. 5, 6, 8, 9, 15, 16, 24 and 28 were incorporated into Claim 1 to address objections related with clarity, conciseness, definitiveness. Further, Claims No. 3-6, 8, 9, 11-13, 15, 16, 18-22, and 24-33 were cancelled.

4. The claims of subject application were further amended by the applicant at the time of filing written submission post-hearing held on August 10, 2020 (*"second amendment"*). The applicant amended the claims in view of the primary objection in the hearing notice raised under Section 59 (1) of the Act. The applicant restored the preamble of Claim 1 by retaining the original expression *"marketing"* to address the objection raised on account of substituting the expression *"marketing"* with *"testing"* in the *first amendment*. Collectively, technical features disclosed in Claims No. 5, 6, 8, 9, 15, 16, 24 and 28 were incorporated into Claim No. 1 to address objections related to clarity, conciseness, definiteness (same as in *first amendment*). Claim No. 1 was also appended with a disclaimer- *"wherein said method of marketing does not comprise any steps related with transaction of goods or services and wherein said method is restricted to evaluating synthetic cyclic tetradecapeptide mini-θ-defensins for their potential to treat chronic inflammatory condition"* for imparting clarity on non-applicability of Section 3(k) of the Act. Claims No. 3-6, 8, 9, 11-13, 15, 16, and 18-33 have been cancelled.

5. The appellant provided a table for comparing the claims filed through the entire prosecution (the original claim, the *first amendment* and *the second amendment*) which is as under:-

Original claims filed with the PCT national phase entry in India	Amended claims as filed with reply to FER on October 31, 2019	Amended claims as filed with hearing written submission on August 10, 2020
(**Claim 1**) A method of marketing a drug composition, wherein the drug composition includes a θ-defensin, analog or derivative thereof, the method comprising: determining efficacy of the drug composition with respect to an anti-inflammatory effect in a human; and providing the drug composition to a marketplace to treat a chronic inflammatory condition.	(**Claim 1**) A method of ~~marketing~~ testing a drug composition intended for treating humans presenting with a chronic inflammatory, ~~wherein the drug composition includes a θ-defensin, analog or derivative thereof,~~ the method comprising: obtaining a synthetic cyclic tetradecapeptide mini-θ-defensin; receiving evidence that the synthetic tetradecapeptide mini-θ-defensin has a tumour necrosis factor alpha (TNF-α)-converting enzyme (TACE) inhibiting activity in a living cell; and determining efficacy of the ~~drug composition~~ synthetic cyclic tetradecapeptide mini- θ -defensin with respect to an anti-inflammatory effect in a model of a ~~human; and~~ ~~providing the drug composition to a marketplace to treat a~~ chronic inflammatory condition.	(**Claim 1**) A method of marketing a drug composition useful for treating chronic inflammatory conditions, ~~wherein the drug composition includes a θ-defensin, analog or derivative thereof,~~ the method comprising: (a) obtaining a synthetic cyclic tetradecapeptide mini-θ-defensin; (b) receiving evidence that the synthetic tetradecapeptide mini-θ-defensin has a tumour necrosis factor alpha (TNF-α)-converting enzyme (TACE) inhibiting activity in a living cell; and (c) determining efficacy of the ~~drug composition~~ synthetic cyclic tetradecapeptide mini- θ-defensin with respect to an anti-inflammatory effect in a model of a ~~human; and~~ ~~providing the drug composition to a marketplace to treat a~~ chronic inflammatory condition **wherein**

		said method of marketing does not comprises any steps related with transaction of goods or services and wherein said method is restricted to evaluating synthetic cyclic tetradecapeptide mini-θ-defensins for their potential to treat chronic inflammatory condition.
(**Claim 2**) The method of claim 1, wherein the drug composition is RTD-1-27.	(**Claim 2**) The method ~~of~~ as claimed in claim 1, wherein the ~~drug composition~~ synthetic cyclic tetradecapeptide mini-θ-defensin is selected from the group consisting of RTD-1-27, RTD-1-28, and RTD-1-29.	(**Claim 2**) The method ~~of~~ as claimed in claim 1, wherein the ~~drug composition~~ synthetic cyclic tetradecapeptide mini- θ-defensin is selected from the group consisting of RTD-1-2~~7~~9.
(**Claim 3**) The method of claim 1, wherein the drug composition is RTD-1-28.	~~(Claim 3) The method of claim 1, wherein the drug composition is RTD-1-28.~~	~~(Claim 3) The method of claim 1, wherein the drug composition is RTD-1-28.~~
(Claim 4) The method of claim 1, wherein the drug composition is RTD-1-29.	~~(Claim 4) The method of claim 1, wherein the drug composition is RTD-1-29.~~	~~(Claim 4) The method of claim 1, wherein the drug composition is RTD-1-29.~~
(Claim 5) The method of claim 1, wherein the step of determining efficacy comprises sponsoring at least one of toxicity study, an efficacy study and a	~~(Claim 5) The method of claim 1, wherein the step of determining efficacy comprises sponsoring at least one of toxicity study, an efficacy study and a~~	~~(Claim 5) The method of claim 1, wherein the step of determining efficacy comprises sponsoring at least one of toxicity study, an efficacy study and a~~

dose-response study with respect to the drug composition.	~~dose-response study with respect to the drug composition.~~	~~dose-response study with respect to the drug composition.~~
(Claim 6) The method of claim 1, wherein the step of determining efficacy comprises relying on data generated by another with respect to at least one of toxicity study, an efficacy study and a dose response study with respect to the drug composition.	~~(Claim 6) The method of claim 1, wherein the step of determining efficacy comprises relying on data generated by another with respect to at least one of toxicity study, an efficacy study and a dose response study with respect to the drug composition.~~	~~(Claim 6) The method of claim 1, wherein the step of determining efficacy comprises relying on data generated by another with respect to at least one of toxicity study, an efficacy study and a dose response study with respect to the drug composition.~~
(Claim 7) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a proinflammatory protease.	(Claim ~~7~~ **3**) The method ~~of~~ as claimed in any of the preceding claims 1-2, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a proinflammatory protease.	(Claim ~~7~~**3**) The method ~~of~~ as claimed in any of the claims 1-2, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a proinflammatory protease.
(Claim 8) The method of claim 7, wherein the proinflammatory protease is tumor necrosis factor alpha (TNF-α)-converting enzyme (TACE).	~~(Claim 8) The method of claim 7, wherein the proinflammatory protease is tumor necrosis factor alpha (TNF-α)-converting enzyme (TACE).~~	~~(Claim 8) The method of claim 7, wherein the proinflammatory protease is tumor necrosis factor alpha (TNF-α)-converting enzyme (TACE).~~
(Claim 9) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a proinflammatory protease.	~~(Claim 9) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a proinflammatory protease.~~	~~(Claim 9) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a proinflammatory protease.~~

(Claim 10) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a sheddase.	(Claim ~~10~~**4**) The method ~~of~~ as claimed in any of the preceding claims 1-3, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a sheddase or of Cathepsin-C.	(Claim ~~10~~**4**) The method ~~of~~ as claimed in any of the claims 1-3, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a sheddase or of Cathepsin-C.
(Claim 11) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of Cathepsin-C.	~~(Claim 11) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of Cathepsin-C.~~	~~(Claim 11) The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of Cathepsin-C.~~
(Claim 12) The method of claim 1, wherein the step of providing the drug composition to the marketplace comprises producing for sale at least one kilogram of the drug composition.	~~(Claim 12) The method of claim 1, wherein the step of providing the drug composition to the marketplace comprises producing for sale at least one kilogram of the drug composition.~~	~~(Claim 12) The method of claim 1, wherein the step of providing the drug composition to the marketplace comprises producing for sale at least one kilogram of the drug composition.~~
(Claim 13) The method of claim 12, wherein the step of producing comprises manufacturing the at least one kilogram of the drug composition.	~~(Claim 13) The method of claim 12, wherein the step of producing comprises manufacturing the at least one kilogram of the drug composition.~~	~~(Claim 13) The method of claim 12, wherein the step of producing comprises manufacturing the at least one kilogram of the drug composition.~~
(Claim 14) The method of claim 1, further comprising packaging the drug composition in an oral formulation.	(Claim ~~14~~ **5**) The method ~~of~~ as claimed in any of the preceding claims 1-4, ~~further comprising packaging~~ wherein the drug composition ~~in~~	(Claim ~~14~~5) The method ~~of~~ as claimed in any of the claims 1-4, ~~further comprising packaging~~ wherein the drug composition ~~in~~ comprises an oral formulation.

	comprises an oral formulation.	
(Claim 15) The method of claim 1, wherein the inflammatory condition is a proteolytic-mediated disease.	~~(Claim 15) The method of claim 1, wherein the inflammatory condition is a proteolytic-mediated disease.~~	~~(Claim 15) The method of claim 1, wherein the inflammatory condition is a proteolytic-mediated disease.~~
(Claim 16) The method of claim 1, wherein the inflammatory condition comprises rheumatoid arthritis.	~~(Claim 16) The method of claim 1, wherein the inflammatory condition comprises rheumatoid arthritis.~~	~~(Claim 16) The method of claim 1, wherein the inflammatory condition comprises rheumatoid arthritis.~~
(Claim 17) The method of claim 1, wherein the inflammatory condition comprises an autoimmune disease.	(Claim ~~17~~ **6**) The method ~~of~~ as claimed in any of the preceding claims 1-5, wherein the chronic inflammatory condition is selected from the group consisting of ~~comprises~~ an autoimmune disease, proteolytic mediated disease, and rheumatoid arthritis.	(Claim ~~17~~**6**) The method ~~of~~ as claimed in any of the claims 1-5, wherein the chronic inflammatory condition is selected from the group consisting of ~~comprises~~ an autoimmune disease proteolytic mediated disease, and rheumatoid arthritis and wherein the chronic inflammatory condition is associated with cancer, a neurodegenerative disease, an inflammatory bowel disease, Alzheimer's disease, osteoarthritis, or to treat persons who are non-responders to an anti-TNF-α treatment.

(Claim 18) The method of claim 1, further comprising marketing the drug composition as a treatment for a cancer.	~~(Claim 18) The method of claim 1, further comprising marketing the drug composition as a treatment for a cancer.~~	~~(Claim 18) The method of claim 1, further comprising marketing the drug composition as a treatment for a cancer.~~
(Claim 19) The method of claim 1, further comprising marketing the drug composition as a treatment for a neurodegenerative disease.	~~(Claim 19) The method of claim 1, further comprising marketing the drug composition as a treatment for a neurodegenerative disease.~~	~~(Claim 19) The method of claim 1, further comprising marketing the drug composition as a treatment for a neurodegenerative disease.~~
(Claim 20) The method of claim 1, further comprising marketing the drug composition as a treatment for an inflammatory bowel disease.	~~(Claim 20) The method of claim 1, further comprising marketing the drug composition as a treatment for an inflammatory bowel disease.~~	~~(Claim 20) The method of claim 1, further comprising marketing the drug composition as a treatment for an inflammatory bowel disease.~~
(Claim 21) The method of claim 1, further comprising marketing the drug composition as a treatment for Alzheimer's disease.	~~(Claim 21) The method of claim 1, further comprising marketing the drug composition as a treatment for Alzheimer's disease.~~	~~(Claim 21) The method of claim 1, further comprising marketing the drug composition as a treatment for Alzheimer's disease.~~
(Claim 22) The method of claim 1, further comprising marketing the drug composition as a treatment for osteoarthritis.	~~(Claim 22) The method of claim 1, further comprising marketing the drug composition as a treatment for osteoarthritis.~~	~~(Claim 22) The method of claim 1, further comprising marketing the drug composition as a treatment for osteoarthritis.~~
(Claim 23) The method of claim 1, further comprising marketing the drug composition to treat	(Claim ~~23~~ 7) The method ~~of~~ as claimed in any of the preceding claims 1-6, wherein the chronic	~~(Claim 23) The method of claim 1, further comprising marketing the drug composition to treat~~

persons who are non-responders to an anti-TNF-α treatment.	inflammatory condition is associated with cancer, a neurodegenerative disease, an inflammatory bowel disease, Alzheimer's disease, osteoarthritis, or ~~further comprising marketing the drug composition~~ to treat persons who are non-responders to an anti-TNF-α treatment.	~~persons who are non-responders to an anti-TNF-α treatment.~~
	(Claim 8) A θ-defensin or analog thereof as and when used in treatment of a chronic inflammatory condition in an animal.	
(Claim 24) A method of manufacturing a medicament for administration to an animal to treat an inflammatory condition, wherein the medicament includes at least one of a θ-defensin, analog or derivative thereof.	~~(Claim 24) A method of manufacturing a medicament for administration to an animal to treat an inflammatory condition, wherein the medicament includes at least one of a θ-defensin, analog or derivative thereof.~~	~~(Claim 24) A method of manufacturing a medicament for administration to an animal to treat an inflammatory condition, wherein the medicament includes at least one of a θ-defensin, analog or derivative thereof.~~
(Claim 25) The method of claim 24, wherein the medicament includes at least one of RTD-1-27, RTD-1-28 and RTD-1-29.	~~(Claim 25) The method of claim 24, wherein the medicament includes at least one of RTD-1-27, RTD-1-28 and RTD-1-29.~~	~~(Claim 25) The method of claim 24, wherein the medicament includes at least one of RTD-1-27, RTD-1-28 and RTD-1-29.~~
(Claim 26) The method of claim 24, wherein the	~~(Claim 26) The method of claim 24, wherein the~~	~~(Claim 26) The method of claim 24, wherein the~~

medicament is effective to produce a clinically relevant inhibition of a proinflammatory protease.	~~medicament is effective to produce a clinically relevant inhibition of a proinflammatory protease.~~	~~medicament is effective to produce a clinically relevant inhibition of a proinflammatory protease.~~
(Claim 27) The method of claim 26, wherein the proinflammatory protease is tumor necrosis factor alpha (TNF-a)-converting enzyme (TACE).	~~(Claim 27) The method of claim 26, wherein the proinflammatory protease is tumor necrosis factor alpha (TNF-a)-converting enzyme (TACE).~~	~~(Claim 27) The method of claim 26, wherein the proinflammatory protease is tumor necrosis factor alpha (TNF-a)-converting enzyme (TACE).~~
(Claim 28) The method of claim 24, wherein the medicament is effective to produce a clinically relevant inhibition of a proinflammatory protease.	~~(Claim 28) The method of claim 24, wherein the medicament is effective to produce a clinically relevant inhibition of a proinflammatory protease.~~	~~(Claim 28) The method of claim 24, wherein the medicament is effective to produce a clinically relevant inhibition of a proinflammatory protease.~~
(Claim 29) The method of claim 24, wherein the medicament is effective to produce a clinically relevant inhibition of a sheddase.	~~(Claim 29) The method of claim 24, wherein the medicament is effective to produce a clinically relevant inhibition of a sheddase.~~	~~(Claim 29) The method of claim 24, wherein the medicament is effective to produce a clinically relevant inhibition of a sheddase.~~
(Claim 30) The method of claim 24, wherein the inflammatory condition comprises rheumatoid arthritis.	~~(Claim 30) The method of claim 24, wherein the inflammatory condition comprises rheumatoid arthritis.~~	~~(Claim 30) The method of claim 24, wherein the inflammatory condition comprises rheumatoid arthritis.~~
(Claim 31) The method of claim 24, wherein the inflammatory	~~(Claim 31) The method of claim 24, wherein the inflammatory~~	~~(Claim 31) The method of claim 24, wherein the inflammatory~~

condition comprises an autoimmune disease.	~~condition comprises an autoimmune disease.~~	~~condition comprises an autoimmune disease.~~
(Claim 32) The method of claim 24, further comprising marketing the drug composition as a treatment for a cancer.	~~(Claim 32) The method of claim 24, further comprising marketing the drug composition as a treatment for a cancer.~~	~~(Claim 32) The method of claim 24, further comprising marketing the drug composition as a treatment for a cancer.~~
(Claim 33) The method of claim 24, further comprising marketing the drug composition as a treatment for a neurodegenerative disease.	~~(Claim 33) The method of claim 24, further comprising marketing the drug composition as a treatment for a neurodegenerative disease.~~	~~(Claim 33) The method of claim 24, further comprising marketing the drug composition as a treatment for a neurodegenerative disease.~~

6. Appellant's counsel submitted that the impugned order passed by respondent No.2 was arbitrary and arose out of a wrong and incorrect interpretation of the provisions of Section 59(1) of the Act, *inter alia* on the following grounds:-

(i) Amendment of claims was done by way of correction, explanation and disclaimer as permitted under Section 59(1) of the Act.

(ii) Scope of amended claims was narrower, rather than expanding the original claims, and was a subset of the original specification in claims.

(iii) Amended claims were already disclosed in the original claims and specification, both implicitly and explicitly.

(iv) Scope offered by the originally filed description read along with the claims and examples, particularly examples 1-3, 5 and 6, all

supported evaluation of θ-defensins, analog or derivative thereof for their TACE blocking potential.

(v) Amended claims were clearly derived by merging features of multiple dependent claims of the original specification, and did not enlarge the scope of the claims. Support for claims in the description must be seen from the perspective of a person skilled in the art and processes, one having common knowledge, and one who is able to identify the inventions and substance. It is in this context that the expression *"not in substance"* used in Section 59(1) of the Act has been specifically introduced by the legislature.

(vi) Respondent No.2 failed to apply the test for added matter and appreciate that from the perspective of a skilled person, nothing new was discernable from the amendments.

(vii) An explanation was permissible under Section 59 of the Act, and therefore, additional words are permissible from the unamended specifications in order to explain more clearly.

(viii) Renumbering and introducing new numbering and rewording of the technical features to impart definiteness and conciseness cannot be construed to take away or change the inherent scope of the originally filed claims.

7. In the context of the submissions, the appellant focused essentially on following aspects of the amendment of claims:-

(i) Substitution of the phrase *"marketing"* with *"testing"* in the *first amendment* and thereafter again to *"marketing"* in the *second amendment* was in the context as explained above in para 3.

(ii) Addition of expression *"useful for treating chronic inflammatory conditions"* as introduced in the *second amendment* was merely descriptive and was already present in the original Claim No.1.

(iii) The expression *"obtaining a synthetic cyclic tetradecapeptide mini-θ-defensin"* is only referring to procurement of the said compound and not manufacturing the same.

(iv) Particularization in Claim No.1 *vide* para (a), (b) and (c) was already part *inter alia* of Example 5, submitted in support of the claims and specifications originally filed.

Submissions by the Respondent

8. Mr. Harish Vaidyanathan Shankar, CGSC appearing for the Controller General of Patents, Designs and Trademarks submitted in support of the impugned order *firstly*, reference in the claims to *"a method of marketing"* was non-specific and could not have been acceptable; *secondly*, use of the word *"obtaining"* as part of para (a) of Claim No.1 did not emanate from the original claim and, therefore, could not be allowed under Section 59(1) of the Act; *thirdly*, para (b) of Claim No.1 which reads as " *receiving evidence that the synthetic tetradecapeptide mini-θ-defensin has a tumour necrosis factor alpha (TNF-α)-converting enzyme (TACE) inhibiting activity in a living cell*" added additional specification which was not found in the initially filed claim;

fourthly, the expression *"synthetic cyclic tetradecapeptide mini-θ-defensins"* in para (c) of Claim No.1 was also beyond the scope of the initially filed claim. Thus, he justified the reasoning in the impugned order which is extracted as under:

"

Originally filed claims	Amended claims filed with hearing response
A method of marketing a drug composition, wherein the drug composition includes a θ-defensin, analog or derivative thereof, the method comprising: determining efficacy of the drug composition with respect to an anti-inflammatory effect in a human; and providing the drug composition to a marketplace to treat a chronic inflammatory condition.	A method of marketing a drug composition useful for treating chronic inflammatory conditions, the method comprising: (a) obtaining a synthetic cyclic tetradecapeptide mini-θ-defensin; (b) receiving evidence that the synthetic tetradecapeptide mini-θ-defensin has a tumour necrosis factor alpha (TNF-α)-converting enzyme (TACE) inhibiting activity in a living cell; and (c) determining efficacy of the synthetic cyclic tetradecapeptide mini-θ-defensin with respect to an anti-inflammatory effect in a model of a chronic inflammatory condition, wherein said method of marketing does not comprises any steps related with transaction of goods or services and wherein said method is restricted to evaluating synthetic cyclic tetradecapeptide mini-θ-defensins for their potential to treat chronic inflammatory condition.

Although Applicant is saying that features of dependent claims 5, 6, 8, 9, 15, 16, 24 and 28 have been incorporated into principal claim 1, however same is not the case. Although the preamble of claims is same, however the steps (a), (b) and (c) as incorporated in amended claim 1 are not disclosed in the originally filed claims and also are not as such disclosed anywhere in specification. As the scope of amended claims are beyond the scope of claims as originally filed and also it describes matter not in substance disclosed or shown in the specification, thus the amendments cannot be allowed u/s 59(1) of the Act."

(emphasis added)

Analysis

9. Since the controversy revolves around acceptance of refusal of amendment of claims under Section 59 (1) of the Act, it would be useful first to extract the provision for ease of reference:

"S. 59. ***Supplementary provisions as to amendment of application or specification****. —*

[(1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment."

(emphasis added)

10. It is, therefore, evident that amendments to the original application can be made only by way of the following:-

(i) Disclaimer; or

(ii) Correction; or

(iii) Explanation.

Additionally, the proposed amendments are tested against the following parameters:

(iv) Amendment should serve the purpose of incorporation of actual facts;

(v) Effect of the amendment should not allow matter not in substance, disclosed originally or shown in the specification;

(vi) Amended claim of the specification should fall within the scope of the original claim of the specification.

11. What needs to be, therefore, assessed is whether the Controller was correct in its assessment of the amended claims on these six benchmarks and parameters. For this purpose, the Court must systematically assess the amendments, in particular, amendments to Claim No.1, whether they fall within the rubric of Section 59(1) of the Act or not.

12. *Firstly*, reference to *"method of marketing"* may not, in the opinion of this Court, non-suit the patent applicant considering that the expression used in original Claim No.1 was *"method of marketing a drug composition",*

which was changed to *"method of testing a drug composition"* when the amended claims were filed with reply to the FER. However, this was subsequently reverted to the expression *"method of marketing a drug composition"* in the *second amendment* filed with the written submission. Therefore, in essence, the appellant was merely reverting to the original expression used in the original claims and not outside the scope of the original claims, but quite within it and mirroring the same. In any event, the appellant provided a sufficient explanation for why the expression was changed from "*marketing*" to "*testing*" in *the first amendment*. Since an objection was raised in response to the FER, the appellant in its reply to the FER amended Claim No.1 to revise the preamble to *"a method of testing a drug composition"*. The basis was to be found, *inter alia,* in para [0010] which discloses that the aim of the invention is a medicament that treats inflammatory and inflammation related condition and methods of the same, and in para [0012] which discloses that invention involves toxicity, efficacy and dose response studies and determining efficacy of the drug composition. It was, therefore, clear that the scope of the claim involved the method of determining the efficacy of the said compound.

13. However, pursuant to the clarification provided in the *first amendment*, the expression was changed back to "*marketing*", in response to the hearing notice. In para 1 of *"Other Requirements"* of the hearing notice the following was stated by respondent No.2 - "*As filed claims 1-23 for instant application were directed to "method of marketing a drug composition" and claims 24-33 to "method of manufacturing a medicament ..." respectively.*

After amendment new claims have been filed wherein claims 1-7 are directed to "A method of testing a drug composition"..." This objection being taken in the hearing notice, the appellant, therefore, in order to address this suitably and out of abundant caution, reverted back to the original expression *"method of marketing a drug composition".* Even at this stage, there was no doubt that the claim related to testing the inhibitory effect of TACE (*Tumour Necrosis Factor Alpha Converting Enzyme*). For this purpose, it would be useful to extract relevant portions of the specification along with Example 5 as under:-

> *"**Summary of The Invention***
>
> ***[0010]** The inventive subject matter provides apparatus, systems and methods in which a drug composition that includes a θ -defensin, analog or derivative thereof is researched and marketed to treat an inflammatory condition.*
>
> *xxxxx xxxxx xxxxx xxxxx*
>
> ***[0013]** The anti-inflammatory effect(s) contemplated herein should be interpreted to broadly include all clinically relevant inhibition of inflammation-related compounds, including for example, inhibition of tumor necrosis factor alpha (TNF-α)-converting enzyme (TACE), Cathepsin C, or other proinflammatory proteases, the ADAMs family of metalloproteases and other sheddases.*
>
> xxxxx xxxxx xxxxx xxxxx
>
> *Example 5 -Anti-TNF-a and TACE inhibition by mini-θ-defensins*
>
> ***[0067]** Structure-activity analyses of natural and modified θ-defensins suggested certain sequence features that predicted to*

mediate the anti-inflammatory effects of these peptides. As an example, three tetradecapeptides (mini-θ-defensins) were designed to contain features deemed important for the anti-inflammatory properties of natural θ-defensins. These were incorporated into the sequences of the peptides shown in Fig. 8A. Each peptide was evaluated for its efficacy in murine CLP sepsis. As shown in Fig. 8B, all three mini-θ -defensins reduced lethality in mice compared to the PBS sham treatment. The inventors further evaluated each mini-θ-defensin for its effect on TNF-α release from stimulated human blood (Fig. 8C) and for its inhibitory activity against TACE (Fig. 8D). As the data in Figure 8 show, the mini-θ-defensins had similar or superior activity to RTD-1 in the CLP assay (compare to Fig. 3), the TNF-α inhibition assay (Fig. 8C), or the TACE inhibition assay (Fig. 8D.)"

14. In the opinion of this Court, therefore, the use of the expression *"method of marketing"* was clearly mirroring the original claim and, therefore, could not be considered, in any manner whatsoever, to be outside the scope and purview of Section 59(1) of the Act.

15. *Secondly*, as regards objection taken *qua* para (a), (b) and (c) of Claim No.1 being not reflected in the original claim, it is quite clear that the same detail was provided in the dependent claims in particular Claim Nos.7 and 8 which are extracted as under:-

"*7. The method of claim 1, wherein the anti-inflammatory effect comprises clinically relevant inhibition of a proinflammatory protease.*

8. The method of claim 7, wherein proinflammatory protease is tumour necrosis factor alpha (TNF-α)- converting enzyme (TACE)."

16. A perusal of Claim No. 7 would bear out that the method of Claim No.1 was to measure the anti-inflammatory effect of a pro-inflammatory protease, which in turn was further clarified in dependent Claim No.8 as being TACE [*Tumour Necrosis Factor Alpha (TNF- α) Converting Enzyme*].

17. As regards dependent claims and their scope, reference may be made to a decision by a Division Bench of this Court in ***F. Hoffmann-La Roche Ltd. v. Cipla Ltd.*** 2015 SCC OnLine Del 13619, relevant portion of which is extracted as under:

> "*(xi) Where claims are 'dependent' it incorporates by reference 'everything in the parent claim, and adds some further statement, limitations or restrictions'. (Landis on Mechanics of Patent Claim Drafting).*"

18. *Thirdly*, as regards objection to the phrase *"obtain"* by the respondent, it was usefully clarified by the counsel for the appellant, that it was not meant to state that they would be manufacturing the same but was only meant in terms of procuring the said compound from existing sources and finally testing the same.

19. Succinctly stated, para (a), (b) and (c) of the amended Claim No. 1, in other words claim that *firstly*, the compound (*synthetic cyclic tetradecapeptide mini-θ-defensins*) would be procured; *secondly*, the said compound had a TACE inhibiting activity in a living cell and evidence of the same would be obtained; and *thirdly*, is to determine the efficacy of the said compound with respect to the anti-inflammatory effect in a chronic inflammatory condition. It was further clarified in para (c) of Claim No.1 that

"the said method of marketing" does not comprise any steps related with transaction of goods or services and said method is restricted to evaluating *"synthetic cyclic tetradecapeptide mini-θ-defensins"* for their potential to treat chronic inflammatory condition.

20. These aspects already formed part of the original claims and specifications in that the composition was explained in Example 5, the pro-inflammatory protease TACE formed part of the dependent Claim No.8, and the issue of the anti-inflammatory effect was stated in dependent Claim No.7.

21. Moreover, substantial part of para (c) was already part of Claim No.1 in terms of the process of *"determining efficacy of the composition"* with respect to an anti-inflammatory effect in a human. The explanation for "*marketing*" is also quite sufficiently provided in the expression used in original Claim No.1 *"providing the drug composition to a marketplace to treat a chronic inflammatory condition".*

22. Thus, in the opinion of this Court, the amendments serve only as an explanation to the original claims, amount to incorporation of actual facts, and do not disclose any matter which was not originally disclosed in the claims of specification filed before the amendment. Therefore, the impugned order would not be sustainable in that it seeks to disallow the amendments carried out on 10th August, 2020 under Section 59(1) of the Act. The specific observation in the impugned order that para (a), (b) and (c) as incorporated in the amended claim No.1 *"are not disclosed in the originally filed claims and are also not disclosed anywhere in specification"* is not an accurate analysis

nor a correct conclusion by respondent No.2, in view of what has been detailed above.

23. Therefore, the impugned order is set aside, the appeal is allowed, and the Patent Application of the appellant is remanded back for fresh consideration of the claims as amended, to be assessed on their own merits.

24. Subject Patent Application of the appellant shall now be examined afresh along with the amendment. Considering that time has already lapsed since filing of the present Patent Application, it is directed that the application shall be examined within three months from the date of the receipt of the order. A hearing would be provided to the appellant within the said period.

25. Registry is directed to supply a copy of the order to the Office of the Controller General of Patents, Designs and Trademarks of India on the email llc-ipo@gov.in for compliance.

26. The Office of the CGSC may also communicate the order to the Office of the Controller General of Patents, Designs and Trade Marks, for compliance.

27. Judgment be uploaded on the website of this Court.

(ANISH DAYAL)
JUDGE

FEBRUARY 05, 2024/MK