2024:DHC:7041

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

Reserved on: August 22nd, 2024
% Pronounced on: September 13th, 2024

\+ **C.A.(COMM.IPD-PAT) 288/2022**

AXCESS LIMITED .....Appellant
Through: Mr. Hari Subramaniam, Ms. Aditi Subramaniam and Mr. Sanuj Das, Advs.

Versus

CONTROLLER OF PATENTS AND DESIGNS .....Respondent
Through: Mr. Srish Kumar Mishra, Mr. Alexander Mathai Paikaday and Mr. Sagar Mehlawat, Advs.

CORAM:
HON'BLE MR. JUSTICE SAURABH BANERJEE

J U D G M E N T

1. The appellant herein filed an Indian Patent Application No. 2427/DELNP/2011 titled "BILE ACIDS AND BIGUANIDES AS PROTEASE INHIBITORS FOR PRESERVING THE INTEGRITY OF PEPTIDES IN THE GUT" [hereinafter referred to as '***subject patent application***'] involving certain compounds and compositions used as inhibitors of gut proteases as national phase application following PCT application dated 1st October, 2009 with a priority date of 1st October 2008 before the Indian Patent Office.

2. The said subject patent application has been refused by the Deputy Controller of Patents and Designs [hereinafter referred to as '***Controller***']

under *Section 15* of the Patent Act, 1970 [hereinafter referred to as '***Act***'] vide the impugned order dated 27th April, 2020 [hereinafter referred to as '***impugned order***'] in view of *Section[s] 59(1), 3(d)* and *3(e)* of the Act.

3. The present appeal is seeking to challenge the said impugned order passed by the Controller.

4. The facts involved are that in the proceedings before the Controller the appellant filed amended claims on 20th April, 2018 pursuant to the PCT original claims on 1st April, 2011 and an amended set of claims on 18th December 2017.

5. Primarily, it is the case of the learned counsel for appellant that the amended claims fall within the scope of the specifications and the claims originally filed, and the respondent's conclusion regarding *Section 59(1)* of the Act is contrary to the facts on record.

6. *Per Contra*, it is the case of the learned CGSC that the proposed amendments by appellant submitted post-hearing are beyond the scope of the original claims and the complete specification disclosed by the appellant, for which reason he is supporting the finding[s] of the Controller in the impugned order.

7. Since, the moot issue before this Court for analysing what the Controller has held qua *Section 59(1)* of the Act in the impugned order, is whether the appellant has deviated from the initial scope. The relevant claims of the complete specification are as under:-

Original Claims filed via PCT	**Amended Claims**	**Amended Claims under dispute**
10. **A product or**	5. **A pharmaceutical**	1. **A pharmaceutical**

pharmaceutical composition containing: (a) compound according to anyone of claims 1 to 9, and (b) a peptide or poly peptide, wherein (a) and (b) are prepared for simultaneous, separate or sequential delivery to a subject for the treatment of a disease or condition affecting the subject, or for preventing a disease or condition affecting the subject. 13. The product or pharmaceutical composition according to claim 11 wherein the compound is present in an amount of at least 50% by weight. 14. The product or pharmaceutical composition according to claim 11 wherein the compound is present in an amount of at least from 60 to 95% 15. The product or pharmaceutical composition according to claim 11 wherein the compound is present in an amount of at least from 80 to 90%. 16. The product or pharmaceutical composition according to claim 11 wherein the compound is chosen from chenodeoxycholio acid, deoxycholic acid, ursodeoxycholic acid, glycochenodeoxycholic	**composition when used in the simultaneous or sequential delivery to a subject** wherein the pharmaceutical composition contains: (a) a compound as claimed in any one of claims 1 to 4, and (b) a peptide or polypeptide, wherein said peptide or polypeptide is for placing in the gut in the treatment of a disease or condition affecting the subject, or for preventing a disease or condition affecting the subject, and wherein said compound is an inhibitor of the degradation of said peptide or polypeptide by one or more gut serine proteases. 9. The product or pharmaceutical composition as claimed in claim 7 wherein the compound is present in an amount of at least 50% by weight. 10. The product or pharmaceutical composition as claimed in claim 7 wherein the compound, is present in an amount of from 60 to 95% 11. The product or pharmaceutical composition as claimed in claim 7 wherein the compound is present in an amount of from 80 to 90%. 12. The product or pharmaceutical	**composition comprising** one or more peptide(s) or polypeptide(s), and at least 50% by weight of gut serine proteases inhibitor compounds selected from the group consisting of chenodeoxycholic acid, ursodeoxycholic acid, glycodeoxycholic acid, glycochenodeoxycholic acid, metformin, phenformin or chlorhexidine or pharmaceutically acceptable salts thereof. 2. The pharmaceutical composition as claimed in claim 1 wherein the compound is present in an amount of from 60 to 95 %>. 3. The pharmaceutical composition as claimed in claim 1 wherein the compound is present in an amount of from 80 to 90%. 4. The pharmaceutical composition as claimed in claim 1 wherein the peptide is a cyclic peptide.

acid, glycodeoxycholic acid or pharmaceutically acceptable salt of these compounds. 17. The product or pharmaceutical composition according to claim 11 wherein the compound is chosen from metformin, phenformin or chlorhexidtne or pharmaceutically acceptable salts thereof. 18. The product or pharmaceutical composition according to claim 11 wherein the peptide is a cyclic peptide	composition as claimed in claim 7 wherein the compound is chosen from chenodeoxycholic acid, ursodeoxycholic acid, glycochenodeoxycholic acid, or pharmaceutically acceptable salt of these compounds. 13. The product or pharmaceutical composition as claimed in claim 7 wherein the compound is chosen from metformin, phenformin or chlorhexidine or pharmaceutically acceptable salts thereof. 14. The product or pharmaceutical composition as claimed claim 7 wherein the peptide is a cyclic peptide.	

8. After identifying certain portions of complete specifications to show that the scope of the subject application is limited to new use of a known compound or composition, the Controller has in the impugned order held that the amendment sought to be made by the appellant to a product claim should not be permitted under *Section 59(1)* of the Act.

9. However, after a detailed examination of the complete specification by this Court, the same reveals otherwise since the same contains descriptions in the amended claims related to the composition as a product also along with the use as another aspect of the invention. The same is apparent from the scope of the original PCT claims illustrated in the table in paragraph 7 hereinabove. In fact, relevant portion[s] of the

complete specification supporting the amended claims describing composition as a product are reproduced as under:-

> "*[0025] Another aspect of the invention provides a pharmaceutical composition comprising:*
> *(i) a peptide or polypeptide; and*
> *(ii) a compound chosen from ursodeoxycholic acid, glycochenodeoxychofate, glycodeoxycholate, glycooholate and their pharmaceutical acceptable salts,*
> *wherein said compound is present In the composition at a concentration of 20 to 100 mg/ml. Although the bile acids and their derivatives in component (ii) are known, they have not previously been used at the high concentrations.*
> ……
> …… ……
> *[0033] Pharmaceutical compositions of the present Invention that are suitable for oral administration are preferably coated with an enteric coating which becomes permeable at a pH of from 3 to 7. More preferably the coating becomes permeable at a pKof 4 to 6.5 and most preferably 5 to 6. Suitable enteric coatings are known In the art. The compounds of the present invention are typically formulated with such an enteric coating.*
> *[0034] A pharmaceutical composition of the present invention may comprise other standard pharmaceutical exclpients in admixture, to provide a composition in the form of a powder, a liquid, a gel, a paste, a wax or a suspension. For Instance, pharmaceutical excipients capable of enhancing dissolution of the compound of the Invention or the peptide, or which act as antioxidants, preservatives, glidants (for example magnesium stearate, stearic acid or talc), swelling agents.*"

10. Interestingly, recently a co-ordinate bench of this Court while dealing with similar issues qua amendment of claim[s] made in the complete specification in ***The Regents of The University of California v Controller General of Patents, Designs & Trademarks & Anr.*** [C.A.(COMM.IPD-PAT) 143/2022 dated 05th February, 2024] has held as under:-

> "*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. Applying the same parameters to the facts involved herein, this Court has no hesitation in inferring that the amended claims in the latest complete specification filed by the appellant to the original/ initial claims made by it are well within the scope of the original PCT claims. More so, since the detailed description supports the same amendment concerning the composition as a product.

12. Therefore, in view of the factual matrix involved coupled with the existing position of law with respect to what is/ are the permissible limits of amendment[s] by an applicant like the appellant under *Section 59(1)* of the Act, in the considered opinion of this Court, the amended claims to the complete specifications sought by the appellant and as they stand now are permissible and can be allowed.

13. As such, the rejection by the Controller under *Section 59(1)* of the Act by way of the impugned order cannot sustain and has to be reversed. In view thereof, since the newly amended claims to the complete specifications of the appellant as they stand now have not been considered by the Controller at all, the present appeal has to be remanded back to the Controller. For this reason, this Court is not considering and/ or adjudicating the remaining objections raised by the appellant by way of the present appeal.

14. Thus, the present appeal is disposed of with the following directions:-

[i] The impugned order dated 27th April, 2020 passed by the Controller rejecting Patent Application No. 2427/DELNP/2011 of the appellant is set aside and the matter is remanded back to the respondent for *de novo* consideration; and

[ii] The aforesaid Patent Application No.2427/DELNP/2011 is restored to its original number; and

[iii] The Controller shall, *de hors* the previous finding in the impugned order dated 27th April, 2020, issue a fresh Hearing Notice clearly delineating the objection[s] therein, and thereafter grant a fresh hearing[s] to the appellant and decide the same by passing a fresh order preferably within a period of four months from the date of conclusion of the hearing[s].

15. Resultantly, the Registry of this Court is directed to supply a copy of this judgment to the office of the Controller General of Patents, Designs and Trademarks of India on email llc-ipo@gov.in for compliance of the directions in the judgment.

16. The learned CGSC is also directed to communicate the aforesaid directions to the office of the Controller General of Patents, Designs and Trademarks of India.

SAURABH BANERJEE, J.

SEPTEMBER 13, 2024/rr