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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **01.07.2025**

CORAM

THE HONOURABLE **MR.JUSTICE SENTHILKUMAR RAMAMOORTHY**

(T)CMA(PT)/38/2023
(OA/61/2014/PT/CH)

Srinivas Jegannathan,
10, V.K.Flats, First Cross Street,
Sundaram Colony, Tambaram,
Sanatorium, Chennai 600 047. ... Appellant

-vs-

The Controller of Patents,
Patent Office, Chennai,
Intellectual Property Building,
GST Road, Guindy,
Chennai 600 032. ... Respondent

PRAYER: Transfer Civil Miscellaneous Appeal (Patents) is filed under Section 117-A of the Patents Act, 1970, praying that the order of the Controller dated 26.03.2014 refusing Patent Application No.122/CHE/2006 be dismissed and Patent Application No.122/CHE/2006 be allowed to proceed to grant.

For Appellant : Mr.Surya Senthil
for M/s.Surana and Surana

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For Respondent : Mr.Rajesh Vivekananthan,
Deputy Solicitor General

JUDGMENT

This appeal is directed against the order dated 26.03.2014 rejecting Patent Application No.122/CHE/2006 for grant of patent for a claimed invention titled 'Formulation of Ceftazidime, Tazobactum and Linezolid for Enhancement of Antibacterial Activity'.

2. Upon receipt of the above mentioned application, at the request of the appellant, the First Examination Report (FER) was issued on 03.12.2012. The appellant replied to the FER on 24.09.2013. The hearing was held on 10.02.2014 and the appellant filed written submissions on 18.02.2014. The order impugned herein was issued thereafter on 26.03.2014.

3. Learned counsel for the appellant submitted that the original claims related to a pharmaceutical composition of ceftazidime in a fixed dose combination with linezolid (which belongs to a new class of antibiotics called oxazolidinones), which has excellent activity against methicillin-resistant staphylococcus aureus (MRSA) and vancomycin-resistant

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enterococci (VRSA), and is further combined with an enzyme inhibitor, such as tazobactum, to enhance antimicrobial activity. He points out that the said claims were amended in response to the FER and further amended after the hearing.

4. According to learned counsel, the conclusion that the claimed invention is obvious from the cited prior arts is erroneous. By referring to prior art D1, which is in respect of an invention titled 'Admixture of Linezolid and other Antibacterial Agents', learned counsel submits that D1 relates to a composition wherein the primary active pharmaceutical ingredient is linezolid and that linezolid is combined with one or more antibacterial agents selected from a group consisting of aminoglycosides, cephalosporins, aztreonam, quinolones and penincillins. Learned counsel contends, in this regard, that prior art D1 does not disclose the use of a beta-lactamase inhibitor, such as tazobactum.

5. As regards prior art D2, which relates to an invention titled 'Composition and Methods for Treating Bacterial Infections', learned

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counsel submits that D2 discloses the use of oxazolidinones and ampicillin along with sulbactum, but does not disclose the use of the class of antibiotics called cephalosporins (such as ceftazidime). With regard to D3, learned counsel submits that it relates to the use of clavulanate and that it is targeted at enhancing antibacterial activity in the face of penicillin-binding-protein mediated resistance mechanism. Since none of the cited prior arts teach, motivate or suggest the combination of a cephalosporin with linezolid and a beta-lactamase inhibitor, learned counsel submits that these prior arts do not render the claimed invention obvious to the person skilled in the art (PSITA).

6. As regards the objection that the amendments fall outside the scope of Section 59 of the Patents Act, 1970 (the Patents Act), learned counsel submits that the patent applicant is an individual and had modified the claims based on interaction with the Controller at the hearing. He also submits that the appellant is ready and willing to submit the original claims for consideration, if the matter were to be remanded. In such event, learned counsel also contends that prior arts D4 to D6 would no longer hold

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relevance.

7. In response to these contentions, learned counsel for the respondent submits that the appellant voluntarily amended the claims more than once. Therefore, he submits that the respondent cannot be faulted for considering and rejecting the last amended claims on the basis of cited prior art. By relying on an earlier order of this Court dated 19.03.2024 in *Genomatica Inc. v. The Controller of Patents and Designs, CMA(PT)/4/2023*, learned counsel submits that the amended claims get superimposed on the previous set of claims and, therefore, the Controller is required to examine the last amended claims and not the original claims.

8. By referring to prior art D1, learned counsel submits that the active pharmaceutical ingredients, linezolid and cephalosporin, are disclosed therein. With reference to prior art D2, learned counsel submits that the said prior art discloses oxazolidinone, and that linezolid belongs to the same class of drugs. He further submits that it also discloses sulbactum, which was disclosed in the provisional specification of the appellant. With reference to

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prior art D3, learned counsel submits that it discloses the use of clavulanate, which is a beta-lactamase inhibitor. He further submits that the drug delivery system in respect of which monopoly claims were made in the rejected claims were disclosed in prior arts D4 to D6. Since the claimed invention was rejected upon a detailed analysis of cited prior art, learned counsel submits that no case is made out for interference.

9. At the outset, it is pertinent to set out independent claim 1 of the original claim and independent claims 1 and 4 of the rejected last amended claims. They read as under:

> *"1. A Pharmaceutical composition of Ceftazidime and its sodium, salts or esters containing betalactam antibiotic, which acts as an active ingredient, in fixed dose combination with Linezolid, a new class of antibiotic, oxazolidinones, with an excellent activity against MRSA & VRSA. Besides, Ceftazidime is combined with an enzyme inhibitor, such as, Tazobactum to enhance antimicrobial activity."*
>
> **"***1. A Drug Delivery System consisting of a) Ceftazidime, b) Betalactamase inhibitor such as Tazobactum*

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and c) Oxazolidinone such as Linezolid, characterized in such a way that the said active ingredients are provided in the range of a) 25-4000 mg, b) 1:1.5 to 1:2.5 with regards to Ceptazidime and c) 10-600 mg, incorporated in biodegradable polymers belonging to Aliphatic Polyesters and their co-polymers with Hydroxyvalerate for tailored release of the drugs for one week or more.

4. A composition with extended spectrum of activity consisting of a) Ceftazidime, b) Betalactamase Inhibitor such as Tazobactum, and c) Oxazolidinone such as Linezolid, characterized in such a way that the said active ingredients are provided in the range of a) 25-4000 mg, b) 1:1.5 to 1:2.5 with regards to Ceftriaxone and c) 10-600 mg, incorporated in biodegradable polymers more specifically, Poly (DL-Lactide-co-glycolide) 50:50 or any other suitable ratio and Hydroxyvalerate."

10. As is evident from the above, independent claim 1 of the original claim is broadly in line with independent claim 4 of the rejected claims. The difference is that, in independent claim 4 of the rejected claims, the concentration of each ingredient is specified, whereas it is absent in independent claim 1 of the original claims. The ratios, however, are

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indicated in dependent claim 2 of the original claims.

11. With this background, an examination of cited prior arts is warranted. Independent claim 1 of prior art D1 is as under:

> *"1. An aqueous pharmaceutical composition for IV administration of linezolid and one or more antibacterial agents selected from the group consisting of an aminoglycosides, cephalosporins, aztreonam, quinolones and penicillins and pharmaceutically acceptable salts thereof where such exist."*

It is noticeable that the composition claim of D1 contains linezolid and one or more antibacterial agents selected from multiple classes, including cephalsoporins. Conspicuous by its absence is any reference to an enzyme inhibitor such as tazobactum.

12. Prior art D2 contains 30 claims. Independent claim 1 thereof is as under:

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> *"1. A composition having antibacterial activity comprising an antibacterial effective amount of an oxazolidinone compound, an antibacterial effective amount of ampicillin, and an antibacterial enhancing amount of sulbactam."*

While the use of an oxazolidinone, such as linezolid, is disclosed in D2, oxazolidinone is combined with ampicillin and not with a cephalosporin. Prior art D3, in independent claim 1, discloses the use of clavulanate, which is a beta-lactamase inhibitor, to enhance antibacterial activity against microorganisms having an antibiotic resistance mechanism other than beta-lactamase enzyme mediated resistance. It does not, however, disclose the active pharmaceutical ingredients of the claimed invention.

13. On perusal of the impugned order, the respondent has extracted from prior art documents D1 to D3 and recorded the following conclusion:

> *"From the above finding it is clear that the active ingredients used in the present invention claims 1-9 consisting of Ceftazidime, Betalactamase inhibitor such as Tazobactam, oxazolidinone such as Linezolid, their effective amount ratio and their administrations are well known in the prior art."*

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The above conclusion is bereft of any reasoning and the impugned order does not indicate as to how and why PSITA would arrive at the above conclusion on the basis of prior arts D1 to D3. Put differently, individually, none of the cited prior arts combine a cephalosporin, such as ceftazidime, with an oxazolidinone, such as linezolid, and tazobactam. About two of these ingredients are seen in cited prior arts, but not all three. In the absence of discussion or reasoning as to how and why combining the three ingredients would be obvious to PSITA, interference is warranted.

14. Although the Controller cannot be faulted for considering and rejecting the last amended claims by also relying on prior arts D4 to D6, in view of the submission made on behalf of the appellant that the appellant would confine its claims to the original claims, the reliance on prior art D4 to D6 loses relevance. For the same reason, the objection raised on the basis of Section 59 of the Patents Act also loses relevance.

15. For reasons set out above, impugned order dated 26.03.2014 is set aside and the matter is remanded for reconsideration on the following terms:

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(i) Such reconsideration shall be undertaken on the basis of the original claims submitted along with the complete specification of the appellant.

(ii) In order to preclude the possibility of pre-determination, an officer other than the officer who issued the impugned order shall undertake re-consideration.

(iii) After providing a reasonable opportunity to the appellant, a speaking order shall be issued within a period of ***three months*** from the date of receipt of a copy of this order.

(iv) Since the appellant has opted to revert to the original claims, it is open to the respondent to cite any other prior art after providing a reasonable opportunity to the appellant.

(v) For the avoidance of doubt, it is made clear that no opinion has been made on the merits of the patent application.

16. (T)CMA(PT)/38/2023 is disposed of on the above terms without any order as to costs.

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Index : Yes / No

Internet : Yes / No

Neutral Citation: Yes / No

To

The Controller of Patents,
Patent Office, Chennai,
Intellectual Property Building,
GST Road, Guindy,
Chennai 600 032.

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