2024:MHC:1344

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

Judgment reserved on	30.11.2023
Judgment pronounced on	19.03.2024

CORAM

The Hon'ble Mr. Justice **SENTHILKUMAR RAMAMOORTHY**

(T) CMA (PT) No.92 of 2023
(OA/18/2017/PT/CHN)

Novozymes A/S
Krogshoejvej 36,
DK-2880 Bagsvaerd,
Denmark.

Represented by:
Dr.Avaronnan Harish Chandra ...Appellant

v.

Assistant Controller of Patents and Designs,
The Patent Office,
Intellectual Property Building,
G.S.T. Road, Guindy,
Chennai – 600032.
...Respondent

PRAYER: This Civil Miscellaneous Appeal is filed under Section 117-A of the Patents Act, 1970, praying that (1) the present appeal be allowed; (2) the impugned order of the learned Assistant Controller of Patents & Designs dated 28.02.2017 rejecting the Patent Application

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650/CHENP/2009 be set aside; (3) this Court may be pleased to hold that claimed invention in the present case is patentable subject matter, novel and involves inventive step; and (4) this Court may be pleased to direct the Controller to grant the patent and publish the grant in the journal.

For Appellant : Ms.Vindhya S.Mani,
for M/s.Lakshmikumaran and Sridharan

For Respondent : Mr.A.R.Sakthivel, SPC

JUDGMENT

Background

This appeal is directed against the order dated 28.02.2017 rejecting Patent Application No.650/CHENP/2009, which was filed on 04.02.2009. The appellant filed the above mentioned application, as the national phase application derived from PCT application dated 06.08.2007, by claiming priority from 07.08.2006 for grant of patent for an invention titled "Enzyme Granules for Animal Feed".

2. Upon submitting the request for examination on 20.07.2010, the respondent issued the First Examination Report (FER) on 23.01.2014. In the FER, objections were raised on the grounds that the claims do not

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qualify as an invention under Section 2(1)(j) of the Patents Act, 1970 (the Patents Act) and that they are not patent eligible under Sections 3(d) and (e) thereof. In response, the appellant filed amended claims by deleting original claims 1-2, 4-5, 8, 13-18, 21-22, 26-32 and 34. The amended claims were re-numbered and filed as claims 1-15. Thereafter, a hearing was held on 03.02.2017 and the appellant filed written submissions on 20.02.2017 along with a further amended set of 7 claims (current claims). Eventually, the claims were rejected by impugned order dated 28.02.2017. The present appeal arises in the above facts and circumstances.

Counsel and their contentions

3. Oral submissions on behalf of the appellant were advanced by Ms.Vindhya S.Mani of M/s.Lakshmi Kumaran and Sridharan; and by Mr.A.K.Sakthivel, assisted by Mr.V.G.Saravana Ram Prasad, Assistant Controller of Patents, for the respondent.

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4. Learned counsel for the appellant submitted that the claimed invention relates to a process of preparing granules comprising a core with the enzyme and a zinc organic salt. She submitted that the use of the zinc organic salt promotes enzyme stabilization. She pointed out that the respondent acknowledged that claims 1 to 6 were novel. As regards claim 7, she submitted that it was held to be not novel and it was further held that all the claims lack inventive step on the basis of prior arts D8 and D9. On the issue of novelty, she referred to Paragraph 09.03.02 of the Manual of Patent Office Practice and Procedure, 2019 to submit that a prior art would be considered as anticipating the claimed invention only if all the features of the invention under examination are present in the cited prior art document.

5. The next contention of learned counsel was that the respondent erred gravely in holding that claims 1 to 7 lack inventive step based on the combined disclosures of prior arts D8 and D9. With reference to prior art D8, learned counsel submitted that the said prior art is aimed at improving enzyme stability during steam treatment by coating the core

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containing the enzyme with salt. Although it recites that the granule core may comprise an organic or inorganic salt, she submitted that there is no teaching therein that the use of a zinc salt of organic acid in the core promotes enzyme stability. She further submitted that prior art D8 merely mentioned zinc in a laundry list of metal ions that are used in multiple combinations. As regards the claimed invention, she pointed out that the residual phytase activity is 99%. By referring to the judgment of the House of Lords in *The General Tire & Rubber Company v. Firestone Tyre & Rubber Company Ltd., [1972 R.P.C. 457]*, she contended that prior publication must contain clear and unmistakable directions to do what the patentee claimed to have invented, and that even a clear signpost will not suffice.

6. According to learned counsel, prior art D9 addresses the problem of reducing water uptake during the conditioning step of feed preparation, and reducing the dissolution time of the enzyme granule. After pointing out that the solution in D9 to the above problem is a process for the preparation of an enzyme in a granule coated with a

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dispersion containing particles of a hydrophobic substance, she contended that there is no disclosure therein about the inclusion of an organic zinc salt. She further contended that neither prior art D8 nor D9 teaches the effect of or advantages of using zinc salts of organic acids. Consequently, she contended that a person skilled in the art would not be motivated to combine prior arts D8 and D9 and that, even if so combined, it would not lead to the claimed invention.

7. By referring to judgments of the Delhi High Court such as *F.Haffmann-La Roche & Another v. CIPLA Ltd., 2016 (65) PTC 1 (DB) DEL, Biomoneta Reasearch (P) Limited v. Controller General of Patents and Designs, 2023 SCC OnLine Del 1482, Gogoro Inc. v. The Controller of Patents and Designs and Another, 2022 SCC OnLine Delhi 2577, and Agriboard International v. Controller of Patents and Designs, 2022 SCC OnLine Del 4786,* learned counsel submitted that obviousness analysis should be undertaken by examining the invention disclosed in the prior art, the invention disclosed in the application under consideration and the manner in which the subject invention would be obvious to the person skilled in the art. Since the respondent did not undertake obviousness

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analysis in the manner specified in the above mentioned precedents, she submitted that the impugned order is liable to be set aside.

8. The last contention of learned counsel for the appellant was that the respondent erred in applying Section 3(d) of the Patents Act in respect of claim 6. In order to substantiate this contention, learned counsel pointed out that the granule in claim 6 is novel and the process for manufacturing the same is also novel. Since claim 6 pertains to a new substance, learned counsel contended that Section 3(d) of the Patents Act is inapplicable. In support of this proposition, she relied on the judgment of the Delhi High Court in *DS Biopharma Limited v. The Controller of Patents and Designs and Another in C.A(COMM.IPD-PAT)6/2021*.

9. In response to these contentions, it was submitted on behalf of the respondent that independent claims were made originally for granules and dependent claims for the process of manufacture. Upon receipt of the objections of the respondent, this was reversed in the amended claims wherein the independent claims are for the process and

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the dependent claims are for granules. The next submission was that prior art D8 teaches a core containing a salt. It was also pointed out from claim 15 of prior art D8 that such salt includes an organic salt. Indeed, it was submitted that even the particle sizes of granules were not disclosed in the claimed invention which, consequently, also suffers from lack of adequate disclosure to enable working the invention after the term of patent.

10. By way of rejoinder, learned counsel for the appellant pointed out that the technical advancement is in the form of enhanced residual activity when zinc acetate, i.e. zinc with an organic salt, is used instead of zinc sulphate, which is zinc with an inorganic salt.

Discussion, analysis and conclusions

11. The claimed invention identified the problem to be solved as enhancing pellet stability in animal feeds by incorporating an organic zinc salt together with the enzyme. The following extract from the

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background of the invention is pertinent to understand the problem that the claimed invention sets out to resolve:

> *"In the process of producing food pellets it is considered necessary to steam mash feed in order to kill pathogenic micro-organisms if present and to partly gelatinize starch in order to improve the physical properties of the feed, whereby a steam treatment of around 70-120°C is appropriate. Active compounds present in the feed such as enzymes are not very stable at high temperatures and humidities, and thus, a large surplus of enzymes has to be used, or enzyme free components are pelletized and steam treated, where after an enzyme containing slurry or solution is coated onto the steam treated pellets. However, this coating process is cumbersome and is often not compatible with feed mill equipment."*

The above extract discloses that coating the enzyme is not only cumbersome but also often incompatible with feed mill equipment. The claimed invention instead recites that a core comprising the enzyme and a zinc salt of organic acid resolves the problem. This is evident from the summary of the invention, which is set out below:

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"SUMMARY OF THE INVENTION

One object of the present invention is to provide an enzyme granule with good pelleting stability. A second object of the present invention is to provide a simple process for obtaining enzyme granules with good pelleting stability.

It has surprisingly been found that zinc salts of organic acids have a very positive effect on enzyme stability during pelleting, and per se stability if formulated together with the enzyme.

The present invention provides thus in a first aspect a granule suitable for use in animal feed composition comprising a feed enzyme and a zinc salt of an organic acid.

The present invention further provides feed compositions comprising the enzyme granule of the invention."

12. Before proceeding further, it is also relevant to set out the amended independent claims of the appellant, which are as under:

"1. A process of preparing granules, comprising the steps of:

a) preparing a core comprising a zinc salt of an organic acid and an enzyme

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b) coating the core with a coating material

6. A granule suitable for feed comprising an enzyme and a zinc salt of an organic acid as obtained by the process as claimed in claims 1 – 5.

7. A method for manufacturing a feed composition comprising the steps of:

i) mixing feed components with any of the granules comprising a mixture of an enzyme and zinc salt of an organic acid.

ii) steam treating said composition (i), and

iii) pelleting said composition (ii)"

13. Out of the claims, except claim 6, the remaining claims are process/method claims. These claims relate to a process for preparing granules with a core comprising an enzyme and a zinc salt of a organic acid. Claim 7 envisages a process of mixing feed components with the above mentioned granule, steam treating and thereafter pelleting the said composition.

14. Because the respondent concluded that prior art documents D1 to D7 do not disclose either the granule or the method of preparation, as regards claims 1-6, novelty was acknowledged and it is unnecessary to

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examine the same. What warrants consideration, however, is whether these claims satisfy the requirements of Section 2(1)(ja) of the Patents Act since the impugned order records that the claims were rejected as lacking an inventive step by referring to prior arts D8 and D9.

15. Prior art D8 is an invention titled 'Enzyme Granules'. The publication date is 06.04.2006, which predates the priority date of the claimed invention. The invention disclosed in prior art D8 relates to steam treated pelletized feed compositions comprising salt coated granules. After noticing the prior art, the problem was identified in the background section of the complete specification of D8 as follows:

> *"....But the industry still demand improved enzyme activity after steam pelleting. Furthermore there is a demand for small enzyme granules that also comprise a significant amount of active enzyme after pelleting, for production of feed for broiler chickens. It makes it much easier to control the amount of enzyme in the feed pellets if small enzyme granules are used. Broiler chickens only eat few pellets per day and are believed to get a more homogenous enzyme intake if small enzyme granules are used in the manufacturing of*

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the feed pellets. It is easier to solve this demand with the granules of the present invention compared with known enzyme granules in the market today."

16. The solution indicated in D8 to the above problem is evident from the following extract from the background of the invention:

" The present invention solves said demands by coating an enzyme containing granule with a salt before steam pelleting. It has shown that it is possible to steam treat salt coated granules comprising an active compound and maintain a significant amount of activity"

The summary of the invention throws further light and, in relevant part, is set out below:

"The present invention provides thus in a first aspect a steam treated pelletized feed composition comprising a granule comprising a core and a coating wherein the core comprises an active compound and the coating comprises a salt."

The following extract from internal page 20 of prior art D8 is also relevant in this regard:

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> "<u>The Salt coating</u>
>
> *The granule of the present invention comprise besides a core at least one coating which is here to be understood as the layer surrounding the core.*
>
> *The coating which comprises a salt, may in a particular embodiment of the present invention comprise at least 60% w/w, e.g.65% w/w or 70% w/w salt, which in particular may be at least 75% w/w. e.g. at least 80% w/w, at least 85% w/w, e.g. at least 90% w/w or at least 95% w/w, even at least 99% w/w."*

17. Thus, prior art D8 offers a solution to the problem of ensuring that enzymatic activity is retained after steam pelleting by coating the core containing the enzyme with a salt. By contrast, as is evident from the extracts set out in preceding paragraphs, the claimed invention envisages a core comprising both the enzyme and a zinc salt of an organic acid. Specifically, therefore, two differences are discernible: in the claimed invention, the core is not coated with but comprises a salt; and such salt is a zinc salt of an organic acid. The conclusion of the respondent,

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however, was that D8 also teaches a core with a salt. Therefore, this finding warrants close examination and I turn to this aspect next.

18. At internal page 17 of the complete specification of prior art D8, disclosures are made with regard to the core. The said paragraph is set out below:

> *"The core may comprise a salt. The salt may be an inorganic salt, e.g. salt of sulfate, sulfite, phosphate, phosphonate, nitrate, chloride or carbonate or salts of simple organic acids (less than 10 carbon atoms e.g. 6 or less carbon atoms) such as citrate, malonate or acetate. Examples of cations in these salt are alkali or earth alkali metal ions, although the ammonium ion or metal ions of the first transition series, such as sodium, potassium, magnesium, calcium, zinc or aluminium. Examples of anions include chloride, iodide, sulfate, sulfite, bisulfite, thiosulfate, phosphate, monobasic phosphate, dibasic phosphate, hypophosphite, dihydrogent phyrophosphate, carbonate, bicarbonate, metasilicate, citrate, malate, maleate, malonate, succinate, lactate, formate, acetate, butyrate, propionate, benzoate, tartrate, ascorbate or gluconate.*

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In particular alkali- or earth alkali metal salts of sulfate, sulfite, phosphate, phosphonate, nitrate, chloride or carbonate or salts of simple organic acids such as citrate, malonate or acetate may be used. Specific examples include NaH2PO4, NaHPO4, NaPO4, (NH4)H2PO4, K2HPO4, KH2PO4, Na2SO4, K2SO4, ZnSO4, MgSO4, CuSO4, Mg(NO3)2, (NH4)2SO4, K,HPO4, KH2PO4, Na2SO4, K2SO4, KHSO4, ZnSO4, MgSO4, CuSO4, Mg(NO3)2, (NH4)2SO4, sodium borate, magnesium acetate and sodium citrate."

The above extract discloses that prior art D8 optionally teaches a core comprising a salt and that such salt may be an inorganic salt or a salt of simple organic acids. Multiple examples are set out therein, as is also evident from the extract.

19. If prior art D8 is compared with the claimed invention, it is noticeable that D8 teaches that enzymatic activity may be retained after steam treatment if the granule containing the enzyme is coated with a salt, whereas, the claimed invention discloses that if the core consists of the enzyme and a zinc salt of organic acid, residual enzymatic activity is

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99%. Although D8 does indicate the use of inorganic or organic acids in the core, as an option, there is nothing in D8 that recites or teaches the benefits of using a zinc salt of organic acid. In order to better understand the claimed invention, the following extract from internal page 10 of the complete specification of the claimed invention is relevant:

> *"**Zinc salts of organic acids***
> *The zinc salt of an organic acid is in a particular embodiment water soluble.*
> *When working with feed for animals it is important that the materials used in the granule have a certain purity thus in one embodiment of the present invention the zinc salt of organic acid is food grade. The organic zinc salt of an organic acid may be selected but is not limited to the group consisting of zinc salts of citrate, malate, maleate, malonate, methionate, succinate, lactate, formate, acetate, butyrate, propionate, benzoate, tartrate, ascorbate, gluconate, zinc chelates of amino acids hydrates and combinations thereof."*

In sum, it is noticeable that the solution in D8 is by coating the enzyme containing granule with a salt. In contrast, the solution in the claimed

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invention is in producing a core containing the enzyme and a zinc salt of an organic acid. The recitals in D8 regarding the use of either inorganic or organic salts in the core in multiple combinations do not teach or even suggest any benefit therefrom especially by use of a zinc salt of organic acid.

20. I next propose to examine prior art D9. Prior art D9 is an invention titled "Granulate Containing Feed Enzymes". This invention was published on 24.07.2003, which is prior to the priority date of the claimed invention. The field of the invention is the formulation of enzymes, preferably feed enzymes into granulates for use as animal feed. From the background of the invention, the problem identified by such invention is evident. The solution proposed by the invention is clear from the detailed description of the invention, which is set out in relevant part below:

> *"The present invention discloses a process for the preparation of an enzyme-containing granulate suitable for use in an animal feed, the process comprising obtaining a dry enzyme-containing*

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granule and coating the granules with a dispersion comprising particles of a hydrophobic substance dispersed in a suitable solvent. The coating of an enzyme granulate with such a dispersion provides for a low water uptake during the conditioning step of the feed preparation process and, surprisingly, an attractively short dissolution time of the enzyme granule."

The above extract reveals that the invention in prior art D9 is intended to enable reduction of the dissolution time of the granule, and that this is achieved by coating the granule containing the enzyme with a dispersion. Thus, prior art D9 is designed to provide a solution to a different problem from that of the claimed invention. The nature of the invention is discernible from the following disclosure of one embodiment thereof, which is contained at internal page 5 of the prior art D9. The said extract is as under:

"In one embodiment of the invention, the additive comprises a water soluble inorganic salt (as suggested in EP 0 758 018). Preferably, the granules comprise at least 0.1% of a water soluble inorganic salt comprising a divalent cation, more preferably

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zinc. Most preferably, the inorganic salt is zinc-sulphate."

21. When the claimed invention is compared with prior art D9, it, therefore, becomes clear that the two are directed at different problems and, therefore, provide different solutions. In fact, prior art D8 is closer to the claimed invention than prior art D9. However, even prior art D8, for reasons set out earlier, would not lead a person skilled in the art to the claimed invention.

22. In the impugned order, the respondent concluded that the claimed invention would be evident from prior art D8 by recording the following findings:

"On the contrary to applicant's argument, D8 discloses a granule comprising a core and a coating wherein the core comprises a salt, and wherein the granule comprises at least 75% of active compound with retained activity after steam pelleting and wherein the granule further comprises one or more of the following: i. The particle size of the granule is below 400 microns, ii. The thickness of the salt

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coating is at least 8microns, iii. The active compound is thermo labile, iv. The granule further comprise a wax coating, v. the granule further comprise a lactic acid source, and vi. The active compound in the core of the granule is an enzyme. The core may comprise a salt. Further, the salt may be an inoganic salt, e.g. Salts of sulfate, sulfite, phosphate, phosphonate, nitrate, chloride or carbonate or salts of simple organic acids (less than 10 carbon atoms e.g. 6 or less carbon atoms) such as citrate, malonate or acetate. The salt may also be a hydrated salt, i.e. A crystalline salt hydrate with bound water(s) of crystallization, such as described in WO 99/32595. Examples of hydrated salts include magnesium sulfate heptahydrate (MgSO4(7H2O), zinc sulfate heptahydrate (ZnSO4(7HcO), sodium phosphate dibasic heptahydrate (Na2HPO4(7HcO), magnesium nitrate hexahydrate (Mg(NO3)2(6H2O)), sodium borate decahydrte, sodium citrate dihydrate and magnesium ace tate tetrahydrate. Hence the disclosure of prior art document encompass all features of the present invention."

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23. The respondent noticed that prior art D8 discloses a granule comprising a core and coating and that the core may comprise either an organic salt or an inorganic salt. After noticing that the core may comprise either an organic or inorganic salt, the impugned order does not contain any discussion as to how and why a person skilled in the art would select a zinc salt of an organic acid, such as zinc citrate or zinc acetate, in order to address the problem of enzyme stabilization, which is the subject of the claimed invention. As regards enzyme stabilization, the appellant relied on examples 13 and 14 of the complete specification of the claimed invention to demonstrate the increase in enzyme stabilization on account of using an organic zinc salt during granulation and steam pelleting. This contention was rejected by the respondent merely because the particle size was not disclosed in the claimed invention. Indeed, the respondent was acutely conscious that prior art D8 did not exemplify the effect of a zinc salt of organic acid, but surprisingly concluded that such effect would be obvious to a person skilled in the art by the teaching of prior art D8. As discussed earlier, prior art D8 teaches the use of a core comprising either an inorganic or

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organic salt by setting out multiple combinations. Consequently, without the benefit of hindsight, in my view, it would not be possible to arrive at the claimed invention on the basis of prior art D8.

24. Nonetheless, it should be noticed that claim 7, as framed, lacks specificity. In order to lend specificity and curtail the width thereof, said claim should be amended as under:

> *"7. A method for manufacturing a feed composition consisting of all the following steps:*
> *i) mixing feed components with any of the granules of claim 6 comprising a mixture of an enzyme and zinc salt of an organic acid as claimed in claims 1-5.*
> *ii) steam treating said composition (i), and*
> *iii) pelleting said composition (ii)"*

All that remains to be tested is the conclusion that claim 6 falls within the scope of Section 3(d).

25. In the impugned order, the respondent concluded as under with regard to claims 1 to 6:

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"It is found that the prior art documents D1-D7 does not disclose the granule and its method of preparation as claimed in the present invention. Therefore, novelty is acknowledged for claims 1-6."

The above findings indicate that the respondent acknowledged and admitted that claims 1 to 6 are novel because the granule is not disclosed in prior art documents D1 to D7. If the granule of claim 6 is novel, it cannot be considered as a known substance. If it is not a known substance, Section 3(d) of the Patents Act is not applicable. Thus, the impugned order is liable to be set aside.

26. For reasons set out above, (T)CMA(PT)No.92 of 2023 is allowed and the impugned order is set aside. Hence, Application No.650/CHENCP/2009 shall proceed to grant on the basis of current claims 1-6, which were filed with the written submissions before the respondent, and claim 7 as amended in the manner indicated *supra*. There shall be no order as to costs.

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Index : Yes/No
Internet : Yes/No
Neutral Citation : Yes/No

To

Assistant Controller of Patents and Designs,
The Patent Office,
Intellectual Property Building,
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Chennai – 600032.

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