IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: **18.03.2025**

CORAM:

THE HON'BLE **MR. JUSTICE SENTHILKUMAR RAMAMOORTHY**

CMA(PT).No.46 of 2024

KEMIN INDUSTRIES, INC.
2100 Maury Street, Des Moines,
Iowa 50317, United States of America,
E:mlp@mlpchambers.com
P:95994 34779 ... Appellant

Vs.

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

Prayer: This Civil Miscellaneous Appeal (Patents) is filed under Section 117-A of the Patents Act, 1970 for a direction to the Controller of Patents to allow the application to proceed to grant in the regular course and permit the appellant to make any such amendments to the claim set that was finally placed on record, or any other order as this Court may find suitable and sufficient to enable grant of the application.

For Appellant : Mr.Nitin Masilamani

For Respondent : Mr.S.Janarthanam, SPC
Ms.R.Hemalatha, Assistant Controller

J U D G M E N T

Background

This appeal is directed against order dated 19.07.2022 rejecting patent application no.201617013577 for grant of patent to an invention titled "USE OF FERULIC ACID ESTERASE TO IMPROVE PERFORMANCE IN MONOGASTRIC ANIMALS".

2. Upon request from the appellant, the respondent issued First Examination Report (FER) dated 27.09.2019. In such report, objections were raised *inter alia* on grounds of lack of novelty and inventive step by citing prior art documents D1 and D2. The appellant responded to the FER on 27.03.2020. In the reply, the appellant contended that the claimed invention is distinguishable both from D1 and D2. In particular, it was stated that D1 and D2 teach only the use of xylanase and not the other main chain degrading enzymes used in the claimed invention, namely, cellulase, glucanase and amylase. Pursuant to hearing notice dated 06.05.2021, a hearing was held on 07.06.2021. After the hearing,

the appellant filed written submissions on 21.06.2021 along with the amended claim. The order impugned herein was issued in the above facts and circumstances.

Counsel and their contentions

3. Oral arguments on behalf of the appellant were advanced by Mr.Nitin Masilamani, learned counsel, and on behalf of the respondent by Mr.S.Janarthanam, learned SPC, assisted by Ms.R.Hemalatha, Assistant Controller.

4. Learned counsel for the appellant submitted that the scope of the monopoly claim is evident from the sole claim. He submits that the claim relates to a method of supplementing ferulic acid esterase (FAE) produced from bacteria with four main chain degrading enzymes, namely, cellulase, xylanase, glucanase and amylase. By adopting this method, he submits that there is significant improvement in the metabolizable energy. By referring to and relying upon Table 1 of the complete specification, learned counsel submits that the enzymatic activity of prototype I therein discloses the enzymatic activity of each

main chain degrading enzyme forming part of the monopoly claim. By further referring to Table 7 of the complete specification, learned counsel submits that the ferulic acid released from the relevant animal feed is set out therein in relation to the use of only FAE, prototype I, prototype I + FAE and the control group. As regards prototype I + FAE, he points out that the ferulic acid released is far higher than in the case of the other groups. According to learned counsel, the combination of the four main chain degrading enzymes to produce such result was unknown in the prior art and was certainly not obvious therefrom.

5. By referring to the two cited prior arts, namely, D1 and D2, learned counsel submits that they do not teach the combination of cellulase, xylanase, glucanase and amylase, and that the combination taught therein is limited to FAE and xylanase. As regards the statement in the background section of the complete specification that "the use of xylanase, cellulase and glucanase in degradation of NSP is well documented", learned counsel submits that the appellant did not state that the combination of these three main chain degrading enzymes is well documented, but merely that the separate use of these enzymes in the

degradation of non-starch polysaccharides (NSP) is known as part of common general knowledge or prior art. Since the appellant has provided experimental data to establish the synergistic effect of the combination of these four enzymes with FAE, learned counsel submits that the claimed invention satisfies all the requirements of Section 2(1)(j) of the Patents Act, 1970 (the Patents Act), including those in Section 2(1)(ja).

6. As regards the rejection on the ground of Section 3(d), learned counsel submits that the limb of Section 3(d) relating to “the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant” was relied on by the respondent. Even on the assumption that the monopoly claim relates to the use of a known process, learned counsel submits that the appellant has employed more than one new reactant. Consequently, he contends that the claimed invention is not excluded from patent protection under Section 3(d).

7. As regards the rejection under Section 3(i), learned counsel submits that the said provision only applies to a process for the treatment

of human beings or animals. By inviting my attention to the nature of the claim, learned counsel contends that the claim is in respect of a method of supplementing FAE with the main chain degrading enzymes, cellulase, xylanase, glucanase and amylase in the diet of monogastric animals. Put differently, his contention is that the claimed invention is directed solely at a method of supplementing an animal feed and not a method of treating animals. As regards some of the embodiments of the claimed invention and the experimental data, learned counsel submits that the appellant was required to both establish synergistic effect and that the claimed invention is capable of industrial application. On that basis, he submits that it cannot be concluded that the claimed invention is excluded under Section 3(i).

8. In support of these contentions, learned counsel referred to and relied upon the following judgments:

(i) *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries Ltd., AIR 1982 SC 1444*, particularly with reference to the test for determining obviousness;

(ii) *F.Hoffman La Roche v. Cipla, 2016 (65) PTC 1 (Del),* regarding the five steps formulated therein by the Division Bench of the Delhi High Court while undertaking obviousness analysis;

(iii) *Bristol-Myers Squibb Holdings Ireland Unlimited Company v. BDR Pharmaceuticals International Private Limited, Manu/DE/0299/2020*, with regard to the necessity of avoiding a hindsight-driven analysis and for the proposition that mosaicing of prior art cannot be resorted to unless the party claiming obviousness is able to show that the the person skilled in the art (PSITA) would combine features or elements of the prior art.

9. In response to these contentions, the respondent submitted that the field of invention is the use of FAE along with main chain degrading enzymes to improve the availability of metabolizable energy in animal feed. By referring to prior art D1, it was contended that the combination of FAE and xylanase is taught therein. As regards the contention that the claimed invention teaches a method wherein four main chain degrading enzymes are deployed, by referring to Table 1 of the complete

specification, it was contended that the data clearly discloses that the enzymatic activity of xylanase is the highest, when compared to the other three enzymes mentioned therein. According to the respondent, prior art D2 contains similar teaching as D1.

10. The second contention on behalf of the respondent is that the claimed invention refers to the production of FAE from bacteria, as opposed to the fungal origin of FAE in D1 and D2, but fails to provide any data in relation thereto. The third contention was with regard to Section 3(d) of the Patents Act. On this issue, the submission is that the claimed invention relates to the mere use of a known process.

11. The penultimate contention on behalf of the respondent was that the claimed invention is excluded from patent protection under Section 3(i) of the Patents Act inasmuch as it is for a process for the treatment of animals so as to increase their economic value. According to the respondent, on examining the complete specification of the claimed invention, it would be evident that the use of the method of the claimed invention would result in the fattening of the poultry to which the animal

feed is administered. With regard to the interpretation of Section 3(i) in relation to animals, the respondent referred to and relied upon the judgment of this Court in *Kymab Limited v. the Assistant Controller of Patents & Designs, 2024:MHC:3498 (Kymab)*. The last contention was that the appellant's application for grant of patent was rejected by the European Patent Office and the US Patent Office. Before concluding, the respondent also added that the claim refers to the step of adding 20 units per kg to 200 units per kg of FAE, whereas the data provided in tables 4 & 5 of the complete specification only deal with 20 to 40 units per kg of FAE.

12. By way of rejoinder, learned counsel for the appellant first dealt with Section 3(i) of the Patents Act. He pointed out that the exclusion therein is confined to a method of treatment of animals, and that the monopoly claim is clearly not in respect of a method of treatment of animals. He also submitted that the fact situation in *Kymab is* distinguishable. As regards Section 3(d), he submitted that the process is new and that more than one new reactant is deployed. As regards obviousness analysis, apart from Tables 1 & 7, learned counsel also

referred to Figures 2, 7 and 8 of the complete specification to emphasize that the appellant had demonstrated the unexpected effects, including significantly lower feed conversion ratio (FCR), arising out of the inventive combination of the four main chain degrading enzymes with FAE. He also pointed out that the structure of xylanase is quite different from that of the other three main chain degrading enzymes. In conclusion, he submitted that there exists a vast array of enzymes and that the appellant exercised ingenuity in picking four enzymes and combining them with FAE.

Discussion, analysis and conclusion:

13. At the outset, it is necessary to set out the sole current claim of the appellant, which is as under:

> *"A method of reducing by 20% to 80% of the main chain degrading enzymes necessary to extract a given amount of the apparent metabolizable energy from a diet comprising feed formulated for a monogastric animal, comprising the step of adding 20 units per kg to 200 units per kg of a ferulic acid esterase produced from bacteria to the animal feed, wherein the ferulic acid esterase is supplemented with*

the main chain degrading enzymes, and wherein said main chain degrading enzymes are cellulase, xylanase, glucanase and amylase."

The scope of the monopoly claim, as gleaned from the above, is in respect of a method of reducing, by 20% to 80%, the main chain degrading enzymes necessary to extract a given amount of apparent metabolizable energy from a diet comprising feed formulated for a monogastric animal. The method comprises the step of adding 20 units per kg to 200 units per kg of a FAE produced from bacteria to the animal feed, wherein the FAE is supplemented with four main chain degrading enzymes, namely, cellulase, xylanase, glucanase and amylase.

14. Against this backdrop, I first examine the rejection on the basis of Section 3(i). Section 3(i) of the Patents Act is as under:

"3(i). any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products. "

The text of the provision discloses that the first limb pertains to forms of treatment of human beings. The second limb relates to processes for a similar treatment of animals. In *Kymab*, I considered the language of Section 3(i) in relation to animals and observed as under:

> *"9. From the above analysis, it follows that Section 3(i) would be attracted in relation to a process for the treatment of animals provided such treatment is for any of the following three purposes:*
>
> *(i) To render them free of disease;*
>
> *(ii) To increase their economic value; or*
>
> *(iii) To increase the economic value of their products;*
>
> *The use of the adjective "similar" to qualify the noun "treatment" in the second limb of Section 3(i) indicates that the form of treatment could be analogous to forms such as medicinal, surgical, curative, prophylactic, diagnostic or therapeutic, which are enumerated in the first limb of Section 3(i) in the context of treatment of human beings. In order to better appreciate the scope of Section 3(i) in relation to animals, it is profitable to consider illustrations. If cattle were to be subjected to treatment to cure such animals of foot and mouth disease, it would clearly qualify as a method of treatment to free such animals of disease and, therefore, patent*

ineligible under Section 3(i). If cows were subjected to treatment for purposes of improving the quality of milk or for purposes of increasing the quantity of milk that such cows are capable of producing, both the economic value of such cows and that of its products would increase, thereby bringing it within the scope of the exclusion. Similarly, if sheep were to be subjected to some form of treatment to improve the quality of wool or to increase wool output from the fleece, it could result both in an increase in the economic value of the sheep and its produce. Substantially similar illustrations are set out in the Biotechnology Applications' Guidelines and, in all these cases, the method of treatment would fall within the ambit of Section 3(i).”

15. In the present case, the claim is in respect of a method of reducing, by a specified percentage, the main chain degrading enzymes necessary to extract metabolizable energy from animal feed. As discussed earlier, this method involves producing FAE from bacteria, supplementing the same with four main chain degrading enzymes, and adding the same to animal feed. Put differently, the monopoly claim is in respect of a method of extracting metabolizable energy more efficiently from animal feed by deploying FAE supplemented with the four enzymes

mentioned above. This is clearly not a method for treating animals, as exemplified by the illustrations in *Kymab,* or even otherwise. If the claim had pertained to a method of administering a drug or feed to an animal or bird - for instance, poultry - so as to fatten the same and thereby increase either its economic value or that of the meat, it would fall within the scope of Section 3(i). In other words, Section 3(i) cannot be extended to a method of supplementing an animal feed merely because the use of such animal feed may ultimately result in improving the economic value of the animal/poultry to which such feed is administered or that of animal/poultry products such as meat or chicken. Section 3(i), which is intended to exclude from patent protection any process for the treatment of human beings or animals (albeit for the three purposes mentioned therein) so as to sub-serve the underlying public policy of not permitting monopoly-based barriers to methods of treatment, is not designed to exclude from patent protection inventions like the claimed invention.

16. I examine the rejection under Section 3(d) next. In the impugned order, the operative portion relating to Section 3(d) is as under:

" Regarding objection no.3 of the hearing notice, in view of the cited documents D1 and D2, the method of improving the apparent metabolizable energy and performance from a diet in a living thing can be increased by adding ferulic acid esterase with degrading enzymes, in the absence of efficacy data if any, the said method in the alleged invention is a mere discovery of a known process. Hence, amended claim 1 falls under Section 3(d) of the Patents Act. "

The above extract reveals that the claimed invention was held to be patent ineligible on the ground that it is a mere discovery of a known process. Such conclusion has been reached by comparing the claimed invention with prior arts D1 and D2.

17. Section 3(d) of the Patents Act is as under:

"3(d). the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—*For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy; ”*

As is evident from the above reproduction of Section 3(d), it consists of three limbs. The first two limbs deal with known substances. For purposes of this case, only the third limb is relevant. The third limb applies to the mere use of a known process, machine or apparatus. It also contains a built-in exemption filter, if such known process results in a new product or employs at least one new reactant.

18. Because a conclusion was reached that the claimed invention is excluded under Section 3(d) on the basis of prior arts D1 and D2, it becomes necessary to examine these prior arts. Consequently, the discussion on this issue is also relevant for obviousness analysis. Prior art D1 is patent literature titled “Phenolic Acid Esterase, Coding Sequences and Methods”. Independent claim 1 of prior art D1 is as under:

> *"1. A method for increasing free ferulic acid content of a plant-derived composition, said method comprising the step of contacting a plant-derived composition with a phenolic acid esterase wherein said phenolic acid esterase comprises the amino acid sequence of SEQ ID NO:18, amino acids 1 to 530 or wherein the phenolic acid esterase consists of an amino acid sequence selected from the group consisting of amino acids 795 to 1077 of SEQ ID NO:12, amino acids 546 to 789 of SEQ ID NO:16, amino acids 20 to 286 of SEQ ID NO:14, amino acids 20 to 307 of SEQ ID NO:14, and amino acids 20 to 421 of SEQ ID NO:14."*

The summary of the invention of prior art D1, in relevant part, is as under:

> *" The present invention provides methods for improving nutrient availability in foods, especially plant-derived feedstuffs and foodstuffs with a significant non-starch polysaccharide content and/or with poorly digestible fiber. The methods comprise the step of combining the foodstuff or feedstuff with a feruloyl esterase as provided herein, desirably together with a xylanase, for example, the xylanase (XynA) protein derived from Orpinomyces PC-2. These enzymes can be prepared from their natural sources or*

the recombinant enzymes can be prepared using the teachings provided herein and in United States Patent No.5,824,533 (Liet al.,1998) for the xylanase A of Orpinomyces PC-2. A foodstuff or feedstuff is combined with feruloyl esterase at a ratio of 0.1 to 200 units per kg dry weight of foodstuff or feedstuff. Where the xylanase A protein is also added, the xylanase ratio is 100 to 25,000 units per kg. An advantageous range is 500 to 10,000.U/kg or 1000 to 5000 U/kg. Where a beverage or liquid food or feed formulation is treated with feruloyl esterase or feruloyl esterase and xylanase A, the ratios are the same, with the calculation based on the dry weight of solids in the beverage or other liquid composition for consumption by a human or an animal."

As is noticeable from the summary extracted above, the combination of feruloyl esterase or FAE with xylanase is clearly taught therein. Conspicuous by its absence in prior art D1 is reference to the other three enzymes forming the subject of the sole claim of the claimed invention.

19. Prior art D2 is also patent literature bearing the title 'Enzyme System Comprising Ferulic Acid Esterate from Aspergillus'. Independent claim 1 and dependent claim 5 of prior art D2 are as under:

"1. An enzyme system comprising an isolated purified ferulic acid esterase (FAE) and at least one enzyme of interest (EOI), wherein the FAE comprises the amino acid sequences of SEQ ID Nos:1 and 2.

.. ..

.. ..

5. The enzyme system as in any one of claims 1 or 2 wherein the EOI is a polysaccharide modifying enzyme selected from the group consisting of a xylanase, an arabinase, a glucanase, a pectinolytic enzyme and a rhamnogalacturonase."

On perusal, it appears that prior art D2 teaches an enzyme system comprising an isolated purified FAE and one polysaccharide modifying enzyme selected from the group consisting of xylanase and arabinase, glucanase, a pectinolytic enzyme and a rhamnogalacturonase.

20. While D2 discloses both xylanase and glucanase, it does not disclose the other two enzymes, namely, cellulase and amylase. More importantly, while D2 discloses the use of one polysaccharide modifying enzyme selected from and out of the enzymes mentioned therein, D2 neither recites nor teaches the combination of enzymes and also does not, consequently, claim unexpected results by use of such combination. In

the case at hand, the process in respect of which the claim is made is not disclosed in D1 or D2. The respondent has also failed to establish that it forms a part of common general knowledge. The above discussion leads to the conclusion that the claimed invention is in respect of a new process. In any event, the process described by the claim deploys more than one new reactant. For these reasons, I conclude that the claimed invention is not excluded from patent protection by virtue of Section 3(d) of the Patents Act.

21. The last aspect to be examined is whether the claimed invention would be obvious from cited prior art in combination with common general knowledge. Since obviousness analysis is required to be undertaken from the perspective of a PSITA, the first step in the process is to identify the PSITA. Such identification should be undertaken with reference to the field of invention. Given that the invention relates to the use of FAE to improve apparent metabolizable energy in animal feed, PSITA would be a biochemical scientist/engineer with exposure to the animal feed industry.

22. As noticed while discussing the rejection under Section 3(d), the claimed invention relates to a process involving the deployment of

four main chain degrading enzymes in combination. In Table 1 of the complete specification, the appellant has recited as under:

"Along with the Prototype I enzymes, FAE was added at the dosage of 20 U and 40 U per kg of feed.

Table 1. Activity profile of Prototype I enzymes

Enzymes	*Enzyme activity / g of Prototype 1**
Cellulase	*6351.84 ± 48.07*
Xylanase	*42358.98 ± 192.3*
Glucanase	*8426.18 ± 119.04*
Amylase	*1394 ± 3*

** The enzyme assays were performed on specific substrates, following standard techniques"*

It is noticeable from Table 1 that the enzymatic activity of each enzyme is set out therein. Table 7 sets out data on the amount of ferulic acid released from DSWB in four groups, including if FAE is used with Prototype I (as per claimed invention). Table 7 is as under:

Table 7. Synergy between FAE and Prototype I enzymes in the release of ferulic acid from DSWB

Groups	*Ferulic acid released from DSWB(uM)*
FAE	*35 ± 2*
Prototype I	*3.73 ± 0.40*
Prototype I + FAE	*441.54 ± 3.10*
Control	*2.44 ± 0.09*

The above table provides experimental data to establish that the amount of ferulic acid released from DSWB when prototype I is combined with FAE is far higher than the amount released in the other groups referred to in the said table. Learned counsel for the appellant also referred to Figures 2, 7 and 8. Figure 2 depicts four groups, which include prototype I with FAE of 20 units per kg and prototype I with FAE of 40 units per kg. The bars in respect of these two groups are higher in comparison to the control group and prototype I. Figure 8 is as under:

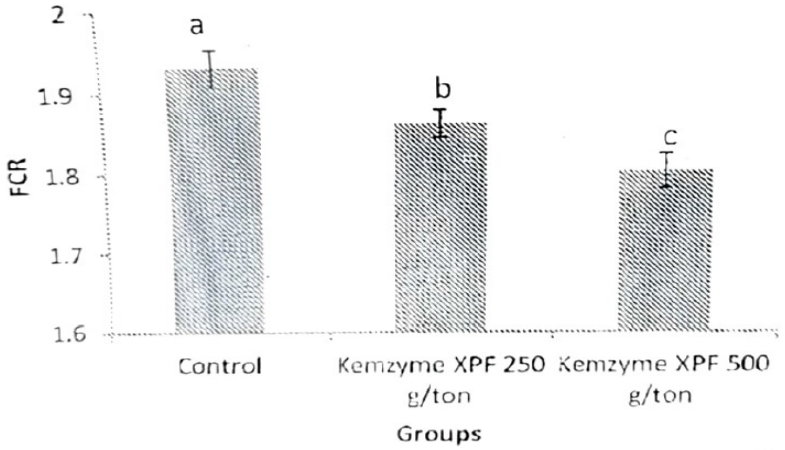

FIG. 8

The above figure shows that the FCR of the control group is higher than the FCR of the two groups wherein the claimed method or process is deployed. This data supports the claim of increased efficiency in extracting metabolizable energy.

23. The cited prior arts should be revisited in order to determine whether the claimed invention would be obvious therefrom. It is clear from the first paragraph of the summary of D1 that it discloses the combination of feruloyl esterase and xylanase. Claim 1 thereof deals with a phenolic acid esterase comprising the amino acid sequences set out therein. As the record shows, D1 does not make any reference to the other three enzymes referred to in the monopoly claim of the appellant.

24. When a specific question was put to the respondent, the respondent stated that there are a large number of NSP degrading enzymes. Learned counsel for the appellant submitted that the full complement of enzymes - for instance, in a human being - would be in the region of 75000. From Table 1 of the claimed invention, it is evident that the enzymatic activity of each enzyme constituting prototype I enzyme has been specified therein. Thus, it is clear that the claimed invention involves the use of all four enzymes in combination with FAE. The results of, including synergistic effect, the use of these four enzymes in combination with FAE are set out at Table 7 as discussed earlier. It does not appear that prior art D1 contains teaching, suggestion or

motivation to arrive at the claimed invention. Prior art D2 remains to be discussed.

25. As noticed earlier, prior art D2 recites the use of not only xylanase, but also glucanase and cellulase. D2 recites, in relevant part, as under:

> *"Preferably, the enzyme is used in combination with any one of a glucanase, a proteinase, an acetyl esterase, a rhamnogalacturonase, an arabinase, a pectinase, a cellulase or a xylanase, preferably an endoxylanase."*

In addition, dependent claim 5 of D2 discloses the enzyme system as one wherein the enzyme of interest (EOI) is a polysaccharide modifying enzyme selected from the group consisting of a xylanase, arabinase, glucanase, pectinolytic and rhamnogalacturonase. D2, however, does not teach the combination of the different polysaccharide modifying enzymes referred to therein, or even provide pointers to the use of such combination. In any event, it should be noticed that the claimed invention is in respect of the combination of four specific NSP modifying enzymes,

namely, cellulase, xylanase, glucanase and amylase. The appellant has also demonstrated the synergistic effect arising out of such combination in Table 7. In Figures 7 and 8, experimental data to establish increase in body weight and lower FCR, respectively, has been provided. Especially in the absence of any evidence of a limited set of options, with regard to the NSP modifying enzymes, I conclude that the deployment of a particular combination by the appellant constitutes an inventive step, and conclusions to the contrary in the impugned order are untenable.

26. For reasons set out above, CMA(PT)No.46 of 2024 is allowed on the following terms:

(i) Impugned order dated 19.07.2022 is set aside.

(ii)Patent Application No.201617013577 shall proceed to grant.

(iii) There will be no order as to costs.

18.03.2025

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

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SENTHILKUMAR RAMAMOORTHY, J.

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To

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CMA(PT).No.46 of 2024

18.03.2025