2024:MHC:4188

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 17.12.2024

Pronounced on : 20.12.2024

CORAM:

THE HON'BLE MR. JUSTICE ABDUL QUDDHOSE

(T) CMA (PT) No.45 of 2023

ITALFARMACO SPA,
Italy.
Rep. by their constituted
Attorney Ms.Monika Gupta .. Appellant

vs.

Deputy Controller of Patents & Designs,
The Patent Office,
Intellectual Property Building,
Guindy, Chennai – 32. \ .. Respondent

Prayer: This appeal is filed under Section 117A of the Patents Act, 1970, against the order dated 20.04.2020 issued by the Deputy Controller of Patents and Designs under Section 15 of the Patents Act, 1970, rejecting the grant of Patent in the manner of the Patent Application No.10810/CHENP/2012.

For Appellant : Mr.K. Shitji Saxena
for Mr.Arun C.Mohan for Kan and Krishme

For Respondent : Mr.S.Diwakar, CGSPC
Mr.B.Ahilan, Joint Controller of Patents and Designs

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JUDGMENT

This appeal has been filed under Section 117A of the Patents Act, 1970 (in short "the Act") aggrieved by the order dated 20.04.2020 passed by the respondent refusing to grant patent for the claimed invention of the appellant on the ground that the said claimed invention lacks inventive step as it falls under Section 3(d) of the Act.

2. The learned counsel for the appellant drew the attention of this Court to the impugned order and would submit as follows:-

(a) The respondent has failed to appreciate that different types of casein with different levels of purity are available in the market. Specifically, it is marked as (a) technical grade casein; and (b) food grade casein and casein for pharmaceutical use.

(b) The respondent has failed to appreciate that technical grade casein is used in various industrial fields such as production of paints, adhesives and textile materials. Equipment and substances used for the production of technical grade casein are unsuitable for the production of products for human use, and stronger operating conditions can be used for technical grade casein. The technical grade casein has more protein impurities and a higher fat content. The characteristics of

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casein for food and pharmaceutical use are established in the corresponding monograph of the USP-NF before the respondent.

(c) The respondent has failed to appreciate the differences between the different types of casein and the meaning of the phrase "casein of suitable purity for a pharmaceutical process" reported in the prior art document (D1) is evident, but, this phrase does not imply the importance of the purity criteria claimed by the appellant, that is, protein impurities content lower than 15% by weight and/or inorganic impurities content lower than 1% by weight and/or a phosphorous/nitrogen ratio greater than 5%; that allows to increase the solubility of iron (III) caseinsuccinylate and to reduce the viscosity of its aqueous solutions.

(d) The respondent has also not appreciated the claimed purity criteria of the appellant and this was also also not mentioned in the prior art documents in which the purity parameters of casein for human use are defined.

(e) The respondent has failed to consider that not even in the prior art document (D2), the claimed characteristics of the casein are mentioned . In D2, it is not even specified that in the process, it is necessary to use casein for human use and not technical grade casein. A similar situation can be found in the prior document (D5).

(f) The respondent, with respect to the document GB 2115821, has failed to take into consideration that the definition of the raw material is so broad as to

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include proteins in general and on this basis, one could arrive at the extreme situation of an iron derivative in which there is no iron (III) caseinsuccinylate at all.

(g) The respondent, instead of the specific parameters of casein, such as, P/N ratio, ought to have determined the advantageous results of the invention and not the simple fact that the quality of the casein is more or less good; or more or less suitable for its use in the pharmaceutical field.

(h) The respondent has failed to appreciate that the method for preparing iron (III) caseinsuccinylate could not have been easily made before filing the present application by a person with ordinary skill in the art, and therefore, the appellant possesses inventive step over D1 to D6 alone, or in any fair combination. In view thereof, the method as claimed in claims 1 to 6 is not obvious and thus fulfill the requirement of Section 2(1)(ja) of the Act.

(i) The respondent has failed to appreciate the graphical representation of table 2 submitted along with post hearing written submissions on 16.10.2019. The respondent has failed to take into consideration pages 1 and 2 in the attachment, wherein the comparison of the solubility in 11.5 parts of water for products according to the examples in the specification comprising 5% and 6% of iron

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respectively, in function of the phosphorous/nitrogen ratio is evidenced.

(j) The respondent has failed to appreciate that in the complete specification submitted by the appellant, the higher solubility of iron (III) caseinsuccinylate of the invention and the lower viscosity of the liquid compositions containing it are particularly useful for the preparation of formulations of iron (III) caseinsucceinylate at high concentration of iron. Such low viscosity characteristic also allows microfiltration of liquid compositions containing iron (III) caseinsuccinylate of the invention.

(k) The respondent has merely passed a mechanical order of rejection of the present patent application under Section 2(1)(j) and Section 3(d) of the Act. The differences of the present invention with respect to cited documents would clearly suggest that the present invention is novel and inventive over prior arts and cannot be rejected under Section 2(1)(j) of the Act.

3. On the other hand, the respondent, in their counter affidavit, has reiterated the reasons given in the impugned order for refusing to grant patent to the appellant, as the claimed invention does not involve any inventive step of the appellant and is only a mere new form of a known substance and thus, it is hit by Section 3(d) of the Act.

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DISCUSSION:-

4. As seen from the impugned order, the grounds raised in this appeal have already been well considered by the respondent and only thereafter, on the ground that the appellant claimed invention does not involve any inventive step and is only a new form of a known substance, the respondent has refused to grant patent under Section 3(d) of the Act. The reasons given by the respondent for refusing to accept the contentions of the appellant are found in paragraph Nos.17 and 18 of the impugned order, and the same is re-produced hereunder:-

> *"17. The applicant stressed the fact that the present invention uses purified casein as the reactant which is having a protein impurities content lower than 15% by weight and/or inorganic impurities content lower than 1% by weight and/or a phosphorous/nitrogen ratio greater than 5%. Though the given cited documents are very closest to the present invention as a whole the applicant did not comment or bring any other differences except the reactant description and product description. The applicant is also stressing the fact that the prior art uses commercial casein as a starting material without any further step of purification. It is very clear that if the starting material is in good quality the product also in good quality. Because the quality and description of the starting material decides the quality and description of the product. Therefore it is obvious to the person skilled in the art.*

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18. It is obvious to the person skilled in the art to replace the commercial grade casein with that of the purified casein as starting material. Moreover it is evident from the page 4 of D1 as it starts the process with the reactant casein of suitable purity."

Overall the process of synthesis of the iron succinyl casein and iron acetyl-aspartate casein complex comprises the following steps:

1) The casein of suitable purity for a pharmaceutical process, dissolved with water with an addition of caustic soda having a pH of less than

The term "casein of suitable purity" is enough for the person skilled in the art to prepare the iron succinlyateed casein with different range of qualities of starting material casein. If the purified casein is used as raw material the product iron succinlyateed casein also of good quality of product description. The product description claimed in the instant invention are inherent property of the good quality product if good quality of the starting material is used. The examples of the present invention also fall within the disclosures of D1, D2, D3 and D5 as discussed above in para 12 to 15. It is obvious to the person skilled in the art to arrive the product of the present invention from the disclosures of D1, D2, D3 and D5. Therefore the present invention does not involve inventive step under section 2(1)(ja) of the Patents Act.".

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5. While coming to the conclusion that the process of claimed invention falls within the scope of Section 3(d) of the Act, since they relate to a mere use of a known process which does not result in new product or any new recreant, the respondent has also relied upon five prior art documents, namely, D1 to D5. A detailed explanation has also been given as to how D1 to D5 (prior art documents) are almost identical to the appellant's claimed invention. Discussion made in the impugned order with regard to D1, D2, D3 and D5 is extracted hereunder:-

> ***D1 discloses*** *a process for producing Iron succinyl casein and acetyl aspartate casein and it claims the process for producing an iron complex (III) with succinyl casein. In page 4 it explicitly disclose the process of synthesis of the iron succinyl casein and iron acetyl aspartate casein complex, as follows;*
>
> *Overall the process of synthesis of the iron succinyl casein and iron acetyl- aspartate casein complex comprises the following steps:*
>
> *1) The casein of suitable purity for a pharmaceutical process, dissolved with water with an addition of caustic soda having a pH of less than eleven, preferably less than 9, is made to react with succinyl anhydride or acetyl-aspartate anhydride in order to obtain succinyl casein or acetyl-aspartate casein which are precipitated for acidification at a pH of between 2.5*

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and 3.

2) The succinyl casein and acetyl-aspartate casein obtained in step 1 are dissolved in water with addition of caustic soda with a pH of less than 11, preferably less than 9, and are then reacted with iron chloride to obtain the iron succinyl casein and iron acetyl-aspartate casein complexes which precipitate from the solution when a pH of 2.5 to 3 is reached.

3) The complexes obtained in step 2 can be purified by pulping in water or alternatively by dissolving in water and caustic soda at a pH of less than 11, followed by a further precipitation at pH 2.5 to 3. The iron succinyl casein or iron acetyl-aspartate casein complexes are then dissolved in water with the help of caustic soda at a pH of less than 11, preferably less than 9, and are then added to by suitable preservatives (e.g. parabens) before being sent on to a spray-drier, where a powder is obtained that is directly usable for the pharmaceutical mixtures it is destined for."

D2 discloses *a detailed process for the preparation ferri-succinylcasein as given below;*

120 g casein are suspended in 1622 g water at a temperature of 20 °C. The pH value is adjusted to 8 by the addition of 9.8 ml 30% NaOH solution within 40 min. 20 g succinic anhydride are added in four portions within 20 min. During that time the pH value is maintained at 8 by the addition of 32.8 ml 30% NaOH

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solution. The resulting solution is stirred for 30 min, maintaining the pH value at 8. The succinylcasein is precipitated by adjustment of the pH value to 4 with 60.5 ml 20% HCI solution. 57.2 g of a FeCl, solution (12%) are added within 10 min, maintaining the pH value at 4 by the addition of 32.9 ml 30% NaOH solution. The resulting suspension is stirred for 30 min at a pH value of 4 and then heated up to 30 °C in 25 min. The pH value is adjusted to 9 by the addition of 45.0 ml 30% NaOH solution. The solution is stirred for 1 hour at 30 °C and a pH value of 9. After filtration the product is precipitated by the addition of 70.5 ml 20% HCI solution until a pH value of 3.6 is obtained. The product is filtered, washed with I litre water and then dried for 5 hours at 75 °C and a pressure of 50 mbar on a rotavap. The product is further dried for 15 hours at 75°C and a pressure of 125 mbar in an vacuum dryer. 133 g of ferri succinylcasein are obtained.

D3 discloses *'Bio-available iron derivatives which do not cause gastric lesions, method of Preparation and related pharmaceutical compounds' with its various total iron content from various source. In example 1, it discloses 'preparation 5% iron derivative from Succinylated proteins of whole milk powder' as follows;*

EXAMPLE 1

Preparation of 5% iron derivatives from succinylated proteins of whole milk powder, 1 kg of milk

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powder was suspended in 6 litres of 0.3 M sodium bicarbonate and, with mechanical stirring and pH control, 500 g of succinic anhydride were added in successive portions, the pH being maintained within a range of between 7.5 and 8 by means of the addition of 4N NaOH. After the addition. the mixture was stirred for 2 to 3 hours at ambient temperature. During this time, the suspension was completely dissolved. The opalescent solution was centrifuged or filtered until almost clear and slowly acidified with HCl up to pH 3.

The precipitate formed was separated by centrifugation or filtration and re-suspended in water (approx. 8 litres). Noch solution was added until it was completely dissolved (pH approx. 7.51) Centrifugation was carried out and the clear solution was re-acidified to pH 2.5-3 by means of the addition of HCl.

The precipitate was recovered by filtration or centrifugation and washed with an HCl solution having a pH of 3. The residue, constituted by the succinylated proteins (whose degree of succinylation could be varied as a function of the amount of succinic anhydride used; in the case discussed here, this was 90% with respect to the groups which could be succinylated in the initial protein as given below) was, after drying under vacuum, dispersed in distilled water. It was dissolved by the addition of NaOH up to pH 7.5 diluting the solution such that the final protein concentration was approx. 0.04

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g/ml. A solution of an iron salt (for example FeCI,) with a ratio of Fe3+/succinylated protein of 1:10 by weight was added to this solution. This provided a suspension which was finely dispersed by means of mechanical stirring whilst the pH dropped to approx. 2.5. Stirring was continued for 3 hours at ambient temperature and the suspension was then filtered. The solid was suspended in water (approximately 3 volumes) and was dissolved by the addition of NaOH (pH 7.5).

The solution, which was not completely clear, was filtered and the product in the solid state recovered using one of the following methods:

a) the solution was acidified and the precipitate obtained at a pH of 2.5 was filtered off and dried under vacuum:

b) the clear solution was dialysed against water in order to eliminate the sodium chloride and then freeze-dried or dried by a spray dryer.

The finished product yields were the same and amounted to approximately 20% by weight of the initial powdered milk. The characteristics of the product are described in Table I.

D5 discloses *'Ferro-succinylcasein complex, process for its preparation and pharmaceutical compositions containing it' with its total iron content. In example 1, it discloses the detailed process for the preparation of 'Ferro-succinylcasein complex'.*

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6. The appellant's claimed invention is stated below:-

1. Method for preparing iron (III) caseinsuccinylate comprising the following steps:

a) reacting casein and succinic anhydride in water to obtain succinylated casein,

b) reacting succinylated casein with iron (III) chloride to obtain iron (III) caseinsuccinylate having a content of iron comprised between 4.5 and 7% by weight, a solubility in 11.5 parts of water greater than 92% and having its 8% water solution with a viscosity lower than 400 mPa.sec,

c) characterised in that said casein according to step a) is purified casein, having a protein impurities content lower than 15% by weight and/or inorganic impurities content lower than 1% by weight and/or a phosphorous/nitrogen ratio greater than 5%"

On interpreting the present claim we can understand the steps involved in the process of present invention are " a) reacting casein and succinic anhydride in water to obtain succinylated casein and b) reacting succinylated casein with iron (III) chloride ". The second part claimed in step b) of claim 1 describes the product. The step c) characterizes the reactant casein used in the present invention as purified casein by describing its impurity profile and phosphorous / nitrogen ratio.

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7. The respondent has compared the examples of the claimed invention of the appellant with that of the cited prior art documents (D1, D2, D3 and D5), and only thereafter, the respondent has come to the conclusion that reactants casein, succinic anhydride and iron chloride are same and the product iron succinilated casein is a known product, which does not involve any inventive step of the appellant, and therefore, the patent application has to be refused under Section 3(d) of the Act.

8. ***Novartis AG Vs. Union of India [(2013) 6 SCC 1]*** is one of the landmark judgments in the Indian Patent regime. In the said judgment, Section 3(d) of the Act was elaborately discussed by the Hon'ble Supreme Court. Section 3(d) says that 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, is not patentable. In the explanation to Section 3(d) of the Act, it has also been made clear that for the purpose of Section 3(d), salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of

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known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. Section 3(d) also enumerates that discovery of a new form of an already existing substance fails the test of novelty. The enhancement of efficacy is an essential condition for the invention to get patented. Moreover, the invention also needs to be totally new. If there is only the change in molecular formula of the substance used in the drug, then the invention is not patentable, because, it is not new and novel. The product in question needs to be undoubtedly new. Merely to change the molecular formula does not satisfy the test of novelty and hence, such inventions cannot be patented.

9. Patent is one of the intangible forms of property under Intellectual Property. The grant of patents must follow the tests of novelty, non-obviousness and utility. Only then the patent can be granted to the true and first inventor of the patent.

10. In the impugned order, justifiable reasons with scientific reasoning have been given by the respondent, as observed supra, for refusing to grant patent to the appellant's claimed invention as it falls under Section 3(d) of the Act. Since justifiable reasons have been given in the impugned order by the respondent for refusing to grant patent and there is no contra evidence produced by the appellant

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to dispute the same, this Court cannot interfere with the well considered findings rendered by the respondent pertaining to the appellant's claimed invention under the impugned order.

11. For the foregoing reasons, there is no merit in this appeal and accordingly, this appeal is dismissed. No Costs.

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Index:yes
Neutral citation: yes

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To

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