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

Date of decision: 30th August, 2022

\+ **C.A. (COMM.IPD-PAT) 6/2021 & I.A. 12828/2021**

DS BIOPHARMA LIMITED ..... Appellant

Through: Ms. Vindhya S. Mani & Ms. Justina Mathew, Advocates (M-9717065125)

versus

THE CONTROLLER OF PATENTS AND DESIGNS AND ANR ..... Respondents

Through: Mr. Harish V. Shankar, CGSC with Mr. Srish Kumar Mishra, Mr. Sagar Mehlawat, Mr. Alexandar Mathai Paikaday, Advs. (M-9810788606)

CORAM:
JUSTICE PRATHIBA M. SINGH

Prathiba M. Singh, J. (Oral)

1. This hearing has been done through hybrid mode.

2. The present appeal has been filed on behalf of the Appellant - DS Biopharma Limited, under Section 117A of the Patents Act, 1970 *(hereinafter, 'the Act')*, challenging the order dated 13th January, 2021 passed by the ld. Assistant Controller of Patents & Designs *(hereinafter, 'impugned order')*.

Brief Chronology of Events

3. The Appellant is a company based in Ireland. It filed Indian Patent Application No.201717040270 on 10th November, 2017 titled *'Compositions comprising 15-oxo-epaor15-oxodgla and methods of making and using same'.* The bibliographic details of the subject patent application are set out below:

Priority Application No.	US62/160863
Earliest Priority Date	13.05.2015
PCT International Application No	PCT/IB2016/000732
PCT International Filing Date	12.05.2016
Indian Patent Application No.	201717040270
Indian Filing Date	10.11.2017
Request for Examination Filed	13.05.2019
FER Issued	05.03.2020

4. The Appellant filed the Indian Patent Application initially with Claims 1-26, with the priority date of 13th May, 2015. The same was published under Section 11A of the Act on 29th December 2017. A request for examination under Section 11B of the Act was filed by the Appellant on 13th May, 2019. The Appellant, thereafter, voluntarily amended the existing claims and introduced new claims 1-26.

5. The FER was issued on 5th March, 2020 by the Patent Office, New Delhi, in which, the objections raised were as under:

(i) lack of inventive step *qua* all claims 1-26,

(ii) non-patentability under Section 3(i); and

(iii) lack of clarity and conciseness under Section 10(5) and Section 10(4)(c) of the Act.

6. The said FER was responded to by the Appellant on 8th July, 2020, wherein it cancelled claims 7-26. Pursuant thereto, a hearing notice was issued on 25th November, 2020, in which the objection was restricted as under:

*"**Non-Patentability u/s 3***
1. Subject matter claimed in claim 1,4 is not Patentable u/s/ 3 (d) of Patents Act;"

7. In view of the above hearing notice which was received by the Appellant, the Appellant submitted its written submissions and also amended its claims on 28th December, 2020. The claims as they stand now are only Claims 1-4 which are as under:

"1. A composition comprising 0.1g to 4g of (5Z,8Z,11Z,13E,17Z)-15-oxoicosa-5,8,11,13,17-pentaenoic acid ("15-oxo-EPA").
2. A pharmaceutical composition comprising (5Z,8Z,11Z,13E,17Z)-15-oxoicosa-5,8,11,13,17-pentaenoic acid ("15-oxo-EPA") and one or more of antioxidants, surfactants, preservatives, flavoring agents, co-solvents, viscosity aids, suspension aids, and lipophilic phases.
3. A composition comprising 0.1g to 4g of (8Z,11Z,13E)-15-oxoicosa-8,11,13-trienoic acid ("15-oxo-DGLA").
4. A pharmaceutical composition comprising (8Z,11Z,13E)-15-oxoicosa-8,11,13-trienoic acid ("15-oxo-DGLA") and one or more of antioxidants, surfactants, preservatives, flavoring agents, co-solvents, viscosity aids, suspension aids, and lipophilic phases."

8. Thereafter, the ld. Assistant Controller of Patents rejected the said patent application vide the impugned order dated 13th January, 2021.

9. Ms. Mani, ld. Counsel appearing for the Appellant submits that all the initial objections which were raised in the FER were satisfied and the only new objection which was raised in the hearing notice was in respect of Section 3(d) of the Act. She submits that despite this being the position, in the impugned order, the grounds of lack of inventive step under section 2(1)(ja)

in addition to Section 3(d) and lack of clarity under Section 10(4)(c) of the Act have also been used as grounds to reject the patent application. This according to her would be violative of the principles of natural justice. She further submits that there is no clarity as to whether claims 1, 4 have been rejected or claims 1-4 have been rejected. In fact, there is contradiction between the hearing notice which states claim 1,4 and the final impugned order where claims 1,3 are stated to be not meeting the requirement.

10. On the other hand, Mr. Harish V. Shankar, ld. CGSC submits that the initial claims were Claims 1-26. The objection under Section 3(d) of the Act was specified in the hearing notice and all the prior arts being D1 to D6 were in the possession of the Appellant. The Appellant failed to provide efficacy data and accordingly the patent has been rightly rejected. He further submits that the mention of claims 1,4 or 1,3 is merely a technical error being raised inasmuch as the nature of the claims would show that claims 1 and 3 are composition claims and claims 2 and 4 are derivative claims.

11. The Court has perused the FER, the reply, the hearing notice, written submissions as also the impugned order. The objection under Section 3(d) was *qua* claims 1,4. Insofar as these claims are concerned, the relevant portion of the impugned order reads as under:

> *"The claimed compounds differ from the compounds of the prior art only on the account of minor modifications, namely the presence of an oxo group at position 15 of the carboxylic acid chain instead of a OH group of H atom with respect to the compounds of D1 and D4 respectively, and the presence of a double bound between C17-C18 of the carboxylic acid chain instead of a single bond with respect to the compound of D6.*
> *(IV) (i) It is founds that specific known compounds known as stated above,*

(ii) Claimed compounds are trivial and hence obvious modification of the compounds disclosed in the prior art.
(iii)Basis to assert that the alleged 'known' substance and the claimed molecule or substance have the same 'known' efficacy? at is the specific 'known' substance in question? In absence of the data not provided in specification or later, efficacy of the compounds in question is not known,
Due to similar reasons it is not held inventive in the written opinion of the International Searching Authority, hence test applied to section 3(d) given by IPAB also applied to compounds claimed in claim 1,4 is applicable, hence these not meeting requirement of section 3(d) , 2 (j) (a) of Patents Act,"

12. A perusal of the initial FER would show that separate objections were raised under Section 2(1)(ja) of the Act being lack of inventive step, Section 3(i) of the Act being method of treatment of humans and animals and lack of clarity in conciseness under Section 10(5) of the Act. This was responded to by the Appellant in its response to the FER and thereafter the objection was restricted to Section 3(d) of the Act in respect of claims 1,4 in the hearing before the ld. Assistant Controller of Patents & Designs. Section 3(d) of the Act reads as follows:

"3. What are not inventions.—The following are not inventions within the meaning of this Act,—

(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;"

13. Even if the Court ignores the wrong description of the claims by the Patent Office, clearly, the substantive objection was raised under Section 3(d) of the Act. The legal position in respect of an objection under Section 3(d) was considered by the IPAB in ***ORA/22/2011/PT/KOL*** titled ***Fresenius Kabi Oncology Limited v. Glaxo Group Limited & Anr., 2013 SCC OnLine IPAB 121.*** The relevant portion of the order is as follows:

"56. It is true that it is the patentee who must prove the enhanced therapeutic efficacy of his invention. But in a revocation the applicant must plead and prove that it is hit by S.3(d) and that it has the same therapeutic efficacy as the known substance. Then the respondent will counter it either by proving that it is not a derivative of a known substance or by proving that though it is only a new form of a known substance he has shown that it has enhanced therapeutic efficacy. In the present case, there are no such pleadings. It is not enough to plead that because Ex1 and 2 are admitted prior arts, this is only a new form of those compounds. That is vague. It is only when the pleadings show how the invention is one kind of a derivative of known substance the patentee will have to explain how the grant of patent is justified because of the enhancement of therapeutic efficacy. In this case the pleadings are not adequate. We hold that the S.3(d) ground has not been proved."

14. The above observations were made by Justice Prabha Sridevan in a case

where revocation of the patent was sought on the ground of non-patentability under Section 3(d). Though not in the context of a patent office objection, the observations would be relevant to examine as to how the objection under Section 3(d) is to be raised. Section 3(d) bars patentability of a `new form' of `a known substance', without establishing enhanced therapeutic efficacy. For the said objection to be raised, the basic pre-condition would be the identification of the `a known substance'. The said `known substance' could be one substance or a compound/s derived from a Markush formula. However, it has to be identified. It cannot be left to the Applicant to deduce as to what is the known substance and thereafter give efficacy data qua that known substance, based on the said deduction. It is only new forms of substances which are derived from the same known substance that would attract the rigors of Section 3(d). However, in this case, the compound which constitutes the `known substance' was not identified in the hearing notice. For the purposes of a Section 3(d) objection, the one specific known substance is to be identified and the manner in which the claimed compounds are 'new forms' ought to be mentioned by the Patent Office, even if not in detail but at least in a brief manner. The hearing notice does not mention so.

15. The Appellant in the reply to the hearing notice submits that the Ld. Controller has not specified under which part of Section 3(d) of the Act does the objection fall. The Appellant goes on to assert that as per its understanding of the ***Fresenius Kabi judgement*** *(supra)*, for an objection under non-patentability to be raised, the patent office needs to specifically allege and identify at least the following:

(i) What is the specific 'known' substance in question?

(ii) How and why the claimed molecule(s) or substance(s) is a

derivative or is otherwise a new form of a known substance?

(iii) Basis to assert that the alleged 'known' substance and the claimed molecule or substance have the same 'known' efficacy?

16. The Ld. Controller in the hearing notice has failed to identify any of the above three factors. It is also submitted by the Appellant that in the absence of identification of the 'known' compound it is unable to respond clearly to this objection, severely hampering its right to be given a reasonable opportunity to defend its patent application. It further submits that it is under no legal obligation under Section 3(d) of the Act to demonstrate the efficacy of the claimed compound in the absence of identification of the 'known' compound.

17. In the present case, the finding of the Controller is as under:

> *"The claimed compounds differ from the compounds of the prior art only on the account of minor modifications, namely the presence of an oxo group at position 15 of the carboxylic acid chain instead of a OH group of H atom with respect to the compounds of D1 and D4 respectively, and the presence of a double bound between C17-C18 of the carboxylic acid chain instead of a single bond with respect to the compound of D6."*

18. Thus, the Controller clearly holds in the impugned order that the identified compounds are in D1 and D4 in which at position 15, a substitution has been made by the Appellant. The identified known substances are also in D6 where the presence of double bond between C17 and C18 of the carboxylic acid chain, instead of the single bond in the claim of the Appellant. These facts could have been contained in the hearing notice, upon which, the Appellant could have responded as to how the objection under Section 3(d) was not attracted. The Appellant could have also established that the subject

compounds had enhanced therapeutic efficacy to satisfy the pre-conditions under Section 3(d).

19. Therefore, holistically read, the Appellant has not had adequate opportunity to deal with the objection under Section 3(d) in as much as apart from merely specifying the said objection for the first time in the hearing notice, the manner in which the said objection was attracted was completely absent.

20. In the absence of the proper identification of the known substance in the hearing notice and a lack of proper opportunity being afforded to respond to the objection under Section 3(d), the impugned order is not sustainable.

21. At this stage, Ms. Mani, ld. Counsel for the Appellant submits that the corresponding patent application in the U.S.A. has been granted in favour of the Appellant and is pending in other jurisdictions. Be that as it may, Section 3(d) is unique to the Patents Act, 1970 in India. The Appellant would have to deal with this objection which has now been clearly crystallized in the impugned order and has also been captured above.

22. In order to afford the Appellant a fair opportunity to deal with this objection, the following directions are issued:

i) The Appellant shall file its response on the basis of the identified known substances and the extracts of the impugned order as set out above. In response, the Appellant may also produce efficacy data and support its submissions as to how Section 3(d) is not applicable.

ii) The said response shall be filed by the Appellant within a period of 8 weeks - upon which, a fresh hearing shall be granted on the issue of whether the claims 1-4 are liable to be granted or not in

view of the objections under Section 3(d) of the Act.

iii) The Controller is also permitted to consider along with the objection of Section 3(d) the objection relating to lack of inventive step, if any.

23. Insofar as clarity and conciseness in concerned, having perused the final four claims, this Court is of the opinion that the objection under Section 10(4)(c) and Section 10(5) of the Act would not arise in the present appeal. The Controller shall make endeavour to decide the appeal within a period of six months from today.

24. The appeal is allowed in the above terms. The impugned order is set aside. Nothing stated in the impugned order or in the present order would bind the Controller on the merits of the objections which are to be dealt with him under Section 3(d) or under Section 2(1)(ja) of the Act.

PRATHIBA M. SINGH
JUDGE

AUGUST 30, 2022
Rahul/Kt/Aman
(corrected & released on 12th September, 2022)