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\* **IN THE HIGH COURT OF DELHI AT NEW DELHI***Date of decision: 4<sup>th</sup> September, 2023*+ **C.A.(COMM.IPD-PAT) 5/2022 and I.A. 17000/2023**

W R GRACE AND CO CONN ..... Appellant

Through: Mr. Debashish Banerjee, Mr. Ankush Verma, Mr. Vineet Rohilla, Mr. Rohit Rangi and Mr. Tanveer Malhotra, Advocates (M: 9810948290).

versus

THE CONTROLLER OF PATENTS ..... Respondent

Through: Mr. Harish Vaidyanathan Shankar CGSC with Mr Srish Kumar Mishra, Mr Sagar Mehlawat, Mr Alexander Mathai Paikaday, Mr Krishnan V and Mr. M Sriram, Advocates.

**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 by W.R. GRACE & CO. CONN. a US based Company under Section 117A of the Patents Act challenging the impugned order dated 29th July, 2021 by which the patent application number 201717030699 was refused by the Patent Office.
3. The said patent is related to a “CRYSTALLINE FORM OF NICOTINAMIDE RIBOSIDE” along with the method of preparing such crystalline form II of “NICOTINAMIDE RIBOSIDE CHLORIDE” for their use in pharmaceutical compositions. The priority date of the present patent



application is 30<sup>th</sup> August, 2017.

4. The impugned order dated 29<sup>th</sup> July, 2021 by the Patent Office had rejected the Appellant's patent on the ground of lack of inventive step i.e section 2(1)(ja) and also being hit by Section 3(d) and section 3(e) of the Patents Act, 1970.

5. A bare perusal of the impugned order would show the reasoning behind refusing grant of patent to the subject patent application by the Patent Office. The relevant extracts of the order are set out below:

i. *Lack of inventive step i.e. section 2 (1) (ja)*

*“From the teachings of the combination of prior art documents D1-D73, it is obvious to the person skilled in the art to make new crystalline form-11 of the known compound nicotinamide riboside chloride by using very known routine experimentation by changing the solvent system with the knowledge of recrystallisation methods. Hence, the subject matter of the present amended claims 1-16 cannot be allowable under section 2(1)(ja) of the Indian Patents Act, 1970.”*

ii. *Did not met the requisite requirement of enhancement in “therapeutic efficacy” of the known substance i.e. section 3(d)*

*“In the case of medicines, efficacy means “therapeutic efficacy” and physico-chemical properties of substances do not meet the requirement of “therapeutic efficacy”. It was also held that patent applicants must prove the increase in therapeutic efficacy and just increased thermodynamic stability alone and less hygroscopic property may not necessarily lead to an enhancement of therapeutic efficacy, and in any given case enhanced efficacy must be specifically claimed and established by research data (the Hon'ble Supreme Court in the matter of Novartis AG Vs. Union of India, W.P.No. 24760/06).*



*Likewise by performing the routine experimentation preparing new form of known substances by changing the solvent system can be considered as same method.*

*Therefore, the amended claims 1-10 and 12-17 and are not patentable under section 3(d) of the Patents Act as the Applicant fails to prove the increase in therapeutic efficacy of new form of known substance nicotinamide riboside chloride (i.e. Crystallin form-11 of nicotinamide riboside chloride) and for making the crystalline form-11 of nicotinamide riboside chloride performed the routine crystallisation method as already known in the art. Therefore used method is considered as known method.”*

*“Hence, the subject matter of the present amended claims 1-10 and 12-17 are not allowable under Section 3(d) of the Patents Act.”*

*iii Presence of only one active component, which did not met the requirement of composition claim i.e. section 3(e) of the Patents Act, 1970.*

*“The subject matter of the amended claim-11 cannot be considered as composition claim since only one active ingredient present and no composition of components mentioned in the claims. For suppose any composition present in the invention it should have minimum two active components. But in this case only one component present. Therefore the amended claim-11 cannot be allowable under Section 3(e) of the Patents Act”.*

6. Ld. Counsel for the Appellant has now moved an application being **I.A. 17000/2023** as per which they have filed an amended claim set as per which the scope of the claims would be restricted to the method aspect of preparing a Crystalline Form II of nicotinamide riboside chloride and hence



deleted claims 1 to 11.

7. The Court has perused the amended claims and is of the view that the refusal to grant subject patent application in the impugned order primarily is in respect of the product claims. The deletion of the product claims would completely change the nature of the patent application itself. After having perused the amended claims, this Court is of the view that the same appear to be within the overall scope of the patent application filed.

8. Under such circumstances, the amended claims are taken on record and the same shall now be examined by the Patent office, in accordance with law. The amended claims be now filed before the Patent Office and the same shall be re-examined on merits by the Patent Office. The decision in this matter be rendered within a period of four months from today.

9. Ld. Counsel for the Appellant submits that the novelty in the patent application having been acknowledged, the process deserves to be granted a patent. This submission shall be considered by the Patent Office.

10. Accordingly, under these facts and circumstances the present appeal is disposed of and the matter is remanded to the Patent Controller for a fresh consideration of the amended claims.

11. Further, the observations in the impugned order would not come in the way of the amended claims being examined afresh by the Patent Office.

**PRATHIBA M. SINGH, J.**

**SEPTEMBER 4, 2023**

*mr/am/ks*