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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
Date of Decision: 13th March, 2024.

\+ C.A.(COMM.IPD-PAT) 255/2022
BAYER PHARM AKTIENGESELLSCHAFT

..... Appellant

Through: Mr. Debashish Banerjee, Mr. Ankush Verma, Mr. Vineet Rohilla, Ms. Vaishali Joshi, Mr. Pankaj Soni, Mr. Rohit Rangi and Mr. Tanveer Malhotra, Advocates.

versus

THE CONTROLLER GENERAL OF PATENTS AND DESIGNS

..... Respondent

Through: Mr. Srish Kumar Mishra, Mr. Harish Vaidyanathan Shankar, Mr. Alexander Mathai Paikaday, Mr. Lakshay Gunawat and Mr. Krishnan V., Advocates.

CORAM:
HON'BLE MR. JUSTICE SANJEEV NARULA

JUDGMENT

SANJEEV NARULA, J. (Oral):

1. Appellant's patent application No. 5818/DELNP/2006 [hereinafter '*subject application*'] has been refused through order dated 16th May, 2012 [hereinafter, 'impugned order'] under Section 15 of the Patents Act, 1970 [hereinafter '*Act*'] on the ground that the claims recited in the subject application do not fulfil the criteria laid down under Section 3(e) and Section 3(i) of the Act.

2. Before taking note of the controversy, it would be appropriate to take

note of the claim 1 of the subject application, which reads as follows:

> ***"We Claim:***
>
> *1. A composition comprising;*
> *i) two units containing 3 mg estradiol valerate,*
> *ii) 5 units containing 2 mg estradiol valerate and 2 mg dienogest,*
> *iii) 17 units containing 2 mg estradiol valerate and 3 mg dienogest,*
> *iv) 2 units containing 1 mg estradiol valerate, and*
> *v) 2 units containing placebo."*

3. The ground for refusal, as delineated in the impugned order, reads as follows:

> *"FINDING AND CONCLUSION:*
>
> *The issue before me was to decide whether the finally amended claims falls within the scope of section 3(e) & section 3(i) of the patents Act 1970.*
>
> ***Section 3(e) & 3(i)***
>
> ***"A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substances"***
>
> ***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.***
>
> *As we understand that the composition should have a synergistic effect over the combination of the components. The invention claims composition comprising (i) two units containing 3 mg estradiol vale rate,*
> *ii) 5 units containing 2 mg estradiol valerate and 2 mg dienogest,*
> *iii) 17 units containing 2 mg estradiol valerate and 3 mg dienogest,*
> *iv) 2 units containing 1 mg estradiol valerate, and (v) 2 units containing placebo.*
>
> *The Agents for applicant has stated that the "composition of the invention comprises a synergistic admixture with improved efficacy and other enhanced and new properties which are disclosed or taught in any of the prior art" and also provide the Studies with previous tested pharmaceutical compositions (2B versus 2C).*
>
> *but they have failed to substantiate these arguments to prove the*

synergistic effect of the composition over the prior art cited documents, and also failed to prove that the invention is not a method of treatment the used ingredients does not have any % ratio it has shown only doses form of the ingredients and therefore claimed composition is a method of treatments in the form of daily doses units as indicated in page 4 of the complete specification. Therefore the claimed invention cannot patentable u/s 3(e) & 3(i) of the patent Act 1970.

In view of all the circumstances, submissions made by the agent for applicant during the hearing including all the documents on the record and in view of my above findings, I hereby refuse to grant of Patent for application no. 5818/DELNP/2006. U/S 3(e) and 3(i) of the Patent Act 1970."

APPELLANT'S CONTENTIONS:

4. Mr. Debashish Banerjee, counsel for the Appellant, contends as follows:

4.1. The Appellant was deprived of a fair opportunity to address the objection under Section 3(e) of the Act, as this specific ground was not mentioned in the notice preceding the hearing. This omission undermines the procedural fairness owed to the Appellant, preventing them from preparing a defence against a contention that was never formally raised.

4.2. Respondent's decision is flawed due to a critical misinterpretation of Section 3(i) of the Act. The crux of this argument is the Respondent's failure to distinguish between a composition and a method of treatment. The claim, as delineated, underscores that the patent application was directed towards a product – a composition – rather than a process or method of treatment. This distinction is critical, as it challenges the basis upon which the subject application was rejected.

RESPONDENT'S SUBMISSION:

5. *Per contra,* Mr. Srish Kumar Mishra, counsel for Respondent, argues that the objections and findings of the Respondent are well-founded, citing

the working examples detailed in the subject application. These examples, according to him, conclusively demonstrate that the claimed invention pertains to a method of treatment, thus, justifying the decision made and negating the need for any further review or interference. He further argues that Claim 1 describes a composition designed for administration in accordance with the days of the menstrual cycle – one tablet per day. Mr. Mishra contends that this specification outlines not merely a composition, but a dosing regimen that is intrinsically linked to the treatment of menstrual cycle disorders. In essence, the claim, as articulated, embodies a method of treatment through its prescribed use of the composition. He thus challenges the Appellant's classification of the invention as a product, asserting instead that its true nature and intended application render it a method of treatment, which falls within the exclusions specified under Section 3(i) of the Act.

ANALYSIS AND FINDINGS:

6. The Court has considered the aforenoted contentions. As regards non-communication of objection under Section 3(e) of the Act, this Court has consistently maintained, across multiple decisions, that the Controller of Patents is obliged to enumerate all pending objections in the hearing notice. This practice is fundamental to ensure procedural fairness, as it allows the Applicant to adequately prepare and present their arguments concerning the specified objections. A failure to do so is violative of the principles of natural justice that can significantly prejudice the Applicant's ability to effectively address and counter the objections raised.[1] Furthermore, Circular

[1] ***Perkinelmer Health Sciences INC and Ors v. Controller of Patents***, C.A. (COMM.IPD-PAT) 311/2022; ***Dolby International AB v The Assistant Controller of Patents and Designs***, C.A.(COMM.IPD-PAT) 10/2021.

No. 4 of 2011 published by the Controller General of Patents, Designs, and Trade Marks, states as follows:

> "*k. If upon Examination of the response submitted by the Applicant, the Examiner reports that some objections are still outstanding or raises further objection(s),* ***such objections shall be communicated alone with the notice of hearing****, giving reasonable time to the Applicant.*"

7. Evidently, in the present case, the hearing notice failed to enumerate the objections under Section 3(e) of the Act. Consequently, the Court concurs with Mr. Banerjee's argument that the order in question infringes upon the principles of natural justice. The omission deprived the Appellant of the opportunity to address this specific ground, thereby impairing their ability to defend their application fully. Therefore, the impugned order to that extent, is arbitrary and suffers from procedural irregularities, and ought to be remanded to the Patent Office.

8. Regarding the objection under Section 3(i) of the Act, the Court observes that the impugned order lacks a substantive basis for dismissing the subject application on this specific ground. Moreover, under Section 10(4)(c) of the Act, to consider the invention as articulated by the Applicant, it is imperative to interpret the scope of the claims. Claim 1, as delineated, clearly indicates to the Court that it pertains exclusively to a product rather than a process. Consequently, based on the claim's composition and its representation within the application, the Court determines that Section 3(i) of the Act, which pertains to methods of treatment, does not apply to the case at hand.

9. Therefore, the Court finds merit in the contention of Mr. Banerjee that

mere recitations of the unit numbers of the components in claim 1 cannot render it ineligible for patent protection under Section 3(i) of the Act. Notably, in the said claim, as defined, there is neither any reference to a particular disease/ treatment, nor any reference regarding the modes/ manner of administration of the composition. In patent law, the claims of a patent define the boundaries of the patent protection. That is, they set out the legal limits of what the patent covers. The claims must be clear, specific, and supported by the description within the patent application. They are the most critical part of a patent application because they determine the extent of protection granted by the patent. Working examples, on the other hand, are provided in the subject application to demonstrate the practical implementation of the invention. These examples are intended to show that the invention is feasible and workable and how it can be carried out in practice. They provide support and understanding for the claimed invention, showing that it is not just a theoretical concept, but has practical applicability. Thus, while working examples are essential for demonstrating the feasibility and workability of an invention, they do not define the patent's scope. The scope is determined by the claims, which must be interpreted in light of the description and any examples provided. The reasoning for applying Section 3(i) of the Act to the subject application is therefore, misplaced. Mr Banerjee also relies on the decision of this Court in ***Societe Des Produits Nestle SA v. The Controller of Patents and Design and Anr.***,[2] where, in a similar situation, the Court referenced the Manual of Patent Office, Practice and Procedure, which gives the guidance for examination with respect to exclusion of medical, surgical, curative,

[2] 2023/DHC/000774

prophylactic, diagnostic, therapeutic or other treatment, and held that the claims in respect of the composition are patentable, and not hit by Section 3(i) of the Act. In the present case as well, the claim 1, as defined, in the opinion of the Court, does not render the application to be non-patentable.

10. It must also be clarified that although in the hearing notice, several other grounds were raised, however, the impugned order does not clearly specify whether such objections were met or remained outstanding. The Court has thus, not expressed any opinion regarding those objections.

11. In view of the above, the present appeal deserves to be allowed and the following directions are issued:

(i) The impugned order dated 16th May, 2012 is set aside and the matter is remanded to the Respondent for *de novo* consideration.

(ii) The subject application is restored to its original number.

(iii) Prior to deciding the matter afresh, Appellant shall be granted a hearing, and the notice of such hearing must clearly delineate the objection(s), if any.

(iv) After completion of hearing, the decision thereon shall be rendered within a period of three months from the date of conclusion of hearing.

(v) The Respondent shall decide the application uninfluenced by any observations made in the impugned order, and all rights and contentions of the parties are left open.

12. With the above directions, the appeal stands disposed.

SANJEEV NARULA, J

MARCH 13, 2024/as