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

\+ C.A.(COMM.IPD-PAT) 415/2022

ARTHROGEN GMBH ..... Appellant

Through: Mr. Sudhir Kumar, Advocate.

versus

CONTROLLER GENERAL OF PATENTS, DESIGNS AND TRADEMARKS AND ANR ..... Respondents

Through: Mr. Manish Mohan, CGSC with Mr. Jatin Teotia, Advocate for UOI.

CORAM:
HON'BLE MR. JUSTICE SANJEEV NARULA

O R D E R

% 05.02.2024

1. The present appeal, under Section 117A of the Patents Act, 1970 [hereinafter '*the Act*'], is directed against decision dated 28th November 2019 [hereinafter '*impugned order*'], in the matter of Indian patent application No. 11377/DELNP/2012 dated 31st December, 2012, wherein Respondent No. 2, under Section 15 of the Act, rejected the invention as non-patentable under Section 3(j) and 3(i) of the Act.

2. Appellant, ARTHROGEN GMBH, is a limited liability company incorporated in Germany. They filed patent application for the same or substantially same invention in various countries. Their International Patent Application No. PCT/DE2011/001322 was filed on 21st June, 2011 titled as "GELSOLIN ENRICHMENT OF BLOOD SAMPLES USING GOLD Union which was granted on 8th November, 2017 under Patent No.

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EP2590659B1. Similar Patents have been granted in Australia, Japan, Mexico, USA as well.

3. The invention is claimed in the preferred embodiment describing a method of producing a protein enriched blood serum comprising of steps (a) collecting a blood serum; (b) mixing the blood serum and gold particles in a container; (c) incubating the blood serum and gold particles to produce protein-enriched body fluid serum; and (d) removing the gold particles from the protein enriched blood serum.

4. The First Examination Report [FER] was issued on 23rd April, 2018 on the basis of originally filed thirty-one claims. The objections of non-patentability were raised under Section 3(c), (d), (e), (f) and (j) of the Act in the FER. The Appellant filed a reply to the same and revised the claims to comply with the objections raised in the FER. Pursuant thereto a hearing notice was issued on 13th September 2019 and besides other objections, non-patentability objections were raised under Section 3(b) and (i) of the Act. The Appellant attended the hearing and filed its written submissions post hearing. However, the impugned order was passed to the following effect:

> ***"Findings and Analysis:***
>
> *Considering the agent's submission in response to the examination report, submission made in the written note of arguments, I find that observations and submission made by the agent is not satisfactory with respect to the objection 2 communicated in the hearing notice.*
>
> *I observed that Claim 1-6 filed on 24/10/2019 along with the written note of arguments refers to method and product claims. The claims are as follows:*
>
> *1. A method of producing a protein enriched blood serum comprising the steps of: collecting a blood serum;*
> *mixing the blood serum and gold particles in a container;*
> *incubating the blood serum and gold particles to produce protein-enriched body fluid serum; and*
> *removing the gold particles from the protein enriched blood serum.*

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2. The method of producing a protein enriched blood serum as claimed in claim 1 wherein the blood serum is autologous or homologous blood to produce a protein enriched blood serum.

3. The protein enriched blood serum as claimed in claim 1 wherein the protein enriched blood serum contains gelsolin in an amount which is at least twice the corresponding value for standard blood gelsolin;

4. The protein enriched blood serum as claimed in claim 1 wherein the protein enriched blood serum contains gelsolin above the relevant standard blood level for gelsolin and cytokines above the relevant standard blood level for cytokines.

5. The method of producing a protein enriched blood serum as claimed in claim 2 wherein said blood and protein enriched blood serum have not undergone configuration or filtration to remove blood cells.

6. The method of producing a protein enriched blood serum as claimed in claim 2 wherein said blood or protein enriched blood serum have undergone centrifugation or filtration to remove blood cells.

Claims 3 of the present application claims for the protein enriched blood serum as claimed in claim 1 wherein the protein enriched, blood serum contains gelsolin in an amount which is at least twice the corresponding value for standard blood gelsolin. Claims 4 of the present application claims for the protein enriched blood serum as claimed in claim 1 wherein the protein enriched blood serum contains gelsolin above the relevant standard blood level for gelsolin, and cytokines above the relevant standard blood level for cytokines. Both the claims are claiming for blood serum with higher protein content. Further claim 5 claims that blood serum have not undergone centrifugation or filtration to remove blood cells. In other words it also claims for the protein enriched blood. In the present invention the blood or blood serum is incubated with gold particles for certain period of time followed by separation or removal of the gold particles. Then the blood or blood serum is used for autologous or homologous blood transfusion. Hence, amended claims 3 and 4 claims for protein enriched blood or blood serum i.e. a part of animal (human) and these claims fall under the scope of section 3(j) of the Act.

The claim 1 of the present invention claims for a method of producing a protein enriched blood serum. The claim 5 of the present invention claims for a method of producing a protein enriched serum with blood cells i.e. blood. Thus, the method refers to the protein enriched blood or blood serum by using gold particles. In the present method the

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blood or blood serum is incubated with gold particles for certain period of time followed by separation or removal of the gold particles for protein enrichment of the blood or blood serum. ***<u>The protein enriched blood or blood serum is used for autologous or homologous blood transfusion</u>****. Hence, amended claims 1, 2, 5, 6 claims for a method of treatment of human being and these claims fall under the scope of section 3 (i) of the Act.*

In view of the above findings and upon consideration to the submission to examination report and the written note of arguments, I find the alleged invention as claimed in revised claims fall within the scope of such clause (j) and (i) of Section 3 of the Act. Hence, I hereby order to refuse the instant application no. 11377/DELNP/2012 for grant of patent."

[Emphasis supplied]

5. Mr. Sudhir Kumar, counsel for Plaintiff submits as follows:

5.1. The findings of the Respondent No.2 are incorrect and based on misinterpretation and incorrect determination with respect to section 3(i) and 3(j) of the Act.

5.2. The hearing notice dated 13th September, 2019 [hereinafter '*the hearing notice*'], raised objections under sections 2(1)(j), 3(i) and 3(b) of the Act. While Respondent No. 2 was satisfied with the response to objection under Section 2(i)(j) of the Act, they hold that the response and submissions made were unsatisfactory with respect to non-patentability under Section 3(i) and 3(j) of the Act. However, it is pertinent to note that section 3(j) of the Act wasn't even included as a ground for objection in the hearing notice. Had such objection been included, the Appellant would have had a chance to adjust the claims accordingly. Therefore, because of failure to raise this objection in the hearing notice, Appellant was deprived of the opportunity to properly address and revise the claims in response. Therefore, the impugned order, to that extent, is in violation of principles of natural justice.

5.3. As regards objection under section 3(i) of the Act, Respondent No. 2 has failed to take note of the fact that the Appellant had not made any claim

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to the effect that "*then blood or blood serum is used for autologous or homologous blood transfusio*n". Respondent No. 2 has also failed to see the difference between "method of treatment" and "method for producing a substance or composition which may have a specific use in a method of surgery, therapy or diagnosis" and the present invention falls under the latter category. Therefore, the objection of non-patentability is clearly a misdirection on the part of Respondent No. 2.

5.4. The abovementioned contention is further supported by the fact that Patent with respect to the present invention has been granted by the Patent office of the European Union. Similar to section 3(i) of the Act, even Article 53(c) of the European Patent Convention prohibits patents for "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body". Despite this, the Patent office of the European Union determined that the present invention does not fall under 'methods of treatment', thereby allowing the grant of patent.

6. Mr. Manish Mohan, CGSC for the UOI, on the other hand, defends the impugned order and submits that the claims as worded, indicate that they are methods for treatment of human beings and therefore are non-patentable under Section 3(i) of the Act.

7. The Court has considered the aforenoted contentions. It is not in dispute that the hearing notice dated 13th September, 2019 issued by Respondent No. 2, did not raise any objection under Section 3(j) of the Act, which is however one of the grounds for rejecting the application. Therefore, to that extent, in the opinion of the Court, the Appellant was not afforded an opportunity to contest the said ground. Thus, there is an evident violation of principles of natural justice.

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8. With regards to objection under section 3(i) of the Act, it is noted that the claims of Appellant's invention, clearly articulate a method for producing a protein-enriched blood serum using gold particles. This process is claimed to be an innovative method that results in a novel composition—protein-enriched blood serum. The potential use of this serum could be for autologous or homologous blood transfusion. However, that is an application of the product, rather than the claimed invention itself. Therefore, the invention does not claim a "method of treatment" but rather a "method of producing" a specific substance, which is a significant distinction that affects its patentability. Respondent No. 2 has failed to take note that *"the protein enriched blood or blood serum is used for autologous or homologous blood transfusion"*[1] is not part of the claims. Respondent No. 2's failure to recognize this distinction has led to an erroneous application of section 3(i) of the Act. It overlooks the fact that the process itself, as claimed, is directed towards the production of a novel composition, and not towards direct treatment of human beings or animals. Therefore, the objection of non-patentability is clearly a misdirection on the part of Respondent No. 2.

9. To conclude, the objection under section 3(i) of the Act should be reconsidered in light of the clear distinction between a method of treatment and a method of producing a novel substance. The Appellant's invention falls squarely within the latter category. Thus, in the opinion of the Court, the impugned order deserves to be set aside with following directions:

(i). The impugned order dated 28th November 2019 is set-aside and the matter is remanded to the Respondents for *de novo* consideration.

[1] See, extracted and highlighted portion of Impugned order.

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(ii) The patent application for the subject patent 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 four 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.

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

SANJEEV NARULA, J

FEBRUARY 5, 2024
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