IN THE HIGH COURT OF JUDICATURE AT MADRAS

CORAM

DATED : 22.10.2024

THE HONOURABLE MR.JUSTICE K.KUMARESH BABU

(T)CMA(PT) No.191 of 2023

Regeneron Pharmaceuticals, Inc,
777 Old Saw Mill River Road,
Tarrytown, NY 10591, USA. … Appellant

Vs

Controller of Patents and Designs,
Government of India, Patent Office,
Intellectual Property Rights Building,
GST Road, Guindy,
Chennai- 600 032. … Respondent

PRAYER:- This Civil Miscellaneous Petition has been filed under 117-A of the Indian Patents Act, 1970 seeking direction to set aside the impugned order dated 16 December 2020 issued by the Respondent and to grant the patent in respect of the appellant's Application No.1554/CHENP/2013 in accordance with the provisions of the Act and the Rules.

For Appellant : Mr.Shivathanu. Mohan,
for M/s.De Penning and De Penning,
For Respondent : Mr.A.R.Sakthivel SPC

ORDER

This instant appeal has been filed to set aside the impugned order dated 16.12.2020 issued by the respondent and to grant the patent in respect of the Appellant's Application No.1554/CHENP/2013 in accordance with the provisions of the Act and the Rules.

2. Heard Mr.Shivathanu. Mohan, learned counsel appearing for M/s.De Penning and De Penning, counsel for the Appellant and Mr.A.R.Sakthivel, learned counsel appearing on behalf of the respondent.

3. Mr.Shivathanu. Mohan, learned counsel appearing on behalf of the appellant would submit that the application filed by the appellant under Section 15 of the Act had been rejected by the respondent holding that the amendment sought for in the Patent application, if entertained would amount to change the entire scope of invention and hence, the claim could not be entertained. The other reason given by the respondent is that it attracts Section 3(b) of the Patents Act and therefore such amendment cannot be permitted to be made. He would submit that such views were expressed by the respondent in a pre-grant hearing, the appellant had in extensio made submissions that there has been no change in the specifications or the substances that had been disclosed. He would submit, what was the original claim based on the specifications and the substance disclosed was not comprehensive and hence, what was sought to be amended was only to the claim based on the specifications and the substances that had already been disclosed. Therefore, the amendment that is sought for would not fall within the ambit of Section 59 which would deny the amendment.

4.He would submit that in the examination Report with regard to Section 3(b), the applicant had specifically made a statement that it would be for the benefit of the human kind. However, while rejecting the claim under Section 3(b), the Authority had held that such modification of genetic identity of the animal would cause them suffering without any substantial, medical or other benefit to men or women. The said finding according to him is without application of mind that too in the light of the specific statement of the appellant that such genetic modification is for the benefit of the humanity. He had also relied upon the judgment of the Hon'ble Delhi high Court as well as the judgment of this Court and contended that such rejections is without the application of mind and hence would have to be interfered with and remit the matter back to the respondent for being decided by any other Controller other than the Controller who had passed the order.

5. Mr.A.R.Sakthivel, learned counsel appearing on behalf of the respondent would submit that no materials have been placed before the respondent to come to an conclusion that the subject invention namely the modifying the genetic identity of the animal would be beneficial to the mankind. He would further submit that the amendment that is sought for would squarely fall within the mischief of Section 59 and the amendment that is sought for by the appellant cannot be entertained. Hence, he would seek

dismissal of the appeal as being devoid of merits.

6. I have considered the submissions made by the learned counsels appearing on either side and perused the materials available on record before this Court.

7. It is seen from the impugned order that the respondent had rejected the application on two grounds as follows,

(a)Holding that the amendment could not be allowed as per the Section 59 of the Patents Act.

(b)The amendment is not patentable as per the Section 3(b) of the Patents Act.

Section 59 of the Patents Act had been considered by the Hon'ble Delhi High Court in a judgment made in Allergan Inc Vs The Controller of Patents reported in 2023/DHC/000515 dated **20.01.2023.** The case therein was that the appellant therein had originally sought for the method in which the implants were to be used and subsequently, wanted to modify the patent for the implants. The said claim was rejected by the Authority against which the appeal had been filed. After analysing the facts of the case, the Hon'ble Delhi High Court held that the amendment to the claims should be made by considering the complete specifications of the pre-amended claims and not merely textually cabined reading of the pre-amended claims themselves

dehors complete specification. For better appreciation, the relevant paragraph of the said order is extracted hereunder:-

> *35.The question which is before this Court, for the present, is whether the appellant should be completely foreclosed from seeking a patent in respect of the said implants merely because the original application, as filed by the appellant, sought a patent not for the implants but for the method in which the implants were to be used, whereas the amended claims seek patents for the implants themselves, rather than the method of their usage, even if all details of the implants, and every particular of the amended claims stand completely disclosed in the complete specifications accompanying the original claims.*
>
> *36.Any such view, in my considered opinion, would be completely contrary to the very ethos of the Patents Act, as well as the most elementary principles of patent claim construction.* ***Bishwanath Prasad Radhey Shyam***[19] *spoke thus, on patent claim construction, vis-à-vis the complete specifications:*
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> > *"43. As pointed out in* ***Arnold v. Bradbury***[23] *the proper way to construe a specification is not to read the claims first and then see what the full description of the invention is, but first to read the description of the invention, in order that the mind may be prepared for what it is, that the invention is to be claimed, for the patentee cannot claim more than he desires to patent. In* ***Parkinson v. Simon***[24]

Lord Esher, M.R. enumerated that as far as possible the claims must be so construed as to give an effective meaning to each of them, but the specification and the claims must be looked at and construed together.

44. The learned trial Judge precisely followed this method of construction. He first construed and considered the description of the invention in the provisional and complete specifications and then dealt with each of the claims, individually. Thereafter, he considered the claims and specifications as a whole, in the light of the evidence on record."

(Emphasis supplied)

The principle was enunciated, with even greater precision, in the judgement of the Division Bench of this Court authored by S. Ravindra Bhat, J. (as he then was), in the following passage from ***Merck Sharp & Dohme Corporation v. GlenmarkPharmaceuticals***[25]*:*

"48. At this juncture, the Court notes that: -

"the construction of claims is not something that can be considered in isolation from the rest of the specification. Claims are intended to be pithy delineations of the scope of monopoly, and they are drafted in light of the much more detailed text of the description. A specification must be read as a whole, just as any document is. It must moreover be read as having been addressed to a person acquainted with the technology in question. So it must take account of that person's state of knowledge at the time."

(see, Cornish, Llewelyn and Aplin, Intellectual Property, Seventh Ed, Sweet and Maxwell, pages 182-3)."

(Italics in original; underscoring supplied)

37. Dichotomizing the claims and the accompanying specifications is, therefore, contrary to the most fundamental canons of patent law. That, however, is precisely what the Court would be lending its imprimatur to, were it to accept the interpretation that Mr Vaidyanathan seeks to place on Section 59(1).

38. This is not a case in which there is a wide divergence between the claims for which the patent had originally been sought, and the claims as amended subsequently. The amended claims were in respect of the very same implants for the method of use of which the original claims have been filed. Every detail of the implants, as contained in the amended claims, was in fact disclosed in the original claims as filed. This is apparent from the tabular statement in para 22 supra. In fact, the complete specifications, holistically read, clearly indicate that the appellant was effectively claiming both the implants as well as their method of use as its inventions.

39. The question is, therefore, whether, in such circumstances, this Court should uphold the decision of the learned Controller to throw out, at the very threshold, the application of the appellant, on the ground that the amended claims were not within the

scope of the originally filed claims.

40. A hyper-technical view, in that regard, in my opinion, would not be justified, given the philosophy behind the Patents Act. If, indeed, the implants are inventive, the appellant, as the claimed inventor, ought to be given a chance to have the implants patented. If, however, the learned Controller finds, on examination, that the implants are not inventive or stand otherwise disentitled to a patent under the Patents Act for any reason whatsoever, the appellant"s application would naturally stand disallowed. The application cannot, however, be thrown out without examination at the very threshold.

41. Referring back to Section 59(1), what the Section proscribes is permitting of an amendment of the claim where the amended claim would not fall wholly within the scope of the pre-amended claim. Interestingly, even this last part of Section 59(1) uses two expressions. It states that "no amendment of a complete specification shall be allowed, the effect of which would be ... that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment." What the Section compares, therefore, is the amended claim with the scope of the pre-amended claim. Where the amended claim does not fall within the scope of the pre-amended claim, the amendment would not be allowed.

42. The exact ambit of the scope of a claim in a

patent has been the subject of judicial decisions, to which I have already adverted. As I have already noted, the claims and complete specifications in a patent have to be read together and as a whole. The claims have to be understood in the light of the complete specifications. They form an integrated whole, and cannot be treated as two distinct parts of one document. The claim by itself, and de hors the complete specifications which accompany it, cannot convey, to the Court, the exact scope of the claim.

43. The very use of the expression "scope of a claim" in the concluding part of Section 59(1) would, therefore, in my considered opinion and keeping in mind the avowed purpose of the Patents Act, require taking into consideration the complete specifications of the pre-amended claim, and not merely a textually cabined reading of the pre-amended claims themselves, de hors the complete specifications.

8. In the present case, based upon the specifications and the disclosed substances, the appellant had originally claimed the patent of the mouse, cell and the usage of mouse. However, by the amended claim, he sought patent to the method of making a genetically modified mouse, an antigen binding protein, a targeting vector, a nucleic acid construct. There has been no change in the specification or the substances disclosed. However, the respondent herein had only considered the original claim and the amended claim dehors

the complete specification that was before it. Such a decision is squarely covered by the judgment of the Hon'ble Delhi High Court extracted supra, which also, I am in concurrence too. Hence, the reasons attributed by the respondent to reject the claim of the appellant under Section 59 of the Act cannot be countenanced.

9. Similarly, based upon the examination Report, the appellant had indicated in his response that such genetical modification in a mouse would be beneficial to the human kind. The same had been briefly recorded by the respondent in his order. The recording of such statement clearly indicates that there has been a claim made by the appellant that the subject matter of the invention is actually beneficial to the humanity in terms of medical research. However, the reasoning assigned by the respondent that there has been no substantial medical or other benefit to mankind in genetically modifying post is against his own recording of statement of facts.

10. In view of the aforesaid findings and reasonings, I am inclined to interfere with the impugned order in the present appeal. In fine,

i) the order dated 16.12.2020 made by the respondent is set aside and the application for the amendment is directed to be reconsidered by the respondent.

ii) in order to preclude the possibility of predetermination, an officer

other than the officer who issued the impugned order shall undertake reconsideration.

iii) After providing a reasonable opportunity to the appellant, a reasoned decision shall be issued within a period of four months from the date of receipt of a copy of this judgment.

iv) It is made clear that no opinion is being expressed herein on the merits of the application for grant of patent.

22.10.2024

Gba
Index : Yes/ No
Speaking Order/ Non-speaking Order
Copy to:

Controller of Patents and Designs,
Government of India, Patent Office,
Intellectual Property Rights Building,
GST Road, Guindy,
Chennai- 600 032.

K.KUMARESH BABU,J.

GBA

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