



(T)C.M.A.(PT)No.145 of 2023

IN THE HIGH COURT OF JUDICATUE AT MADRAS

DATED: 21.11.2024

CORAM

THE HONOURABLE MR. JUSTICE ABDUL QUDDHOSE

(T)C.M.A(PT).No.145 of 2023

Signal Pharmaceuticals
4550 Towne Centre Court,
San Diego, CA 92121
USA

.. Appellant

Vs

Deputy Controller of Patents and Designs,
Patent Office,
Intellectual Property Rights Building,
GST Road, Guindy,
Chennai – 600 032.

.. Respondent

Prayer: This Appeal is filed under Section 117-A of the Patents Act, 1970, against the order dated 17.05.2019 passed by the respondent.

For Appellant : Mr.Rahul Balaji
for M/s.DE Penning and DE Penning

For Respondent : Mr.Rajesh Vivekanandan,
Standing Counsel



(T)C.M.A.(PT)No.145 of 2023

JUDGMENT

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This appeal has been filed challenging the order dated 17.05.2019 passed by the respondent refusing to grant patent in favour of the appellant on the ground that the appellant's claimed invention is not an inventive step as per Section 2(1)(ja) of the Patents Act and is not patentable under Section 3(d) of the Patents Act.

2. The appellant has challenged the impugned order primarily on the ground that it is a non-speaking order with regard to the appellant's invention process as claimed in its patent application and the amendments made thereafter. According to the appellant, the impugned order reflects the clear lack of reasoning or even consideration of the appellant's contentions. The appellant's invention is titled “mTOR kinase inhibitors for oncology indications and disease associated with the mTOR/P13K/AKT Pathway” and the claims consist of heteroaryl compound and the pharmaceutically acceptable derivatives, and they assist in cancer detection through their high mTOR activity. Under the impugned order, the respondent has rejected 19 claims of the appellant.

3. The learned counsel for the appellant drew the attention of this



(T)C.M.A.(PT)No.145 of 2023

Court to the impugned order and would submit as follows:-

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(a) The respondent has not properly appreciated the evidence placed on record.

(b) The respondent has ignored the clear gap between the amended claims and prior art;

(c) Contrary to the legal principles on uniqueness and inventiveness, the respondent has passed the impugned order refusing to grant patent;

(d) The submission of the appellant has not been considered by the respondent;

(e) The responses submitted by the appellant to the objections made by the respondent which detail the inventive features of the appellant's invention have not been considered by the respondent.

(f) The amended claims in compliance to objections raised by the respondent pursuant to the First Examination Report (FER) have not been considered under the impugned order; and

(g) the respondent has wrongly raised the grounds of lack of inventive step and non-patentability



(T)C.M.A.(PT)No.145 of 2023

under Section 3(d) of the Patents Act.

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4. The learned counsel for the appellant relies upon a decision of the Delhi High Court in *Avery Dennison Corporation Vs. Controller of Patents and Designs [2022/DHC/004697]* and would submit that since the appellant's invention is a technical advancement, the appellant has satisfied the inventive step requirement as defined under Section 2(1)(ja) of the Patents Act.

5. He would further submit that the cited document WO 2008/051493 has a different structure from the claims submitted by the appellant, as the claims of the appellant have a significantly higher biological activity than prior art, but, the said considerable improvement has not been properly analyzed by the respondent and by a non-speaking order, the respondent has refused to grant patent to the appellant.

6. The learned counsel for the appellant would further submit that the core rings of the structure of the compound in Claim-1 have six variable positions, wherein carbon or heteroatom is present with 3 positions where variable substituents are present; and the prior art (D1) in no way teaches any preferred combination of carbon and heteroatoms



(T)C.M.A.(PT)No.145 of 2023

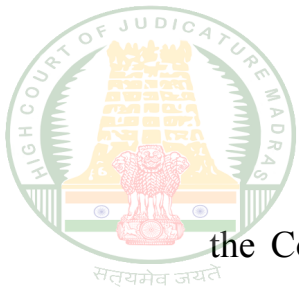
in core ring structure along with substituents, that is similar to claim-1.

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According to him, the prior art is clearly distinguishable, and the biological activity of the claimed compound is significantly higher than prior art.

7. The learned counsel for the appellant would submit that the respondent under the impugned order has not considered several essential technical elements of the appellant's invention. He would once again reiterate that the amended claims as well as their explanation in the reply to FER and written submissions have not been considered by the respondent in the impugned order.

8. The learned counsel for the appellant would also submit that the expert affidavit dated 19.03.2019 submitted by the appellant in respect of their invention has also not been considered by the respondent in the impugned order. He also relies upon a decision of this Court passed in (T)CMA(PT) No.33 of 2023 and would submit that while analyzing Section 3(d) of the Patents Act, this Court has made it clear that if the patent applicant has been able to establish that there is reasonable enhancement of efficacy to the satisfaction of the Controller of Patents,



(T)C.M.A.(PT)No.145 of 2023

the Controller of Patent has to grant patent. According to the learned counsel for the appellant, the appellant has satisfied the said test as its invention establishes therapeutic efficacy. According to him, despite the same, by total non-application of mind to the invention of the appellant, the respondent has refused to grant patent under the impugned order.

9. The learned counsel for the appellant also drew the attention of this Court to a decision of the Hon'ble Supreme Court in *Novartis AG vs. Union of India [(2013) 6 SCC 1]*, wherein the Hon'ble Supreme Court extensively analyzed Section 3(d) and interplay with pharmaceutical claims. In the said decision, it is held that if the patent applicant establishes therapeutic efficacy over the known substance, in such an event, Section 3(d) of the Patents Act does not get attracted. According to the learned counsel for the appellant, since the appellant has satisfied the test of therapeutic efficacy as laid down by the Hon'ble Supreme Court in *Novartis's case (cited supra)*, the respondent, by total non-application of mind, has refused to grant patent without giving reasons as to why the appellant's invention does not satisfy the test of therapeutic efficacy.



(T)C.M.A.(PT)No.145 of 2023

10. According to the learned counsel for the appellant, the claimed

invention of the appellant is overwhelmingly directed to compounds possessing a different core structure and the prior art (D1) is primarily with respect to compounds containing a fused 5-membered ring disclosed in Table 1 of D1, as opposed to the appellant's invention (R1), that is a heterocyclyl with pyrazino pyrazine core. Therefore, according to him, the appellant has clearly demonstrated the difference in core structure between the prior art (D1) and the claimed invention of the appellant.

11. The learned counsel for the appellant also drew the attention of this Court to a decision of the Delhi High Court in *Blackberry Ltd. Vs. Assistant Controller of Patents and Designs [(C.A.(Comm.IPD-PAT) 301/2022]* and would submit that the Delhi High Court had cautioned passing of unreasoned orders by the Patent Office and in the said decision, the Delhi High Court had set aside the order passed by the Assistant Controller of Patents and Designs on the ground that the Controller has merely reproduced objections made during FER and has failed to consider the amended claims or the data. The learned counsel for the appellant would also submit that the respondent has failed to take note of the fact that the appellant has obtained patent for similar



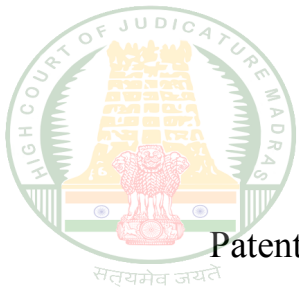
(T)C.M.A.(PT)No.145 of 2023

inventions in US and Europe.

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12. On the other hand, the learned standing counsel for the respondent would submit that the prior art document (D1) and the core structure of the appellant's claimed inventions are one and the same. According to him, the appellant has failed to establish with documentary evidence to prove that the appellant's claimed invention is different from the prior document (D1). He drew the attention of this court to the impugned order and would submit that since the appellant's claimed invention does not satisfy the test of therapeutic efficacy, the respondent has rightly refused to grant patent under the impugned order. He would also submit that the impugned order is a speaking order with regard to the contentions of the appellant insofar as their claimed invention is concerned, and therefore, the question of interfering with the impugned order by this Court does not arise.

13. He would further submit that the grounds raised by the appellant in this appeal do not deserve any merit as only by giving proper reasons, the appellant's patent application has been rejected on the ground of lack of inventive step and non-patentability under Section 3(d) of the



(T)C.M.A.(PT)No.145 of 2023

Patents Act. According to him, there is no technical advancement made by the appellant in its invention and therefore, the appellant's claimed invention squarely falls is hit by Section 3(d) of the Patents Act. Since there is no inventive step in the appellant's invention, the respondent has rightly refused to grant patent to the appellant under the impugned order.

14. This Court has carefully analyzed the evidence available on record before the respondent. The appellant has placed several documents in support of their invention and they have also submitted explanation to the queries raised by the respondent in the FER. They have also filed their written arguments and amended claims to comply with the objections raised by the respondent in the FER. A categorical assertion has also been made by the appellant that their invention is a technical advancement, which may satisfy the inventive step requirement of Section 2(1)(ja) of the Act. The learned counsel for the appellant also drew the attention of this Court to the core structure of the appellant's invention and would point out that the core structure of the appellant's invention is different from the prior art document (D1), which discloses the core structure of the known substance.



(T)C.M.A.(PT)No.145 of 2023

15. On a prima-facie consideration of the impugned order, it is seen

that the respondent has ignored the clear gap between the amended claims and the prior art document. The written submissions of the appellant has not been considered by the respondent under the impugned order. The appellant had also filed responses to the objections raised by the respondent with regard to the inventive step requirement as per Section 2(1)(ja) of the Patents Act; and the appellant had also filed amended claims; but, as seen from the impugned order, the respondent erred in not giving sufficient reasons for rejecting the appellant's amended claims.

16. As seen from the decision relied upon by the learned counsel for the appellant in *Avery Dennison Corporation (cited supra)*, the Delhi High Court has held that a significant technical advancement is sufficient to satisfy inventive step required under Section 2(1)(ja) of the Patents Act. The core structure of the appellant's claimed invention as well as prior document (D1) seem to be different and no proper reasoning have been given for the purpose of coming to the conclusion that prior document (D1) is similar to the core structure of the appellant's invention. The appellant has categorically contended that the appellant's invention has significant technical elements than that of the prior art and therefore, there is inventive step in the appellant's invention.



(T)C.M.A.(PT)No.145 of 2023

WEB COPY 17. This Court, after careful perusal of the impugned order, is of the considered view that no sufficient reasoning has been given by the respondent for coming to the conclusion that there is no inventive step in the appellant's claimed invention. The Hon'ble Supreme Court in the case of *Novartis AG (cited supra)* has also made it clear that in the case of a medicine that claims to cure a disease, the test of efficacy can only be therapeutic efficacy. But, however, as seen from the impugned order, the respondent has not given any reason as to why the appellant's claimed invention does not satisfy the test of therapeutic efficacy. The prior art document (D1), on a prima-facie consideration, is primarily with respect to compounds containing a fused 5-membered ring disclosed in Table 1 of D1, as opposed to R1 (appellant's invention), that is, heterocyclyl with pyrazino pyrazine core. However, as seen from the impugned order, the prior art document (D1) as well as the appellant's invention (R1) have not been properly analyzed and there is no proper reasoning given for coming to the conclusion that the core structure of R1 and the core structure of D1 are one and the same.

18. It is settled law, as laid down by various decisions including the



(T)C.M.A.(PT)No.145 of 2023

decision of the Delhi High Court in *Blackberry (cited supra)*, that unreasoned orders (non-speaking orders) cannot be passed by the Controller of Patents and the Controller should not merely reproduce the objections made during FER while refusing to grant patent. Only through a speaking order by giving proper reasons as to why the applicant's contentions has to be rejected, a patent application can be rejected.

19. In the case on hand, as seen from the impugned order, there is no proper appreciation of evidence by the respondent. The respondent seems to have ignored the gap between the amended claims and the prior art; and has not given reasons as to why the amended claims and the prior art are one and the same; and the respondent has also ignored the legal principles rendered by the Constitutional Courts on uniqueness and inventiveness. While passing the impugned order, the respondent has also not considered the written submissions of the appellant; responses to objections raised by the respondent; and the amended claims of the appellant in compliance to objections raised by the respondent. Through a non-speaking order, the respondent under the impugned order has refused to grant patent to the appellant on the ground of lack of inventive step over the prior art and that the claims are non-patentable under Section 3(d) of the Patents Act.



(T)C.M.A.(PT)No.145 of 2023

WEB COPY 20. On the ground that the impugned order is a non-speaking order in respect of several aspects of the appellant's contentions, necessarily the impugned order has to be quashed and accordingly, the impugned order dated 17.05.2019 passed by the respondent is quashed and the matter is remanded back to the respondent for re-consideration on merits and in accordance with law by issuing the following directions to the respondent:-

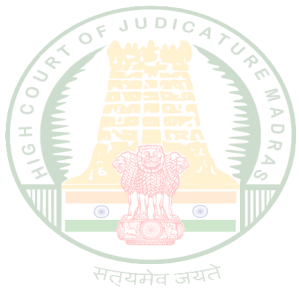
(a) In the interest of justice and in order to avoid the possibility of pre-determination, an officer other than the officer who issued the impugned order shall undertake the re-consideration;

(b) such re-consideration shall be undertaken by taking into account the observations set out in this judgment;

(c) amendment applications, if any, to the complete specification or claims shall be permitted if within the frame work of the complete specification; and

(d) a fresh order in Application No.3500/CHENP/2011 shall be passed within a period of six months from the date of receipt of a copy of this judgment.

No Costs.



(T)C.M.A.(PT)No.145 of 2023

21.11.2024

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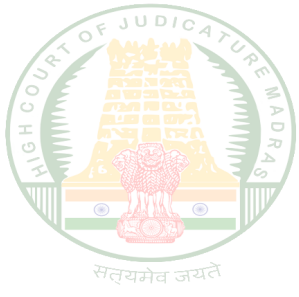
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Index:yes/no

Neutral citation: yes/no

To

Deputy Controller of Patents and Designs,
Patent Office,
Intellectual Property Rights Building,
GST Road, Guindy,
Chennai – 600 032.



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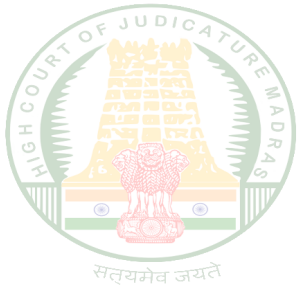


(T)C.M.A.(PT)No.145 of 2023

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(T)C.M.A(PT).No.145 of 2023



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(T)C.M.A.(PT)No.145 of 2023

21.11.2024