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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 28.03.2024

CORAM : JUSTICE N.SESHASAYEE

(T)CMA(PT) No.57 of 2023
(OA/50/2020/PT/CHN)

GENENTECH, INC.
of 1 DNA Way
South San Francisco
California 94080-4990
USA : Nationality : 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 : Appeal filed under Section 117-A of the Patents Act, 1970 praying that (a) the order dated 18th March 2020 issued by the respondent be set aside; (b) the application No.5832/CHENP/2014 for patent be allowed to proceed to grant, in accordance with the provisions of the Act and the Rules.

For Appellant : Ms.Karuna Goleria
for M/s.Depenning & Depenning

For Respondent : Mr.M.Karthikeyan
Senior Panel Counsel

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JUDGMENT

The appellant herein has lost its application for patenting its medicinal compound which it has titled as "*Inhibitors of IAP*".

2. The case of the appellant is that :

(a) Its invention relates to organic compounds useful for therapy and/or prophylaxis in a mammal, and in particular to inhibitors of IAP proteins useful for treating cancers.

(b) In its application, the appellant had made 22 claims, of which one is an independent claim and the rest are dependent claims.

(c) The respondent came out with its FER wherein it cited D1 to D4 as prior arts. It has also indicated its resistance to patent the appellant's invention under Sec.2(1)(j) and (ja) of the Patent Act, both for lack of novelty and lack of any inventive step; and also under Sec.3(d), 3(e) and 3(i) of the Act.

(d) The appellant presented its response and amended the claims, and reduced the total number of claims to six, of which one is its independent claim.

(e) The Controller then came out with its hearing notice wherein it accepted appellant's case against lack of novelty and also under

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Sec.3(e) and 3(i) and cited D1, the first of the prior arts that it has cited in its FER. D1 incidentally is a prior document of the appellant itself. Ultimately, the Controller rejected the claims under Secs.2(1)(ja) and 3(d).

This is now under challenge.

3. Heard both sides. The learned counsel for the appellant argued that:

a) regarding objection under Sec.2(1)(ja) - lack of inventiveness, the respondent has made a hindsight analysis and alleged that a person skilled in the art could have easily replaced 5 member heterocyclic ring (‘ring ‘A’)‘*imidazolyl moiety*’ of compound 131 of D1 with ‘*oxzolyl moiety*’ of the present invention compound. The respondent’s observation is based on the general definition provided for ‘*Heterocyclic group*’ in D1 and not on specific embodiments regarding ring A. Ring A is a pyrrole ring, furan, thiophene, pyrazole, imidazole, oxazole, isoxazole, thiazole, isothiazole; 1,2,3-triazole; 1,2,4-triazole and oxadiazole but there is no reference to ‘*ring of oxazolyl*. The rationale for such reliance by the respondent is purely on the basis of hindsight analysis as there is no pointer for the selection of this substituent. The respondent’s opinion that a skilled artisan will not have any motivation

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to select the '*oxazolyl moiety*' from the innumerable possibilities listed in D1 and arrive at the claimed invention is farfetched and misconceived.

b) D1 does not offer any pointer to a person skilled in the art to particularly select Compound no. 131 as there is no teaching to emphasize its technical advantage either in the form of *invitro data* such as IC50 or Ki value or in vivo tumor inhibition study.

c) On Synthesis of Schemes, D1 does not provide any teaching on the synthesis schemes to arrive at the presently claimed compound. Schemes 1, 16 and 17 indicated by the respondent as schemes representing the production of claimed compounds will not result in their production.

d) So far as the objection founded on Section 3(d), compound of present invention were unknown substance at the priority date of the instant application. They are structurally different from the compounds disclosed in D1. The compounds as calimed in the present invention are neither a *salt, ester, ether nor polymorph* of a known compound nor they can be considered as derivatives of compounds claimed in D1.

e) Insofar as efficacy and Request for Comparative Data, it is pertinent to note that D1 itself is silent about the efficacy of the compounds

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disclosed therein. D1 neither discloses any specific data such as results of IC50 values, Inhibition Constant (Ki) values of any of the compounds listed therein including that for Compound no. 131 nor does it specify about in vivo tumor inhibition assay. Thus there is no rationale involved in the requirement of demonstrating the improved therapeutic efficacy when there is no baseline efficacy disclosed for compound no. 131 of D1. The prior art compound of D1 has been abandoned as a viable drug candidate because of its lower stability in blood.

4.1 It is very apparent that the appellant had made markush claim. A markush claim refers to a chemical structure by means of symbols indicating substituent groups. In such a claim, one or more parts of the claimed compound comprise multiple functionally equivalent chemical entities. The main intention of drafting markush claims is to include compounds having some common characteristics in a single claim; this modality in the case of pharmaceutical inventions allows covering multiple compounds under single patent. The markush claims are drafted to cover a family of large number of similar compounds with probable permutations and combinations of such compounds which are theoretically presumed to have the same therapeutic properties. And the claim of the appellant based on oxazolyl moiety needs to be understood in

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the context as it is one which falls within the same compound with same therapeutic effects.

4.2 While examining a patent application with markush claims, it is important to look at the language to ensure that it complies with the provisions under the Patents Act, 1970 ('Act'), as disclosure of the invention, specification, enablement and the process of performing the invention and definitive claims should be clear, precise and concise. Sec. 10(4)(a) and (b) of the Act stipulate that the complete specification should describe the invention and its operation, use, process and the method by which it is performed. Sec. 10(4)(c) of the Act provides that every specification of the invention should conclude with claim/s defining the objective of the invention to provide a better understanding. Here it is amusing to find the observation/finding of the respondent that none skilled in the field will have any motivation to select the '*oxazolyl moiety*' from the innumerable possibilities listed in D1 is surely farfetched. The respondent is not required to make any prediction as to whether a person skilled in the field will ever select a particular moiety, but is only required to examine if the claims are patentable.

5. In conclusion, this appeal is allowed and the order of the respondent dated

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18.03.2020 passed in Patent Application No.5832/CHENP/2014 is set aside and the matter is remanded back to the Controller for a *de novo* consideration. To save embarrassment to the Controller who passed the impugned order, this court, now requires some other Controller to consider appellant's application for grant of patent. Since the application is filed in the year 2014, the Controller who would now be in-charge of the matter is required to dispose of appellant's application within a period of six months from the date on which he takes cognizance. No costs.

28.03.2024

Index : Yes/No
Speaking/Non speaking order

ds/Asr

N.SESHASAYEE, J.,

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(T)CMA(PT) No.57 of 2023

28.03.2024

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