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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 26-08-2025

CORAM

THE HON'BLE MR. JUSTICE SENTHILKUMAR RAMAMOORTHY

(T)CMA(PT) No. 158 of 2023

Syngene International Limited
Biocon SEZ, Biocon Park, Plot No. 2 and 3,
Bominasandra Industrial Area, IV Phase,
Bommasandra-Jigani Link Road,
Bangalore - 560 099, Karnataka.

..Appellant

Vs

1. The Assistant Controller of Patents and Designs
   The Patent Office,
   Intellectual Property Office Building,
   Plot No. 32, Sector 14, Dwarka,
   New Delhi - 110078, India.

2. The Controller of Patents
   Patent Office Intellectual Property Building,
   G.S.T. Road, Guindy, Chennai – 600032.

..Respondents

Prayer: Transferred Civil Miscellaneous Appeal (Patents) filed under Section 117-A of the Patents Act, 1970, to allow the present Appeal and set aside/quash the impugned order dated February 17, 2020 passed by the Respondent in Indian Patent Application No. 3091/CHE/2008 and to direct grant of patent in respect thereof said Indian Patent Application No. 3091/CHE/2008.

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For Appellant: Mr.Shatadal Ghosh
Mr.K.Muthuselvam
for M/s. K and S Partners

For Respondents: Mr. M. Karthikeyan, SPC

JUDGMENT

This appeal is directed against order dated 17.02.2020 rejecting Patent Application No.3091/CHE/2008 for the grant of patent for the claimed invention titled "A METHOD FOR PREDICTING ORGAN TOXICITY AND A SYSTEM THEREOF". Upon a request being made for an examination of the application, the First Examination Report (FER) was issued on 28.09.2017. In the FER, objections were raised *inter alia* on grounds of lack of novelty, inventive step and exclusion from patentability under Section 3(i) & (k) of the Patents Act, 1970. The appellant responded to the FER on 27.06.2018 and enclosed amended claims. By hearing notice dated 14.10.2019, the objection on the grounds of lack of inventive step and under Sections 3(i) & (k) were retained. After the hearing on 03.01.2020, the appellant filed post hearing written submissions on 17.01.2020. The order impugned herein was issued in the said facts and circumstances.

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2. Learned counsel for the appellant assailed the impugned order on multiple grounds. His submissions may be summarised as under:

(i) The impugned order records the erroneous finding that a Computer Related Invention (CRI) cannot be granted a patent unless the computer programme is used in conjunction with novel hardware. This conclusion is contrary to the Guidelines for the Examination of Computer Related Inventions, 2017 and the latest guidelines issued in 2025 in this regard.

(ii) The hearing notice recorded that D1 failed to disclose all the nonlinear ordinary differential and algebraic equations mentioned in claims 1 & 16 and proceeded to record that such equations are disclosed in D2 and D3. On perusal of D2 & D3, it would be evident that the equations listed in the complete specification and referred to in the rejected claims were not disclosed in D2 & D3.

(iii) The Controller erroneously records that D1 disclosed all the features of the claimed invention. In recording the said conclusion, the Controller has extracted from paragraphs 37 & 39 of D1. The Controller has also endeavoured to map the flow chart of the claimed invention against paragraphs 101 & 105 to 109 of D1. While doing so, the Controller failed to appreciate that paragraphs 101, 105 to 109 of D1 should be read with figure 8 of the complete specification of D1. Figure 8 pertains to the identification of the toxic state of

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the biological system. By contrast, the flow chart of the claimed invention relates to arriving at a homeostatic in silico liver model (a state describing the normal behaviour of the liver based on concentrations of various metabolites and rates of processes) and thereafter perturbing/disturbing the homeostatic liver model to mimic injury/toxicity condition. Without appreciating these material differences, erroneous conclusions were recorded in the impugned order with regard to alleged lack of novelty and inventive step.

3. In response to these contentions, learned counsel for the respondents submits that D1 was correctly identified as the closest prior art, but in view of dissonance between the hearing notice and the impugned order, reconsideration may be necessary. Such reconsideration may also be necessary in view of the revised guidelines on the examination of CRI not being taken into account.

4. Independent claim 1 of the rejected claims is as under:

> *"1. A method for predicting liver toxicity of a drug comprising steps of:*
>
> *(a) listing of drug-induced liver injuries;*
>
> *(b) obtaining molecular mechanisms of toxicity followed by tabulating underlying biochemical pathways which precipitates said liver injuries;*

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(c) identifying biomolecules, inferring biochemical pathways and modeling kinetics of enzymes involved in these pathways to set up a system of nonlinear ordinary differential and algebraic equations for obtaining a homeostatic in silico liver model, wherein said nonlinear ordinary differential and algebraic equations comprise (i), (ii), (iii), (iv), (v), (vi), (vii), (viii), (ix), (x), (xi), (xii), (xiii), (xiv), (xv), (xvi), (xvii), (xviii), (xix), (xx), (xxi), (xxii), (xxiii), (xxiv), (xxv), (xxvi), (xxvii), (xxviii), (xxix), (xxx), (xxxi), (xxxii), (xxxiii), (xxxiv), (xxxv), (xxxvi), (xxxvii), (xxxviii), (xxxix), (xl), (xli), (xlii), (xliii), (xliv), (xlv), (xlvi), (xlvii), (xlviii), (xlix), (l), (li), (lii), (liii), (liv), (lv), (lvi), (lvii), (lviii), (lix), (lx), (lxi), (lxii), (lxiii), (lxiv), (lxv), (lxvi), (lxvii), (lxviii), (lxix), (lxx), (lxxi), (lxxii), (lxxiii), (lxxiv), (lxxv), (lxxvi), (lxxvii), (lxxviii), (lxxix), (lxxx), (lxxxi), (lxxxii), (lxxxiii), (lxxxiv), (lxxxv), (lxxxvi), (lxxxvii), (lxxxviii), (lxxxix), (xc), (xci), (xcii), (xciii), (xciv), (xcv), (xcvi), (xcvii), (xcviii), (xcix), (c), (ci), (cii), (ciii), (civ), (cv), (cvi), (cvii), (cviii), (cix), (cx), (cxi), and (cxii);

(d) perturbing the model and designing assays to measure the perturbation;

(e) applying the assays to a chemical or set of chemicals to generate new assay data; and

(f) feeding the new assay data to the model for predicting liver toxicity and damage. ”

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As is noticeable from clause (c) of the above claim, several equations are referred to therein. The said equations are set out in the complete specification between pages 74 and 81 of the paper book.

5. In the hearing notice, the Controller recorded, in relevant part, as under:

> *"D1 fails to disclose all the nonlinear ordinary differential and algebraic equations as mentioned in claims 1 and 16 which are however disclosed combined in D2 (at 1,2,6-10,15,34, abstract, page 3-4) and D3(at claims 1,2,6, 13-14, 17-18, abstract, para 7-9, 20-22). Hence it would have been obvious to a person skilled in the art to combine the teachings of D1, D2 and D3 and reach the subject matter as disclosed in the current application."*

Thus, the Controller recorded a finding that D1 failed to disclose the various types of equations mentioned in claims 1 & 16 and proceeded to record that equations are disclosed in D2 and D3. On *prima facie* examination of prior arts D2 and D3, it appears that the equations listed in pages 74 to 81 of the paper book are not disclosed therein.

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6. In the impugned order, the following findings were recorded on comparing the claimed invention with prior art D1:

> *"Document DI discloses all the features of present invention which can be clarified by flow chart also. Document DI discloses only methods of the invention can be implemented using a mathematical model that represents a set of biological processes of a biological system. In particular, the mathematical model can represent the set of biological processes using a set of mathematical relations. For instance, the mathematical model can represent a first biological process using a first mathematical relation and a second biological process using a second mathematical relation (See para-37 of D1). Mathematical relations employed in a mathematical model can include, for example, partial differential equations; ordinary differential equations, both linear and nonlinear; stochastic differential equations; differential algebraic equations; difference equations; cellular automata; coupled maps; equations of networks of Boolean or fuzzy logical networks; or a combination thereof (See para-39 of Dl). A skilled person will be the motivated to arrive at different set of nonlinear ordinary differential and algebraic equations as disclosed in claims 1,15 and 17.*
>
> *Hence the said features of the alleged invention are obvious to the person skilled in the art. Therefore the subject*

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matter as claimed in claims 1-17 of the alleged invention is not new, lacks novelty and inventive step and does not meet the requirement of section 2(1)(j) of The Indian Patents Act."

These findings are clearly not in consonance with findings recorded in the hearing notice. The Controller has recorded that the claimed invention not only lacks inventive step but also lacks novelty. In order to record a finding that a claimed invention lacks novelty, it is necessary to conclude that every feature of the claimed invention is disclosed in D1. Even on *prima facie* assessment, there are differences between the features of the claimed invention and D1. Similarly, the conclusions drawn by mapping the flow chart of the claimed invention against figure 8 of D1 appears to proceed on the erroneous assumption that both the flow charts began by identifying the toxic state of the biological system. For these reasons, the conclusion on lack of novelty and inventive step cannot be sustained.

7. As regards the rejection under Section 3(k), the relevant findings are as under:

> *"(2) If the contribution lies only in mathematical method, business method or algorithm, deny the claim;*
>
> *(3) If the contribution lies in the field of computer program, check whether it is claimed in conjunction with a*

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novel hardware and proceed to other steps to determine patentability with respect to the invention. The computer program in itself is never patentable. If the contribution lies solely in the computer program, deny the claim. If the contribution lies in both the computer program as well as hardware, proceed to other steps of patentability.

From the above paragraph, it is clear that the actual contribution of the invention solely lies in software and there is no specific hardware available in the claimed invention. The only hardware mentioned in the present invention is a processor which executes program in a conventional or normal manner. Although the claims are directed towards a system but it is no more than what is there in the method steps of the alleged invention claimed in the disguise of a system without any novel or specific hardware."

The Patent Office has recently issued guidelines on the examination of CRI. These guidelines provide that a claimed invention cannot be rejected as a computer programme per se merely because novel hardware is not deployed. Since the conclusion with regard to exclusion under Section 3(k) was reached primarily on the ground that the claimed invention is not used in conjunction with novel hardware, this conclusion is liable to be interfered with.

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8. For reasons aforesaid, impugned order dated 17.02.2020 is set aside and this appeal is disposed of with the following directions:

(i) The respondent is directed to reconsider Patent Application No.3091/CHE/2008 by taking note of the observations in this order and by applying the current guidelines on the examination of computer related inventions.

(ii) In order to preclude the possibility of pre-determination, an officer other than the officer who issued the impugned order shall undertake reconsideration.

(iii) After providing a reasonable opportunity to the appellant, a speaking order shall be issued within three months from the date of receipt of a copy of this order.

(iv) There will be no order as to costs.

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Index :Yes / No

Internet :Yes / No

Neutral Citation :Yes / No

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To

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