2025:MHC:620

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

Dated: 04.03.2025

Coram

The Honourable Mr. Justice SENTHILKUMAR RAMAMOORTHY

CMA(PT) No.45 of 2024

University College London,
Gower Street, London WC1E6BT,
Great Britain rep. By its Constituted Attorney
Govardhan Gajjal ... Appellant

vs.

1.The Assistant Controller of Patents
and Designs,
Patent Office, Intellectual Property Office
Building, Plot No.32, Sector 14,
Dwarka, New Delhi – 110 078.

2.The Controller General of Patents, Designs &
Trademarks
having its office at Boudhik Sampada Bhavan,
Near Antop Hill Head Post Office,
S.M.Road, Antop Hill, Mumbai – 400 037. ... Respondents

Appeal filed under Section 117A of The Patents Act, 1970 as amended by The Tribunal Reforms Act, 2021 against the order passed in the Patent Application No.8266/CHENP/2014 dated 21.05.2024 by the Assistant Controller of Patents and Designs under Section 15 of the Act.

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For Appellant : Mr.P.V.Balasubramaniam,
Senior Counsel
for Ms.Anshul Saurastri
and Ms.Preetha Natarajan

For Respondents : Mr.K.Subbu Ranga Bharathi,
Central Govt. Standing Counsel

JUDGMENT

This appeal is directed against the order dated 21.05.2024 rejecting Patent Application No.8266/CHENP/2014 for grant of patent for an invention titled 'A Delayed Release Drug Formulation'. The parent Patent Application No.5924/CHENP/2008 was titled 'Colonic Drug Delivery Formulation'. Patent was granted in respect thereof under Patent No.531129 on 30.03.2024. The granted claims therein comprised independent claims 1 and 23, which are as under:

> *'1. A delayed release drug formulation comprising a particle with a core and a coating for the core, the core comprising a drug and the coating comprising a mixture of a first material which is susceptible to attack by colonic bacteria and a second material which is a film-forming polymeric material having a pH threshold at pH 6.5 or above,*

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wherein the first material comprises a polysaccharide selected from the group consisting of amylopectin, and starch comprising 0.1 wt % to 75 wt % amylose; and

wherein a ratio of the first material to the second material in the mixture is from 15:85 to 50:50.'

'23. A method of preparing a delayed release drug formulation as claimed in claim 1, said method comprising:

forming a core comprising a drug; and

coating the core with a polymer coating preparation comprising a mixture of a first material which is susceptible to attack by colonic bacteria and a second material which has a pH threshold at pH 6.5 or above,

wherein the first material comprises a polysaccharide selected from the group consisting of amylopectin; and starch comprising 0.1 wt % to 75 wt % amylose;

wherein a ratio of the first material to the second material in the mixture is from 15:85 to less than 50:50.'

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2. On the basis that the complete specification relating to the parent application relates to more than one invention, inasmuch as coating in the parent application was in the form of polysaccharide selected from the group consisting of amylopectin and starch, whereas the divisional application pertains to coating comprising polysaccharide selected from the group of chitosan; chondroitin sulfate; cyclodextrin; dextran and carrageenan, the appellant lodged the divisional application. Upon request, the First Examination Report (the FER) was issued on 28.02.2018. In such report, objections were raised *inter-alia* on the ground of lack of inventive step. The appellant replied thereto on 22.11.2018. Pursuant to hearings on 04.09.2020 and 29.09.2023, the order impugned herein was issued.

3. By referring to the impugned order, learned senior counsel for the appellant submitted that the first respondent misinterpreted Section 16(1) of The Patents Act, 1970 ('Patents Act') as requiring an objection by the Controller on the ground that claims of the complete specification of the parent application relate to more than one invention. By referring to the expression ''if he so desires'' in sub-section (1) of Section 16, learned senior counsel contended that the

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appellant has the choice to file a divisional application unilaterally even in the absence of an objection by the Controller. The second contention of learned senior counsel is that the monopoly claim granted pursuant to the parent application is confined to coating of polysaccharide selected from the group consisting of amylopectin and starch. Consequently, he submits that the claims submitted along with the divisional application are different in scope and that the grant of divisional application would not result in double patenting. He further submits that the priority date is from 2006. Therefore, it cannot be said that the appellant is endeavouring to evergreen the patent. The third contention of learned senior counsel is that sufficient material was placed on record with regard to the gastro resistant effect of the polysaccharide forming the subject of the divisional application. By referring to the graph in the written submissions of the appellant, he contends that data was provided in respect of each polysaccharide. For all these reasons, he submits that the matter warrants reconsideration.

4. In response to these contentions, Mr.K.Subbu Ranga Bharathi submits that the Controller did not duly appreciate the language of sub-section (1) of Section 16 of the Patents Act inasmuch as it enables

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the patent applicant to present a divisional application if he so desires. He further submits that the matter may be remanded for reconsideration as to as enable the Controller to examine whether the divisional application qualifies as a distinct invention.

5. The current claims of the appellant under the divisional application include independent claims 1 and 18, which are as under:

> *'1. A delayed release drug formulation comprising a particle with a core and a coating for the core, the core comprising a drug and the coating comprising a mixture of a first material which is susceptible to attack by colonic bacteria and a second material which is a film-forming polymer having a pH threshold from pH 6.5 o pH 7;*
>
> *wherein the first material is a polysaccharide selected from the group consisting of chitosan; chondroitin sulfate; cyclodextrin; dextran; and carrageenan;*
>
> *wherein the proportion of the first material to the second is from 15:85 to less than 99:1; and*
>
> *wherein the drug is selected from an anti-inflammatory agent and a steroid.'*

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'18.A method of preparing a delayed release drug formulation as claimed in Claim 1, said method comprising:

forming a core comprising a drug; and

coating the core with a polymer coating preparation comprising a mixture of a first material which is susceptible to attack by colonic bacteria and a second material which is a film-forming polymer having a pH threshold from pH 6.5 to pH 7,

wherein the first material is a polysaccharide selected from the group consisting of chitosan; condroitin sulfate; cyclodextrin; dextran; and carrageenan;

wherein the proportion of the first material to the second material in the mixture is from 15:85 to less than 99:1; and

wherein the drug is selected from an anti-inflammatory agent and a steroid.'

6. It is noticeable that independent claim 1 insofar as it deals with polysaccharide is limited to polysaccharide selected from the group consisting of chitosan; condroitin sulfate; cyclodextrin; dextran; and carrageenan. On the contrary, the polysaccharide coating in

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independent claim 1 of the parent application is a polysaccharide selected from the group consisting of amylopectin and starch. Prima facie, it appears that the scope of monopoly claims are different.

7. Section 16(1) of the Patents Act is as under:

> *'Section 16: Power of Controller to make orders respecting division of application:*
>
> *(1) A person who has made an application for a patent under this Act may, at any time before the grant of the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.'*

8. The text of sub-section (1) discloses that the divisional application may be filed at any time before the grant of patent under the parent application. It also provides for such application being filed either if the patent applicant so desires or with a view to remedy the

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objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention. Without doubt, therefore, such application may be filed unilaterally by the patent applicant even if there is no objection by the Controller on the ground of lack of unity of invention. The text of sub-section (1), however, indicates clearly that such divisional application would be sustainable only if the claims of the complete specification relate to more than one invention. Sub-section (2) indicates that the complete specification of the divisional application should not include any matter not disclosed in substance in the complete specification of the parent application. On examining the complete specifications of the parent application and the divisional application, it appears *prima facie* to satisfy this requirement.

9. In the impugned order, the first respondent took note of the fact that the patent office had not raised any objection relating to plurality of invention in the examination report of the parent application. After noticing the expression "if he so desires" in Section 16(1), the first respondent proceeded to record that it does not give an unqualified or unconditional right to the patent applicant to file a

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divisional application. As discussed above, the language of Section 16(1) indicates clearly that a patent applicant, if he so desires, may file a divisional application before the grant of patent under the parent application as long as he satisfies other requirements of Section 16. Upon receipt of such application, however, the Controller is required to examine whether the complete specification of the parent application relates to more than one invention.

10. In the case at hand, the appellant submitted data relating to the asserted unexpected improvement and performance by using a polysaccharide coating of chitosan; condroitin sulfate; cyclodextrin; dextran; and carrageenan. Experimental results with regard to each of these polysaccharides have been included in the written submissions of the appellant. Although these aspects have been noticed briefly at internal pages 56 and 57 of the impugned order, the Controller has not recorded reasons as to why the same does not establish plurality of invention. The Controller has also referred to the decision of the IPAB in *Esco Corporation v. Controller of Patents & Designs (OA/66/2020 PT/DEL dated 27.10.2020)*. In the said decision, the IPAB concluded that there was plurality of invention and that the divisional application is liable to be allowed. In order to provide an opportunity to the first

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respondent to reconsider whether the divisional application qualifies as a distinct invention, a remand is necessary.

11. Therefore, impugned order dated 21.05.2024 is set aside and the matter is remanded for reconsideration on the following terms:

11.1 In order to preclude the possibility of pre-determination, an Officer other than the Officer who issued the impugned order shall undertake reconsideration;

11.2 After providing a reasonable opportunity to the appellant, a reasoned order shall be issued within four months from the date of receipt of a copy of this order;

11.3 While issuing such order, the observations contained in this order shall be taken into account;

11.4 For the avoidance of doubt, it is made clear that no observations have been made herein on the merits of the divisional application.

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12. Therefore, CMA(PT) No.45 of 2024 stands disposed of on the above terms, without any order as to costs.

04.03.2025

Index:Yes
Neutral Citation: Yes
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To

1.The Assistant Controller of Patents
and Designs,
Patent Office, Intellectual Property Office
Building, Plot No.32, Sector 14,
Dwarka, New Delhi – 110 078.

2.The Controller General of Patents, Designs &
Trademarks
having its office at Boudhik Sampada Bhavan,
Near Antop Hill Head Post Office,
S.M.Road, Antop Hill, Mumbai – 400 037.

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SENTHILKUMAR RAMAMOORTHY, J.
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