**IN THE HIGH COURT AT CALCUTTA**

**ORIGINAL SIDE**

**COMMERCIAL DIVISION**

**Present:**

**The Hon'ble Justice Krishna Rao**

**I.P.D.P.T.A. No. 4 of 2024**

**PHARMACYCLICS LLC**

**Versus**

**DEPUTY CONTROLLER OF PATENTS & DESIGNS**

Ms. Archana Shankar
Ms. Mini Agarwal

... For the appellant.

Mr. Swatarup Banerjee
Ms. Sarda Sha

... For the respondent.

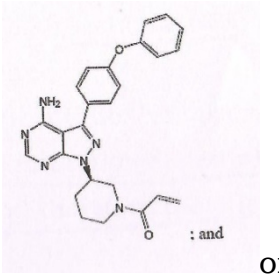
Hearing Concluded On : 05.08.2025

Judgment on : 02.09.2025

**Krishna Rao, J.:**

**1.** This is an appeal under Section 117(A) of the Patents Act, 1970 against the order passed by the Deputy Controller of Patents and Designs dated

5th March, 2024 rejecting the grant of patent to Indian Patent Application No. 201838043708. The said application is a dismissal application filed under Section 16 of the Indian Patents Act being **3985/KOLNP/2012**. The claims of patent application was directed to *"A compound (R)-1-(3-(4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4-d]pyrimidin- 1-yl)piperidin-1-yl)prop-2-en-1-one for use in treating relapsed or refractory non-Hodgkin's lymphoma*".

**2.** On 20th November, 2018, the appellant filed divisional application in order to claim an invention directed to a combination of compound 

: and of formula I an anti-CD20 antibody selected from rituximab and ofatumumab disclosed in the patent specification. The said divisional application was filed with 15 claims. The pending claims of the divisional application are directed to a combination of ibrutinib with an anti-CD20 antibody, such as rituximab or ofatumumab. The said combination demonstrates unexpected results which supports the inventiveness of the claims.

**3.** The claim of the appellant was rejected by an impugned order dated 5th March, 2024, on the following grounds:

***a.*** *The parent application was filed with 133 claims directed to method for treating a hematological malignancy in an individual a need thereof, comprising :*

*i. administering to the individual an amount of an irreversible Btk inhibitor sufficient to mobilize a plurality of cells from the malignancy; and*

*ii. analyzing the mobilized plurality of cells.*

***b.*** *On 24th December, 2012, the Applicant amended the claims of the parent application into product claims (33).*

***c.*** *At the time of filing the divisional application, the Applicant changed the scope of the originally filed claims and amended the claims into combination claims.*

***d.*** *The reason provided for the amendment filed on 24th December, 2012 was given to be voluntary amendment and clearly stated to be restricted in nature.*

***e.*** *The appellant ought to have provided reasons for making the said amendment.*

**4.** In the divisional application, the appellant pursued claims directed a combination of two active ingredients, namely: (a) Ibrutinib and (b) rituximab/ofatumumab.

**5.** For the first time in the hearing notice, the respondent raised the issue with regard to the maintainability of the divisional status of the Indian Patent Application No. 201838043708 as well as amendment of the

claims as not permissible under Sections 57-59 of the Indian Patents Act.

**6.** First Examination Report was issued on 18th December, 2019 in the said report, the following objections were made :

i. *Lack of novelty in view of document US2010041677 (D1) and an observation was made that :*

> *"The applicant has said that the mother application covers the inventive concept of A Heterocycle-Substituted Piperidine of Formula D' wherein the instant divisional application claims the group from which a Piperidine compound is selected. Hence the instant application deserves the merit of a divisional application. But It is also observed that the claimed markush claims of the mother application fall within the scope of claim 1 of the instant application. Hence, amended claims 1 of the instant purported divisional application is anticipated by claims 33 of the purported mother application under Section 13 of the Act and therefore is not patentable and the subject-matter of the claims of the instant application inconsistent with the subject matter of claims of purported mother application."*

**7.** In the First Examination Report, no objection with regard to either the maintainability of the divisional application or amendment of the claims was raised. In the First Information Report, the respondent made an observation that the claims of the divisional application are adequately supported by claim 33 of the mother (parent) application which effectively means that the claims were supported by the mother application. In the divisional application, the appellant pursued claims directed a combination of two active ingredients, namely : (a) Ibrutinib and (b) rituximab/ofatumumab. The request for amendment was filed

in the parent application which is not a divisional application that was pending adjudication before the respondent.

**8.** In the case of ***Guangdong Oppo Mobile Telecommunications Corp., Ltd. vs. The Controller of Patents and Designs*** reported in ***MANU/WB/1263/2023***, the Coordinate Bench of this Court held that on the question of issuance of the Second Examination Report, Section 13(3) of the Act makes it apparent that upon amendment of the claims, the amendment application ought to be examined in a manner similar to the original application. When a complete specification is amended, such amended specification should be re-examined and a Report issued in the manner stipulated under Section 12 of the Act.

**9.** The subject matter of the divisional application under Section 16 is in relation to combination of two active ingredients, namely : (a) Ibrutinib and (b) rituximab/ ofatumumab which was disclosed in the parent complete specification, now forms the subject matter of the divisional application.

**10.** Section 16 of the Patents Act, 1970, reads as follows :

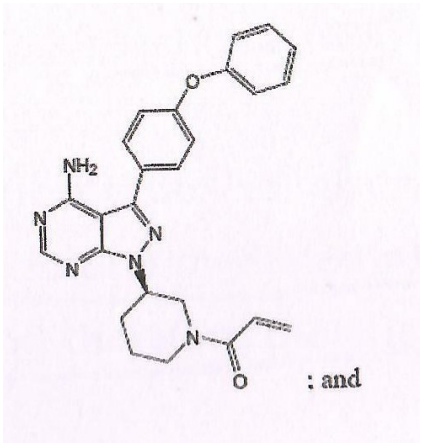
> *"**16. Power of Controller to make orders respecting division of application.—** (1) A person who has made an application for a patent under this Act may, at any time [before the grant of the patent], if he so desires, or with a view to remedy the objection raised by the Controller on the ground that 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.*

> *(2) The further application under sub-section (1) shall be accompanied by a complete specification, but such complete specification shall not include any matter not in substance disclosed in the complete specification filed in pursuance of the first mentioned application.*
>
> *(3) The Controller may require such amendment of the complete specification filed in pursuance of either the original or the further application as may be necessary to ensure that neither of the said complete specifications includes a claim for any matter claimed in the other.*
>
> *[Explanation.— For the purposes of this Act, the further application and the complete specification accompanying it shall be deemed to have been filed on the date on which the first mentioned application had been filed, and the further application shall be proceeded with as a substantive application and be examined when the request for examination is filed within the prescribed period.]"*

Section 16 of the act provides that a further divisional application shall be accompanied by complete specification but such complete specification shall not include any matter not in substance disclosed in the complete specification filed in pursuance of first mentioned application. According to Section 16(3), the complete specification of the divisional application should not include a claim for any matter claimed in other application. The parent application is directed to method for treatment which was later amended to compound *(R)-1-(3-(4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4-d]pyrimidin- 1- yl)piperidin-1-yl)prop-2-en-1-one for use in treating relapsed or refractory non-Hodgkin's lymphoma* whereas the present divisional application. Therefore, the divisional application is filed during the pendency of the parent

application, disclosed in the complete/provisional specification and relates to plurality of inventions. The parent application is for *"Compound"* whereas the claims for the divisional application is for *"a combination of two active ingredients"*.

**11.**

| **CLAIM 1 OF PARENT APPLICATION AS FILED** | **CLAIM 1 OF DIVISIONAL APPLICATION** |
|---|---|
| A method for treating a hematological malignancy in an individual in need thereof, comprising:<br>a. administering to the individual an amount of an irreversible Btk inhibitor sufficient to mobilize a plurality of cells from the malignancy and<br>b. analyzing the mobilized plurality of cells. | A combination comprising a com pound having structure<br><br>: and<br>**And** an anti-CD20 antibody selected from rituximab and ofatumumab. |
| **Claim 1 as amended on December 26, 2012:**<br>A compound (R)-1-(3-(4-amino-3-( | |

| | |
|---|---|
| 4-phenoxyphenyl)-1H-pyrazolo[3,4-d]pyrimidin-1-yl)piperidin-1-yl)prop-2-en-1-one for use in treating relapsed or refractory non-Hodgking's lymphoma. | |

**12.** The requirement of Section 16(3) of the Patents Act, 1907 is met if that divisional application claims is based on the disclosure in the complete specification, there will be no overlapping of the claims of the parent and divisional application and there is no requirement that the claims of the divisional application should be based on the original PCT claims filed with the parent application. In the present divisional application, no voluntary amendment was filed. The application was filed in relation to a combination, specifically, based on the Patent Amendment Rules, 2004. The subject-matter of the divisional application is not limited to what was claimed in the parent application, as long as the divisional claims are supported by the entire specification as originally filed.

**13.** The unexpected technical advantage of the combination of the two active ingredients are:

i. *The problem with administering anti CD20 antibody was that it resulted in infusion related reactions* ***[symptoms experienced by patient during infusion of a drag or an antibody (biological agent following the first day of drug administration)]*** *that resulted in discontinuation of treatment.*

ii. *When a BTK inhibitor (Ibrutinib) is given with anti CD20 antibody, it reduces the immune mediated reactions caused by the anti CD20 antibody and therefore, there is clearly synergistic effect. The patent specification extensively provides different forms of pharmaceutical compositions according to the present invention.*

iii. *The data filed along with the response to the first examination report by the appellant demonstrates that the combination of Ibrutinib with anti-CD20 antibodies provided excellent efficacy.*

**14.** In the case of ***Syngenta Limited vs. Controller of Patents & Designs*** reported in ***2023: DHC: 7473-DB***, the Hon'ble Division Bench of the Delhi High Court held that:

> ***"31.*** *We find ourselves unable to subscribe to the view expressed in Boehringer Ingelheim and when it seeks to base its conclusions on the precept as formulated by Lord Russel for the following additional reasons. It would be apposite to recall that Section 16 speaks both of a provisional or a complete specification. However, in the case of a provisional filing, claims need not be specified at all. If the view as expressed in Boehringer Ingelheim were to be accepted no Divisional Application would be maintainable in a case where a provisional specification has been presented. This since the decision bids us to discover the invention solely in the claim.*
>
> ***32.*** *We thus find ourselves unable to concur with the view as expressed in Boehringer Ingelheim and the said judgment shall consequently stand overruled. We hold that a Divisional Application moved in terms of Section 16 of the Act would be maintainable provided the plurality of inventions is disclosed in the provisional or complete specification that may have*

*been filed. We are further of the considered opinion that Section 16 does not suggest or conceive of a distinction between the contingency of a Divisional Application when moved by the applicant of its own motion or where it comes to be made to remedy an objection raised by the Controller. In either of those situations, the plurality of inventions would have to be tested based upon the disclosures made in either the provisional or complete specification. The Reference stands answered accordingly.*

**15.** In the case of ***Gensquare LLC vs. The Assistant Controller of Patents and Design*** passed in ***CMA(PT) No. 35 of 2023*** dated ***13th March, 2024,*** the Madras High Court held that:

> ***"3.*** *Heard both sides. The learned counsel for the appellant submitted that the authority relied on by the Patent Controller was since overruled by a Division Bench of Delhi High Court in Syngenta Limited Vs Controller of Patents and Designs [2023 SCC OnLine Del 6392]. She further added that Sec.16 of the Patent Act only requires that the divisional application must flow from the specification in the parent application, and does not say that the claims made in the divisional application must flow from the claims made in the parent application. This precisely is the reason why in Syngenta Limited case the Court chose to overrule the earlier view of the learned Single Judge."*

**16.** In the case of ***Victaulic Company vs. The Controller of Patents and Designs*** passed in ***CMA(PT) No. 14 of 2024*** dated ***26th July, 2024,*** the Madras High Court held that:

> ***"6.*** *The Judgment of the Delhi High Court has been followed by this Court also in CMA (PT) No. 35 of 2023 dated 13.03.2024 in the case of GENSQUARE LLC v. Assistant Controller of Patents and Design, Patent Office, Chennai, where this Court, taking note of the decision of the Hon'ble*

*Division Bench of the Delhi High Court, held that the Patent Act only requires that the divisional application ought to flow from the specifications in the parent application, and it does not say that the claims made in the divisional application to flow from the claims made in the parent application. Hence, the issue is no longer res judicata. Unfortunately, the respondent has acted against the ratio laid down by the Hon'ble Division Bench of the Delhi High Court in Syngenta Limited's case and on this limited ground alone, the rejection order passed by the respondent deserves to be set aside.*

***7.*** *In fine, the appeal is allowed and the matter is remitted to the respondent for denovo examination, after affording an opportunity by way of a fresh hearing to the appellant. In order to avoid embarrassment to parties, a different Patent Controller shall be assigned for the scrutiny of the patent application and such exercise shall be completed within a period of three months from the date of receipt of copy of this judgment. There shall be no order as to costs."*

**17.** In the case in hand, the respondent by an order dated 5th March, 2024, rejected the divisional application of the appellant by placing reliance on the claims of the parent application. Under Section 16(4) of the Patents Act, 1970 once having recognized the maintainability of the divisional application in the First Examination Report, under Section 16(3) explanation, the respondent should have proceeded as a substantive application wherein the outcome of the parent has no bearing on the examination of the divisional application.

**18.** Section 16(3) of the Act provides that divisional application (further application) "shall be proceeded as a substantive application and be examined when the request for the examination is filed within the

prescribed period". The appellant has not filed any amendment application as the claims filed along with the divisional application and filed along with written submissions were identical. There is no conflict between claim 1 of the divisional application and the claim 33 of the parent application, as claim 33 is for a compound for Formula D and claim 1 of the divisional is for combination of two actives.

**19.** In the case of ***Allergan INC vs. The Controller of Patents*** reported in ***2023/DHC/000515***, the Delhi High Court held that:

> *"**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, required 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."*

As regard to the amendments are concerned, no amendments were effected in the divisional application. An amendment of claim is permissible as long as it is supported by description.

**20.** Considering the above, this Court finds that the order passed by the respondent dated 5th March, 2024 is not sustainable under law and the same is set aside and quashed. The matter is remanded back to the respondent for consideration of the case of the applicant afresh after giving an opportunity of hearing to the applicant and to pass a reasoned and speaking order within a period of six (6) months from the date of receipt of this order. The case of the applicant shall be heard

and disposed of by the competent authority within the specified period as mentioned above other than the Deputy Controller of Patents and Designs who passed the impugned order dated 5th March, 2024.

**21. I.P.D.P.T.A. No. 4 of 2024** is **allowed**.

**(Krishna Rao, J.)**