

**The Patents Act, 1970
(AS AMENDED)
(Section 15)**

**In the matter of the application for
Patent Application No. 1146/KOLNP/2007 filed on 03/04/2007.**

Merck Sharp & Dohme Corp. - Applicant.

Hearing held on – 05/07/2018

Present: Dr Prosenjit Chattopadhyaya & Dr Malathi Laxmikumaran of Laxmikumaran & Sridharan, New Delhi through videoconference - On behalf of Merck Sharp & Dohme Corp.

Decision

The instant application was filed on 03/04/2007, bearing number 1146/KOLNP/2007 as divisional application to original application 105/KOLNP/2005 [of PCT national phase application of PCT/US2003/021977, international filing date 15/07/2003 and claiming U.S.A. priority dated 29/07/2002]. The application was filed by S. Chakraborty of D. P Ahuja & Co., Kolkata on 03/04/2007 on behalf of Optimer Pharmaceuticals INC. The application was published under section 11A on 01/08/2008 and request for examination (Form 18) was filed on 01/10/2007. The application was examined and First Examination Report (FER) was issued on 09/09/2009. Form 6 was filed on 11/01/2016 for change in applicant from Optimer Pharmaceuticals INC to Merck Sharp & Dohme Corp. Form 13 was filed on 01/03/2017 for change in address of service from D. P Ahuja & Co., Kolkata to Laxmikumaran & Sridharan, New Delhi. During the prosecution of the said application, it was found that objections were outstanding after expiry of last date for putting the application in order of grant. In order to dispose the application and as last date was expired, the applicant was given an opportunity of being heard and accordingly, a hearing under section 14 of the Patents Act was scheduled on 05/07/2018.

The hearing was held on 05/07/2018 and the applicant's agent attended the same. During the hearing applicant submitted their observations in respect of the objections and subsequently submitted the written note of arguments and other required documents on 19/07/2018.

Applicant's Submission:

Primarily, the Applicant submits that the Controller has acknowledged the novelty, inventive step, and industrial applicability of the invention claimed in the instant Application. In response to **Objection 1 of the Hearing Notice**, the Applicant respectfully disagrees with the objection raised by the Controller. The Applicant submits that the instant Application is a valid divisional Application. Further, the Applicant submits that claims of instant Divisional Application are not linked with the invention claimed in the parent Application (105/KOLNP/2005) to form a single inventive concept. In other words, there is plurality of

invention with respect to the claims of the instant divisional Application and the claims of the parent Application. The Applicant submits that a divisional Application can be filed by the Applicant on his own volition for an invention disclosed in the specification of the parent Application, provided the invention claimed in the claims of the parent Application is distinct from the invention claimed in the claims of the divisional Application.

Section 16 of the Patents Act, 1970 (hereinafter referred to as the 'Act') reads as under:

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 include a claim for any matter claimed in the other.*

The Applicant submits that according to Section 16 of the Act,

- An Applicant is permitted to file a divisional Application in respect of an invention, disclosed in the provisional or complete specification of the earlier filed parent Application, any time **before the grant** of the parent Application, provided the parent Application **relates to more than one invention**.
- The filing of the divisional Application may be done either ***suo motu* by the Applicant** or to address the Controller's objection, provided the parent Application relates to more than one invention.
- Sub-section 16(2) of the Act mandates that the divisional Application filed under sub-section 16(1) shall be filed along with a complete specification, and that complete specification shall not contain any matter which is not disclosed in the complete specification of the parent Application.

Instant divisional Application:

- The Applicant submits that the instant Application was filed before the grant of the parent Application;
- Further, the instant divisional Application was filed *suo motu* by the Applicant;
- The claims of the instant divisional Application are not technically linked with the claims of the parent Application;
- The complete specification of the instant divisional Application does not contain any matter which is not disclosed in the complete specification of the parent Application.

In view of the above, the instant Application clearly fulfills all the requirements for a divisional Application under Section 16 of the Act.

The Applicant submits that the claim 1 of the parent Application recites:

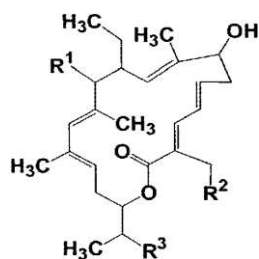
“A process for producing Tiacumicins that comprises culturing a microorganism having the ability to produce Tiacumicins in a nutrient medium comprising at least one adsorbent, such as herein described, capable of adsorbing one or more Tiacumicin during said culturing.”

The Applicant submits that the claim 1 of the parent Application is directed to a process for producing various tiacumicins, such as tiacumicins A-F. The Applicant refers to the as-filed specification of the instant Application or the parent Application, wherein several distinct tiacumicins have been identified (Background Section of the instant Application). The Applicant submits that tiacumicins A-F are known in the art and are structurally distinct.

In this regard, the Applicant refers to the corresponding provisional US patent Application (US Application no. 60/399,956), wherein several distinct tiacumicins have been identified and are defined by their particular pattern of substituents at positions R¹, R², and R³.

The provisional Application discloses that:

“Tiacumicins are a family of related compounds that contain the 18-membered macrolide ring shown below.



At present, several distinct Tiacumicins have been identified and six of these (Tiacumicin A-F) are defined by their particular pattern of substituents as shown in Table 1.”

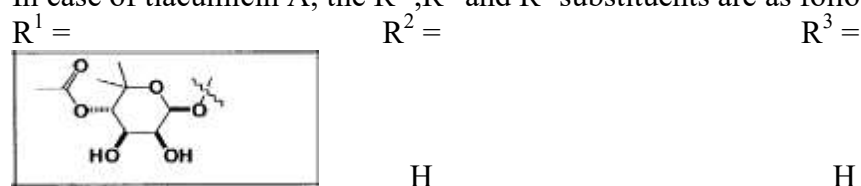
Table 1 Substituents Present In Tiacumicins A-F

	R ¹	R ²	R ³
A		H	H
B			OH
C			OH

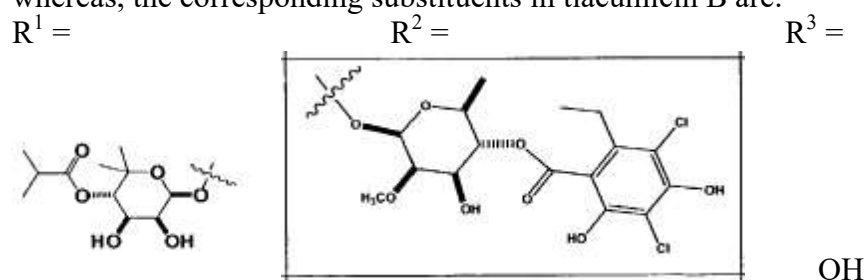
D			OH
E			OH
F			OH

The Applicant submits that the structure of tiacumicin B is different from other tiacumicins (refer Table above). Particularly, the Applicant provides the differences between tiacumicin A and tiacumicin B.

In case of tiacumicin A, the R¹, R² and R³ substituents are as follows:



whereas, the corresponding substituents in tiacumicin B are:



Similarly, the Applicant submits that the structure of tiacumicin B is different from the other tiacumicins, that is tiacumicin C-F.

In view of above, the Applicant reiterates that the structures of tiacumicin A-F are known and distinct from each other. Thus, the processes of preparing structurally different tiacumicins relate to a group of inventions which are not linked to form a single inventive concept.

The Applicant submits that the claim 1 of the instant divisional Application recites:

“A process for producing tiacumicins comprises: culturing a microorganism in a nutrient medium to accumulate **tiacumicin B** in the nutrient medium; and isolating the tiacumicin B from the nutrient medium, wherein the nutrient medium comprises 0.5%- 15% by weight of an adsorbing resin capable of adsorbing the **tiacumicin B**.”

The claim 1 of the instant divisional Application includes: culturing a microorganism to accumulate tiacumicin B; and isolating the tiacumicin B from the nutrient medium. The Applicant submits that the instant divisional Application is directed to a process of preparing tiacumicin B, which is a distinct species from the other tiacumicins A, C, D, E, or F; thus, the process of preparing a distinct entity, tiacumicin B is also technically distinct.

Overall, the Applicant submits that the process of preparing a structurally different compound is not technically linked, thus, the claims of the instant divisional Application are distinct from the claims of the parent Application. Therefore, the instant divisional Application is eligible to be considered as a divisional application under Section 16 of the Act.

Without prejudice to the above, the Applicant submits that the objection on the unity of the invention was raised by the Controller in the First Examination report (FER) of the parent Application (105/KOLNP/2005) over the, then pending claims 1 to 26. The Controller stated that the claims 1-16, 17-25 and 26 appear to define a plurality of distinct inventions in said FER. To overcome the objection raised by the Controller, the Applicant had filed the instant divisional Application (1146/KOLNP/2007). Thus, the instant divisional Application is a valid divisional Application under Section 16(1) of the Act.

Further, the Applicant submits that the pending claim 1 of the instant divisional Application recites the amount of the adsorbent resin, i.e., the nutrient medium comprising 0.5% - 15% by weight of an adsorbent resin. This feature further distinguishes the parent claims from the pending divisional claims.

Thus, the Applicant submits that, there is plurality of the inventions in the parent patent Application and thus the filing of the instant divisional Application is justified and in accordance with Section 16 of the Act.

In view of the above, the Applicant requests the Ld. Controller to withdraw the objection.

In response to **Objection 2 of the Hearing Notice**, the Applicant submits that the source and geographical origin of the biological material, i.e., subculture of *Dactylosporangium aurantiacum* subspecies *hamdenensis* used in the present invention is the Northern Regional Research Centre, the United States Department of Agriculture, 1815 North University Street, Peoria, IL. 6604, U.S.A. (refer, page 8 of the description of the instant Application). The Applicant specifies the same in the beginning of the as-filed specification of the instant Application.

Therefore, the Applicant requests the Ld. Controller to take the above on record and withdraw the objection.

In response to **Objection 3 of the Hearing Notice**, the Applicant has already provided the arguments to rebut this objection in the preceding paragraph, and the same has not been repeated here for sake of brevity. In view of the above, the Applicant requests the Ld. Controller to withdraw the objection.

In response to **Objection 4 of the Hearing Notice**, the Applicant submits an updated Form-3 along with the written submission.

Therefore, the Applicant requests the Ld. Controller to withdraw the objection.

Findings and Analysis:

After carefully considering the submission made by the applicant's agent in the written submission and the claims on record meet the objections raised in para 2 & 4 of the hearing notice.

Considering the applicant's submission in the hearing and in written note of arguments, I find that observations and submission made by the applicant is not persuasive. The objection under section 16 is analysed and discussed here. I observe that the present divisional application (1146/KOLNP/2007) relates process for producing tiacumicins comprises: culturing a microorganism in a nutrient medium to accumulate tiacumicin B in the nutrient medium; and isolating the tiacumicin B from the nutrient medium, wherein the nutrient medium comprises 0.5% - 15% by weight of an adsorbing resin capable of adsorbing the tiacumicin B." I observe that the present application (1146/KOLNP/2007) is a divisional application and is divided out of parent application 105/KOLNP/2005 having USA priority dated 29/07/2002. I observe that the said parent application was examined as per provisions of the Patents Act and First Examination Report (FER) was issued on 04/04/2006. The applicant submitted the reply to FER dated 04/04/2006 (with respect to parent application) on 20/03/2007 and filed the present divisional application (1146/KOLNP/2007) on 03/04/2007. Subsequently submitted a request of withdrawal of the said parent application (105/KOLNP/2005) on 04/04/2007 under section 11(B)(i) of the Patents Act, read with Rule 26 of the Patents Rules.

I observe that the original application 105/KOLNP/2005 was filed (in PCT as well as national phase) with 26 claims. I observe that claims (1-12) of parent application (105/KOLNP/2005) filed in response to first examination report, which was subsequently withdrawn are identical with claims (1-12) of present divisional application (1146/KOLNP/2007) as filed. The amended claim-1 and depended claims (filed on 20/03/2007) of the withdrawn parent application relate to process for producing tiacumicins comprises: culturing a microorganism in a nutrient medium to accumulate tiacumicin B in the nutrient medium; and isolating the tiacumicin B from the nutrient medium, wherein the nutrient medium comprises an adsorbent resin capable of adsorbing the tiacumicin B."

Further, I observe that the present divisional application was examined as per provision of the Patents Act and First Examination Report (FER) was issued on 09/09/2009. In reply to FER, the applicant has submitted amended claims (1-10) wherein claim-1 and depended claims relate to relates process for producing tiacumicins comprises: culturing a microorganism in a nutrient medium to accumulate tiacumicin B in the nutrient medium; and

isolating the tiacumicin B from the nutrient medium, wherein the nutrient medium comprises 0.5% - 15% by weight of an adsorbing resin capable of adsorbing the tiacumicin B.”

I observe that during national phase prosecution of the said parent application, 105/KOLNP/2005, the applicant has voluntarily filed the present divisional application and withdrawn the said parent application (105/KOLNP/2005) as discussed in the preceding paragraphs.

By analyzing the claims of purported divisional application (1146/KOLNP/2007) *vis-à-vis* claims of parent application (105/KOLNP/2005), I observe that the claims of the present divisional application are identical with that of claims of application 105/KOLNP/2005. Further, I observe that amended claims (1-10) of the present divisional application are also identical with that of claims of amended parent application 105/KOLNP/2005.

Now, I would like to refer the pertinent Sections of the Act which I feel relevant in the present context.

Section 7: Form of application:

7(1) Every application for a patent shall be for one invention only.

Section 10: Contents of specification:

10 (5): The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification.

Section 16 deals with Power of Controller to make orders respecting division of application:

Section 16 of the Patents Act states that “ (1) *A person who has made an application for a patent under this act may, at any time before the grant of 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 specification includes a claim for any matter claimed in the other.

Considering the above mentioned sections of the Patents Act, I am of the opinion that the these sections of the Act have not been dealt in appropriate manner for the present divisional application as it has been filed with the same set of claims as parent application (105/KOLNP/2005). *It is pertinent to mention here that the concept of divisional application is basically to protect multiple inventions, but it has been found after scrutiny that the present*

divisional application was filed with identical claims with that of parent application in order to extend the prosecution of the claimed invention. Further, the amended claims submitted after hearing are also same with mother application as discussed above. Hence, I am of the opinion that present divisional application is mere duplication of the parent application which eventually results a clear violation of section 16 and section 10(5) of the Act.

Now I would like to discuss about the Order of Honorable IPAB. The Honorable IPAB has issued the Order (order No. 111/2011) on 10th August 2011 [APPEAL NO. OA/6/2010/PT/KOL, LG Electronics Inc. Vs Controller of Patents and Others in respect of patent application no. 1191/ KOL/ 2005], wherein *The Honorable Board commenced its decision by saying that "The concept of divisional application in the patent law basically addresses the issues of allowability of protection of multiple inventions disclosed in one patent application, where these multiple inventions do not constitute a single inventive concept. The protection of multiple inventions through divisional application is available in the Patents Act 1970 under the provisions of Section 16 and section 10(5)" [Paragraph 22 of the decision]. The Honorable Board has upheld the decision in the LG Electronics and has concluded that "We are convinced that the phrase 'if he so desires' used in Section 16 is not unconditional and it does not give the applicant an unqualified liberty to file a divisional application even when there is no situation of plurality of distinct inventions contained in the mother application".[Paragraph 25 of the decision].*

The said sections are reproduced herein below:

Section 16: as stated above

Section 10: as stated above

On this count the Hon'ble IPAB observed that *"Accordingly, on plain reading of the above referred provisions it is evident that if the claims of the invention disclosed in one patent application do not relate to single invention or to a group of inventions forming a single inventive concept, the applicant can file further application as divisional application out of that applicant either of his own (suo moto) or when the objection of disclosure of more than one invention is raised by the Controller.*

It is further stated that whether the specification cover more than one invention, it is for the Controller to decide" [Paragraph 22 of the order].

In another case OA/17/2009/PT/DEL(order No. No. 19 of 2013)) dated 29th January 2013, [SYGENTA PARTICIPATIONS AG Vs Controller of Patents and Others in respect of patent application no. 748/DEL/2002], wherein said order states that *"the word "division" cannot mean split one invention into splinters, it can only mean splitting one application into more than one so that each application is for a separate invention. That is how the word "division" can be understood."* {Paragraph 22 of the order}.

In view of above findings, it is inferred that the present application does not qualify for a divisional status. Therefore, I am of opinion that the present divisional application does not

meet requirements of section 16 of the Patents Act and hence divisional status cannot be allowed.

Since the divisional status of the present application is not allowed, I do not want to discuss the remaining objections.

Conclusion

Having considered all the facts, the documents on record and submissions made by the applicant during the hearing, in written note of arguments and in view of above analysis and findings, I do not consider the instant application 1146/KOLNP/2007 as a divisional application under section 16 of the Patents Act. Hence, I hereby order to refuse the instant application 1146/KOLNP/2007 under section 15 of the Patents Act to proceed further.

25/09/2018

(Dr. Abhijit Das)

Asst. Controller of Patents & Designs.