

**Sequent**

D/10996



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To

The controller of Patents  
The Patent Office,  
Intellectual Property Building,  
G.S.T. Road, Guindy,  
Chennai- 600032

*Handwritten signatures and initials*

**Kind Attention: AHILAN B, Controller of Patents**

**Subject:** Reply to Examination Report dated 06/01/2017

**Reference Number:** No POC/Application No/3712/CHE/2011 dated 06/01/2017

**Name of Applicant:** SEQUENT SCIENTIFIC LIMITED

**Title of the invention:** A process for preparation of 1-(6-methylpyridin-3-yl)-2-[4-(methylsulfonyl)phenyl]ethanone

Sir,

Further to the examination report email dated January 06, 2017, applicant hereby submits response to the objections raised. The reply to the examination is report is attached in Annexure A. In light of the enclosed submissions of claim amendments and response, applicant requests the Learned Controller to kindly allow the application to proceed in order for grant.

Sincerely,

*C. Valan Amburose*

(C. VALAN AMBUROSE)

Deputy General Manager - IPM

Sequent Scientific Ltd.

Enclosures:

1. Reply to examination report – Annexure A; Five pages
2. Cancelled Claims: Amendments marked copy; One page
3. Amended claims in duplicate; Two pages each
4. Cancelled Abstract: Amendments marked copy; One page
5. Amended Abstract: One page
6. Form 3 in duplicate: One page
7. Copies of ISR and IPRP: Eight pages
8. Form 5 in duplicate: One page

PATENT OFFICE CHENNAI 23/02/2017 16:15

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Annexure A

**Reply to First Examination Report**

Patent Application Number: IN 3712/CHE/2011

SEQUENT SCIENTIFIC LIMITED

Applicant respectfully states that the claims are amended so as to comply with the requirements of the First Examination Report and the amended claims are attached in a separate sheet. Further, the amended claims are fully supported by the specification. No new matter is added by the claim amendments made. Applicant furnishes the following details for better understanding of the invention and to appreciate the novelty and inventive step having regard to the objections raised in the first examination report and complying with current amendment.

**Claim amendments:**

Claim 1: The word 'optional' is deleted.

Claims 2, 3, 4, 5 and 6: 'A' is replaced with 'The'.

Claim 3: The expressions, 'and/or', 'such as' are deleted.

Claims 7: Claim 7 is deleted

**Remarks to the objections raised by the Examiner:**

**NOVELTY:**

*(i) Claim(s) 7 lack(s) novelty, being anticipated in view of disclosure in the document cited above under reference D1 to D4 for the following reasons: Claim 7 is well known in the art, Product by process claim can not be allowed unless the product is new.*

Claim 7 is deleted.

**INVENTIVE STEP:**

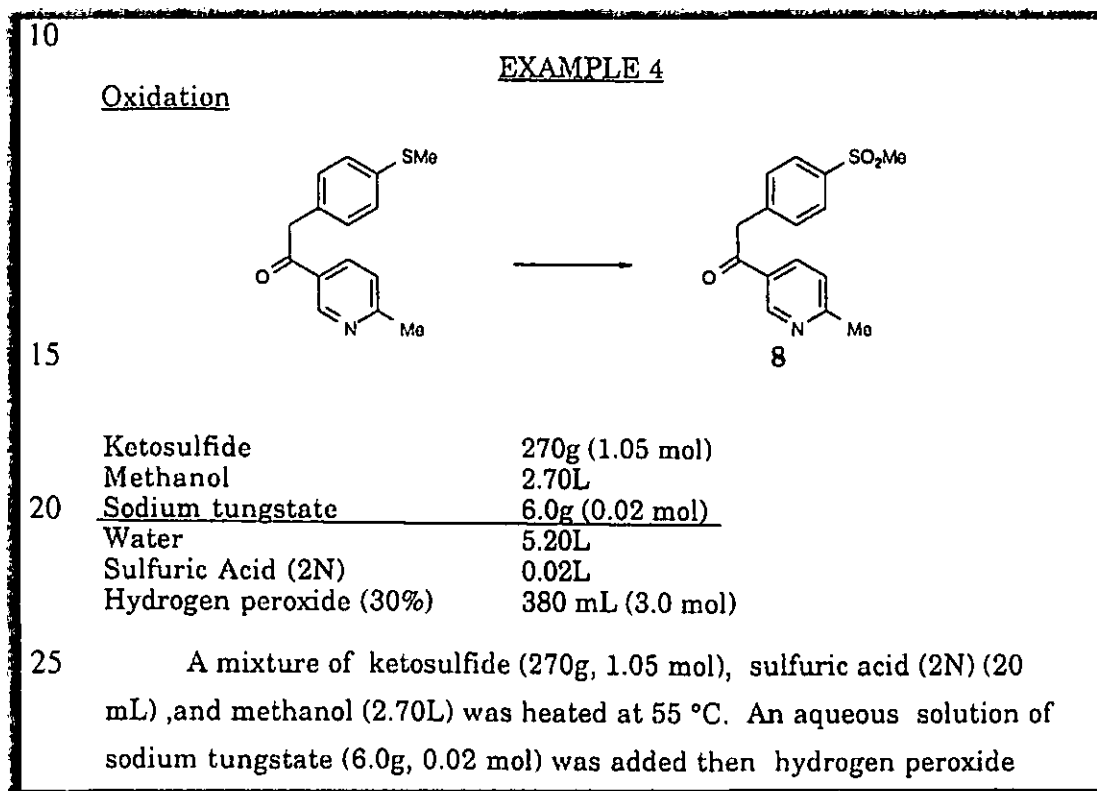
*(ii) Claim(s) 1-7 lack(s) inventive step, being obvious in view of teaching (s) of cited document(s) above under reference D1-D3 for the following reasons: The subject matter of claims 1-7 do not meet the requirements of section 2(1)(ja) of The Patents Act, since they do not involve an inventive step over the disclosure of documents D1-D4:*

Applicant respectfully submits that the present invention involve inventive step compared to all the cited documents as presented below:

Applicant thanks the Examiner for acknowledging that the document D1 does not teach the oxidation in step *c in situ* in the presence of H<sub>2</sub>SO<sub>4</sub> and acetic acid and in the absence of an alkali metal tungstate catalyst.

In D2, WO99/15503 entitled process for making diaryl pyridines useful as COX-2 inhibitors, sodium tungstate was used for the oxidation in Example 4 on page 23, lines 10 to 31. Based on the example 4 and the teaching provided, a skilled person will be motivated to mandatorily use sodium tungstate catalyst for oxidation.

Example 4 on page 23 of D2 WO99/15503 is provided below:



There is no teaching or motivation provided in D2 to a skilled person to avoid tungstate catalyst for oxidation. Assuming that there is a teaching in D2 as indicated by the Examiner, a skilled person shall have to conduct a series of experiments to find out if the oxidation reaction could work without catalyst. Undue experimentation is a must. There is no expectation of success

in oxidation in the absence of tungstate catalyst. Moreover, D2 is not for the preparation of instant invention of aiming to prepare compound of formula I, rather intermediate steps in the preparation of diaryl pyridines useful as cox-2 inhibitors. On page 11, the word 'optionally' is used for catalyst. As per page 13; lines 6 to 7; oxidising agents are preferably oxone or hydrogen peroxide and the catalyst is Na<sub>2</sub>WO<sub>4</sub>. A skilled artisan in chemistry would construe the word 'optionally' as 'mandatory' in view of example 4.

As there is no teaching in D2 to avoid tungstate catalyst, a skilled person will not be able to arrive at the instant invention by combining D2 with D1.

Document D3, US6897339B2 with the title, "Process for the production of high purity lohexol". D3 in column 4 and lines 6-18 of Example 5 teaches a method of producing a 99% pure lohexol compound from 91% lohexol refluxing 6 hours at first and additional four hours next in 1-methoxy-2-propanol solvent. Applicant request Examiner's attention that D3 is not at all relevant to the instant invention of purification along with in situ oxidation step. As there is no teaching of instant invention in D3, a skilled person will never have any motivation to use the teaching of D3 either alone or in combination with the teachings of D1 or D2 or D4.

Document D4 describes a process for preparation of Ketosulfone from N,N-dialkylamino-(6-methyl-3-pyridyl)acetonitrile and 4-(methylsulfonyl)benzyl halogenide using a base which is alkali alcoholate. The process of the present invention is different form the process described in D4. The instant invention does not use compounds described in D4.

The instant invention involves technical advance of avoiding tungstate catalyst and has significant economic significance by reducing the cost involved in using the tungstate catalyst. Environmental concerns of handling and treating the catalyst are avoided. The compound of formula I obtained is free from tungsten.

It is to be noted that the prior art documents D1-D4 cited by the Examiner are all silent on avoiding tungstate catalyst and *in situ* oxidation thereby achieving quality of final product. In view of the above comments, Applicant respectfully requests the Examiner to waive off the inventive step objection under section 2(1)(ja).

**NON PATENTABILITY:**

(iv) Claim(s) 1-7 are statutorily non-patentable under the provision of clause (d) of Section 3 for the following reasons:

Applicant requests the Examiner's attention to pages 6 to 7 of the specification wherein the advantages of the instant invention are provided. For convenience of the Examiner, the advantages are recited herein below:

A person skilled in the art will acknowledge that the present invention overcomes most of the common drawbacks and has following advantages:

- Reduction of a number of step by eliminating isolation of ketosulfide of formula II
- Reduction in generation of toxic effluent
- Elimination of use of methane sulfonic acid which would cause genotoxic impurities
- Elimination of use of alkali metal tungstate as catalyst for the oxidation
- It provides tungsten free Ketosulfone which is highly desired for the industry.

D1 is using tungsten catalyst and oxidation step in D1 was not carried out *in situ*.

The process of D4 is not relevant to the instant process.

Avoiding catalyst in the oxidation step thereby showing tungsten absent in the final compound, carrying out hydrolysis-decarboxylation-oxidation in one-pot *in situ* consequently saving reaction time, would not be considered as a mere discovery. The process of the instant invention resulted in a high quality product with the individual impurity less than 0.1%.

#### CLARITY AND CONCISENESS:

(xvii) Claim(s) 1, 3,7 are not clearly worded in respect of:  
Claims 1, 3 and 7 are not clearly worded with respect to expressions like "optionally", "and/or", "less than" etc., and thereby said claims do not meet the requirements of section 10(4) of The Patents Act.

Claim 1 contains "optional" in step d. This word is now deleted.

Claim 3 contains "and/or" and the same is amended to "or".

Claim 7 contains "less than" and the claim is cancelled.

**PART-III: FORMAL REQUIREMENTS**

Form 3 is attached. Copies of international search report and international preliminary report on patentability are enclosed along with Form 3. Form 3 was submitted twice earlier to the patent office in applicant's letter dated October 29, 2011 and March 21, 2014.

Abstract is amended to commence with the title of the invention. Amended abstract in duplicate is attached.

Form 5 is submitted.

The claims have now been revised as per the Indian patent office requirements as desired by Learned Controller. As all requirements of the application are complete, we request the Learned Controller to kindly grant the patent.