GRÜNENTHAL GMBH



Grünenthal GmbH - 52099 Aachen - Germany

Europäisches Patentamt Erhardtstraße 27

80469 München

FAX

Patent Department

Date 18 April 2008 Your reference

Your letter dated

Our reference

Our letter dated

Contact Dr. Stowasser

Telephone +49 241 569-2599

Telefax +49 241 569-2655

E-Mail
patents
@Grunenthal.com

Patent Application No. 05 770 026.2 - 2103 Our reference: GRA 3111-EP / ST-PN / RS-KN

Reply to the communication according Article 96(2) EPC

In reply to the communication according Article 96(2) EPC an amended claim set is provided on a separate sheet. We are confident that the examiner's objections with respect to the formal issues 1.1, 1.2, 1.3. and 2 of the office action have been overcome by the amendments. Regarding the formal objections 1.1, we would like to emphasis that claim 2, 3 and 4 are dependent claims of claim 1 and that is stated in the description on page 2, line 19-25, that crystalline form A is best and sufficient described by the parameters recited in claim 1.

Regarding 3:

The subject matter of the present claims are regarded as being novel by the examination division.

Regarding 4:

The applicant provides with the enclosed "experiment 1" data that the novel crystalline form A is inventive over the prior art: The crystalline form B disclosed in D1 has the disadvantage that under the influence of pressure (which occurs e.g. in the manufacturing process for the drug tablet) polymorph B (crystalline form of D1) is transformed in a mixture of the crystalline forms A and B.

The underlined problems can be defined in view of D1 to find a crystalline form which can be used in a manufacturing process of drug tablets. Surprisingly and shown by the data enclosed in Table 1 the crystalline form A claimed in the pending application shows stability regarding high pressure. There can be no mixture of polymorphs A and B detected up to the limit of quantification (LOQ) with the starting material B. The experiment shows clear evidence for a change in the



603W/08.04 F.:\text{Pn}\Patentle\text{KOR\Gra3111\text{IGRA3111\text{ER}A3111\text{ER}}} = 080221\text{KN.doc}, \text{VorsitZender des Autsichtsrates: Prol. Dr. Brin-Hagen Hernnerkes Geschaftstührer: Dipl.-Psych. Wolfgang Becker, Dipl.-Klm. Stefan Genten, Prof. Dr. Eric-Paul Päques, Dipl.-Ing. Sebastian Wirtz Sitz der Gesellschaft: Aachen Registergericht: Amtsgericht Aachen, HRB Nr. 3546\text{Ust.-ID\text{VAT}}: DE121737755\text{ St.Nr.} 202\text{5804\text{ 0019}} Bankverbindungen: Sparkasse Aachen, BLZ\text{390\text{ 500\text{ 000}}} 600, Klo 181\text{ 80\text{ 04}}, BIC AACSDE33, IBAN DE20\text{3905\text{ 0000\text{ 0000\text{ 0001}}} 8180\text{ 04\text{ ABN AMRO\text{Bank N.V.}}, BLZ\text{502\text{ 304\text{ 00}}} 001\text{ (liferanschrift: Zieglerstraße 6, 52078\text{ Aachen, Tel.: +49\text{ 241\text{ 569-0, Fax: +49\text{ 241\text{ 569-3300}}}} \text{ Asstrational Control of the Control o





modification of all form B batches exposed to pressure of 2 tons within only 60 seconds. All form A batches remain unchanged.

In the case the amended claim set enclosed are considered to be not allowable by the examination division, a further official communication or, as an auxiliary request, oral proceedings are requested before any decision is taken other than the grant of the patent.

Furthermore the applicant asks to postpone the amendments of the description until the examination division agreed on the amended claim set.

Yours sincerely, Grünenthal GmbH

i. V. Dr. Stowasse

Enclosures:

- Table 1 with experimental data
- amended claim set
- self-addressed envelope (by mail only)

