THE EUROPEAN OMBUDSMAN

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Strasbourg, 18 -03- 2008

Complaint 2560/2007/BEH

Dear Sirs,

I am referring to your observations on EMEA's opinion which you sent on 26 February 2008.

In view of EMEA's opinion as well as your observations I consider it necessary to make further inquiries in your case.

For this reason, I have asked EMEA for further clarification by 30 April 2008 with regard to the following issues:

1. Could EMEA please specify why clinical study reports and corresponding trial protocols are to be considered as covered by commercial interests and in how far their disclosure for scientific purposes would be liable to undermine the protection of commercial interests?

2. In its opinion, EMEA refers to TRIPS. It appears that Article 39(3) of TRIPS allows contracting parties to grant access to data submitted in the process of marketing approval, provided that steps are taken to ensure that the data are protected against unfair commercial use. Could EMEA please explain its understanding of the relationship between the Rules for the implementation of Regulation 1049/2001 and Article 39(3) of TRIPS? The present case concerns a request for access dealt with under the Rules for the implementation of Regulation 1049/2001. In his inquiry into complaint 1776/2005/GG, the EO had to deal with a complaint relating to refusal of access to an audit report. In that case, the European Investment Bank, apart from granting public access to certain excerpts of the report, undertook to grant the complainant private access to certain further sections. Could EMEA please inform the Ombudsman

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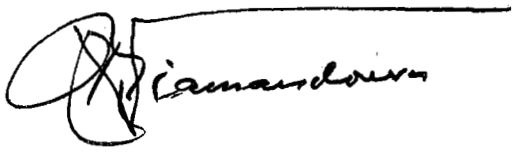
whether, in light of Article 39(3) of TRIPS, it would consider possible a similar approach in the present case?

When the supplementary opinion is received, I will forward it to you with an invitation to submit observations, if you so wish, within one month.

I have also forwarded your observations on EMEA's opinion to EMEA.

Yours sincerely,



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