

IN THE HIGH COURT OF JUSTICE

Claim No. 2007 1585

QUEEN'S BENCH DIVISION

COMMERCIAL COURT

Mr. Justice David Steel

19 December 2007

B E T W E E N:

XYTIS PHARMACEUTICALS SARL

(a company incorporated under the laws of Switzerland)

Claimant

and

LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE

(a company incorporated by Royal Charter)

Defendant

ORDER FOR AN INJUNCTION

PENAL NOTICE

IF YOU LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE DISOBEY THIS ORDER YOU (AND ANY OF YOUR DIRECTORS AND/OR OFFICERS) MAY BE HELD TO BE IN CONTEMPT OF COURT AND MAY BE IMPRISONED, FINED OR HAVE YOUR ASSETS SEIZED.

ANY OTHER PERSON WHO KNOWS OF THIS ORDER AND DOES ANYTHING WHICH HELPS OR PERMITS THE RESPONDENT TO BREACH THE TERMS OF THIS ORDER MAY ALSO BE HELD TO BE IN CONTEMPT OF COURT AND MAY BE IMPRISONED, FINED OR HAVE THEIR ASSETS SEIZED.

YOU SHOULD READ THIS ORDER CAREFULLY. YOU HAVE THE RIGHT TO ASK THE COURT TO VARY OR DISCHARGE THIS ORDER.

The Application

1. An Application was made on 19th December 2007 by Counsel for the Claimant to the Judge and was attended by Counsel for the Defendant. The Judge heard the Application and read the documents listed in Schedule 1 and accepted the undertakings set out in Schedule 2.
2. The Application was made on notice to the Defendant.

The Order

3. Until trial or further order in the meantime, the Defendant, whether through the relevant committees, being the Protocol Committee, the Trial Steering Committee or the Data and Safety Monitoring Board, or otherwise, must not:
 - (1) purport to make any determination or recommendation to terminate the Phase II multi-centre clinical trial of XY2405 (“the Trial”) without the prior written consent of the Claimant;
 - (2) purport to convene and/or hold any meeting of the Trial Steering Committee other than on 5 business days’ prior notice in writing to the Claimant, such notice setting out a full agenda of the business proposed to be conducted at the said meeting together with full supporting papers to be considered at any such meeting, save that if all voting members of the Trial Steering Committee unanimously determine that a meeting on shorter notice is necessary, such meeting may be called on such notice as they regard as sufficient.
4. The Defendant will as soon as practicable and in any event no later than 4pm on Friday 21 December 2007 send a joint instruction in substantially the terms set out in Schedule 3 hereto (which instruction is not to be revoked by either party without the agreement of the other or the permission of the Court) to Clinical Research Associates (“CRAs”) and Investigators participating in the Trial (to apply retrospectively as well as to current and ongoing trial data).
5. The Defendant will as soon as practicable and in any event no later than 4 pm on Friday 21 December 2007 reinstate access to the database relating to the Trial for all CRAs.

Costs of the Application

6. Costs in the case.

The effect of this Order

7. A Defendant which is a corporation and which is ordered not to do something must not do it itself or by its directors, officers, employees, or agents or in any other way.

Directions

8. The Claimant do file and serve a draft list of issues together with a provisional indication of its position in relation to the matters in dispute by 4pm on 24 December 2007.
9. The Defendant do file and serve its response to the draft list of issues with a view to seeking to agree (where possible) the list of issues together with a provisional indication of its position in relation to the matters in dispute by 4pm on 2 January 2008.
10. The Claimant to apply to the Clerk to the Commercial Court for a Case Management Conference to take place in the week commencing 15 January 2008.
11. The Claimant to have liberty to restore its application notice dated 18 December 2007 at the Case Management Conference.
12. Standard disclosure is to be made by 4pm on Friday 18 January 2008 with inspection by 4pm on Wednesday 23 January 2008.
13. Signed statements of witnesses of fact, and hearsay notices where required by rule 33.2, are to be exchanged by not later than 4pm on Friday 8 February 2008.
14. Unless otherwise ordered, witness statements are to stand as the evidence in chief of the witness at trial.
15. Preparation of trial bundles to be completed in accordance with Appendix 10 to the Commercial Court Guide by not later than 15 February 2008.
16. The provisional estimated length of the trial is 5 days.
17. Within 3 days the parties are to attend on the Clerk to the Commercial Court to fix the date for trial which shall be not before Monday 25 February 2008. It is directed that the trial is fit for expedition and should take place as soon after 25 February 2008 as the Clerk to the Commercial Court can accommodate.
18. The progress monitoring date is Friday 15 February 2008. Each party is to lodge a completed progress monitoring information sheet with the Clerk to the Commercial Court by Tuesday 12 February 2008.
19. Save as varied by this order or further order, the practice and procedures set out in the Admiralty & Commercial Courts Guide are to be followed.

Communications with the Court

All communications to the court about this order should be sent to —

Room EB09, Royal Courts of Justice, Strand, London WC2A 2LL quoting the case number. The telephone number is 0207 947 6826.
The offices are open between 10 a.m. and 4.30 p.m. Monday to Friday.

Schedule 1

The Judge read the following before making this Order:

1. The Claim Form, Application Notice and Claimant's Particulars of Claim
2. The Claimant's skeleton argument and the Defendant's skeleton argument.
3. First Witness Statement of Vincent Simmon dated 4 December 2007
4. Second witness statement of Vincent Simmon dated 11 December 2007
5. Third witness statement of Vincent Simmon dated 13 December 2007
6. Witness statement of Dr René Goedkoop dated 13 December 2007
7. Witness statement of Professor Christina Sampaio dated 10 December 2007
8. Witness statement of Professor Peter Andrews dated 10 December 2007
9. Witness statement of Professor Ian Gary Roberts dated 11 December 2007
10. Second Witness statement of Professor Ian Gary Roberts dated 18 December 2007
11. Fourth Witness statement of Vincent Simmon dated 19 December 2007
12. Witness Statement of Bernard Caulfield dated 19 December 2007

Schedule 2

The Claimant gave the following undertakings to the court:

1. If the Court later finds that this Order has caused loss to the Defendant, and decides that the Defendant should be compensated for that loss, the Claimant will comply with any order the Court may make.
2. To maintain the sum of £150,000 by way of fortification of the previous undertaking, such sum having been paid into Court.
3. The Claimant will as soon as practicable and in any event no later than 4pm on Friday 21 December 2007 send a joint instruction in substantially the terms set out in Schedule 3 hereto (which instruction is not to be revoked by either party without the agreement of the other or the permission of the Court) to Clinical Research Associates ("CRAs") and Investigators participating in the Trial (to apply retrospectively as well as to current and ongoing trial data).

Schedule 3

Form of joint instruction referred to in paragraph 4 above.

"Dear Investigators and CRAs

As you know Xytis and the London School of Hygiene and Tropical Medicine are in legal dispute with regard to the BRAIN trial.

We have reached a temporary solution to allow the continuation of the data collection and data cleaning which will allow the review of the 227 patient data. This is to ensure that the safety of all patients in the trial can be determined at the earliest opportunity.

The TCC has no objections to all CRAs continuing to work with Investigators to monitor the trial. Please follow all original instructions in place before the dispute arose.

It has been agreed between the parties that data collection, SAE reporting and all other data collection is to continue as per the Protocol.

To allow Xytis access to data and information being collected, all CRAs are requested to send copies (not originals) of CRF data, data queries and all reports directly to Xytis for their information.”

Name and address of the Claimant’s solicitors

The Claimants’ solicitors are:-

Dechert LLP
160 Queen Victoria Street
London
EC4B 4QQ

Tel: 020 7184 7000
Fax: 020 7184 7001

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