

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
COMMERCIAL COURT

Claim No: 2007 Folio 1585

Before Mr Justice Burton

B E T W E E N:

XYTIS PHARMACEUTICALS SARL
(a company incorporated under the laws of Switzerland)



And

LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE
(a company incorporated by Royal Charter)

Defendant

ORDER

UPON HEARING Counsel for the Claimant (also acting for this purpose for Xytis Inc., a company incorporated under the laws of Delaware) and Counsel for the Defendant

AND UPON the Claimant undertaking that it will not:

- (1) Serve notifications and/or make allegations of breach of the CTSA that are without reasonable foundation;
- (2) Publish any statements falling within Article 10.1 CTSA save in accordance with that clause and, for the avoidance of doubt, shall not publish any repetition of the allegations made in this action and/or in the Claimant's email and letter to trial participants dated 19 November 2007 and 22 November 2007 respectively, and its

letter to regulators dated 21 December 2007 save as may be required by any applicable regulation;

- (3) Give instructions to local investigators or clinical research associates that are inconsistent with the Protocol or the CTSA, which so long as the CTSA and Article 10 of the Protocol continue in their present form shall include any instructions to retain CRFs or other Trial data or to send it to anyone other than the Defendant.

AND UPON the parties agreeing the further terms set out in the Schedule below in full and final settlement of the claims disclosed by the parties in these proceedings (so far as not disposed of by this Order).

AND BY CONSENT

IT IS ORDERED THAT:

1. The Claimant's claim is dismissed;
2. The Defendant shall have permission to apply to enforce the Claimant's undertakings above. The Defendant's counterclaim shall otherwise be stayed;
3. The injunctions against the Defendant made under the Order of Mrs. Justice Gloster dated 4 December 2007 and as modified by the of Order Mr. Justice David Steel dated 19 December 2007 are discharged without inquiry into damages and the Claimant is released from its undertakings thereunder;
4. Subject to paragraph 6, the Claimant shall be liable to pay the Defendant's costs of the action in the sum of £700,000 plus VAT in such sum not exceeding £122,500 as the Defendant shall notify to the Claimant as its good faith estimate of irrecoverable VAT within 7 days;
5. The Defendant shall be entitled to withdraw from Court forthwith the sum of £350,000 in part satisfaction of the Claimant's costs liability specified in paragraph 4.

Any accrued interest on the sums in court shall be paid to the solicitors for the Defendant and shall be deducted from the first payment due under paragraph 6;

6. The Defendant will accept the balance between (1) the sum of £600,000 plus its estimated irrecoverable VAT thereon (in proportion to the notification made under paragraph 4 above) and (2) the sum of £350,000 plus accrued interest (“the Balance”) in full and final settlement of the liability referred to in paragraph 4 provided that the Balance is paid in four equal instalments, which shall be payable by 1 April 2008, 1 May 2008, 1 June 2008 and 1 July 2008;
7. In the event that the Claimant fails to make an instalment payment by 1 April 2008 or any subsequent instalment payment by the due dates specified in paragraph 6, the Claimant shall pay forthwith the balance between the sum of £700,000 plus VAT and the sum of £350,000 (less, where appropriate, the amount of any payments made under paragraph 6);
8. Under section 51 of the Supreme Court Act 1981 Xytis Inc, a company incorporated under the laws of the State of Delaware, shall be jointly and severally liable with the Claimant to pay the Defendant’s costs of the action in the sum set out in paragraph 4.

SCHEDULE

1. The Claimant and the Defendant have agreed a joint statement in the following terms, which (for the avoidance of doubt) they shall be entitled to publish and/or communicate without restriction:

“Xytis, having reviewed the evidence in the litigation with LSHTM, has now withdrawn its claims and allegations in full.”

2. Following the suspension of patient recruitment to the BRAIN Clinical Trial on 1 November 2007, the Defendant will continue under the CTSA and shall be entitled to complete the collation and cleaning of information and data for re-submission to, and recommendation by, the Data Safety Monitoring Board, and subsequent decision by

the Trial Steering Committee. The Defendant acknowledges that it is obliged under the CTSA to use reasonable endeavours to complete the collation and cleaning of information and data as quickly as practicable, assuming full co-operation from the Claimant and CRAs;

3. The Defendant will use its best endeavours to ensure that a meeting of the TSC is convened within seven business days of receipt of a recommendation by the DSMB in respect of the cleaned and re-submitted Clinical Trial data (but will not be responsible for any difficulties in availability of TSC members);
4. The Defendant acknowledges that there are circumstances which might bring the Clinical Trial to an end. Those circumstances include scientific grounds and the inability of the Claimant to fund the clinical trial further and/or to fund further the manufacture and supply of the Trial Drug;
5. The Defendant further acknowledges that it will be unable to conduct the Clinical Trial beyond completion of the exercise and steps specified in paragraphs 2 and 3 without further funding from the Claimant and/or if the Claimant is unable to fund the manufacture and supply of the Trial Drug;
6. In the event that the TSC decides (on the recommendation of the DSMB or otherwise) that the Clinical Trial should be terminated on scientific grounds and/or the TSC decides that the Clinical Trial should be terminated by reason of the Claimant's inability to fund the Clinical Trial further and/or to fund further the manufacture and supply of the Study Drug, the Defendant shall bring the Clinical Trial to an orderly conclusion in accordance with the Protocol, the CTSA, Good Clinical Practice and all applicable laws and regulations, with the cooperation (where requested) of the Claimant.
7. For the avoidance of doubt, and for the purposes of carrying into effect those obligations hereunder that are contingent on the termination of the Clinical Trial, the Clinical Trial shall be deemed to have terminated on the date of any decision of the TSC to terminate the Clinical Trial;

8. Subject to (1) the Defendant's entitlement to take and retain copies of Trial documents (including copies of the CRFs) and (2) the Defendant's right to retain copies of the Clinical Trial Database, the Defendant will return Trial documents and materials as contemplated by Article 9.4 CTSA as soon as reasonably practicable following any termination of the Clinical Trial. In any event, as soon as the Clinical Trial is terminated, and subject to the co-operation of RackSpace (which the Defendant shall request), the Claimant shall be entitled, at its own expense and risk, to seek to take a copy of the Clinical Trial Database excluding any personal contact details of the Defendant's staff or investigators;

9. In the event that the TSC decides (on the recommendation of the DSMB or otherwise) that the Clinical Trial should be terminated on scientific grounds and/or on the basis that the Claimant has informed the Defendant that it is unable to fund the Clinical Trial further and/or the manufacture and supply of the Study Drug:
 - (a) The Defendant shall relinquish any claim that it has asserted or may assert against the Claimant (whether in damages or in debt) arising from or relating to Article 3 and Exhibit C of the CTSA;

 - (b) The Claimant shall not in the future make any claims or allegations (whether by way of legal proceedings or otherwise) that the compensation payable to the Defendant by the Claimant under the CTSA was or is to be payable on a "costs-plus" basis and any claims (whether in damages or in debt or restitution) arising from or relating to Article 3 and Exhibit C of the CTSA;

10. The Claimant and the Defendant agree that unless and until the Clinical Trial proceeds following completion of the collation and cleaning of the information and data currently available, no further sums are due and owing from the Claimant to the Defendant, and any outstanding invoices issued to the Claimant by the Defendant are not payable and are hereby withdrawn;

11. Subject to paragraph 9, the Claimant shall withdraw any and all claims (so far as not covered by dismissal of the proceedings).

12. The Claimant accepts and acknowledges that it has no intellectual property rights whatsoever in or in connection with the design, construction or programming (including source code) of the Clinical Trial Database;
13. The Claimant will erase permanently all copies of the Clinical Trial Database obtained from the Defendant during the course of these proceedings;
14. The Claimant accepts and acknowledges that it has no intellectual property rights that might be infringed by the issuing of a publication or communication by the Defendant in connection with the Clinical Trial as contemplated by Article 6 CTSA and shall refrain from taking any steps (whether by way of legal proceedings or otherwise) to hinder or frustrate the Defendant's publication rights under Article 6 CTSA.
15. It is agreed that as from 13 June 2008 the Claimant shall be entitled at its own risk and expense to send representatives to the premises of the Defendant in order to begin the process of copying and removing original CRFs and other Trial materials, under the supervision of the Defendant.

Dated this third day of March 2008.