

Neutral Citation Number: [2009] EWHC 281 (Admin)

**IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT**

CO/2469/2008

THE HONOURABLE MR JUSTICE HOLMAN

B E T W E E N:

**THE QUEEN
on the application of
SERVIER LABORATORIES LIMITED**

Claimant

- and -

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Defendant

THE NATIONAL OSTEOPOROSIS SOCIETY

Interested Party

ORDER

UPON hearing Counsel for the Claimant and Leading and Junior Counsel for the Defendant

AND UPON reading the revised submissions of the Interested Party dated 19th December 2008 and the letter from the Interested Party to the Court dated 18th February 2009

AND UPON the Defendant providing the following undertakings to the Court:

1. Within 7 days of this Order, the Defendant will offer to disclose to the Claimant and all other consultees and commentators a fully-executable, unredacted copy of the economic model used by the Defendant in Technology Appraisals TA160 and TA 161

("the Model"), on condition that the respective Claimant, consultee or commentator gives undertakings in the form required by Professor Kanis and annexed to this Order ("the Offer to Disclose"). The Offer to Disclose shall remain open for 28 days.

2. Within two working days of the Offer to Disclose lapsing, the Defendant will provide to any of the respective Claimant and/or consultees and/or commentators who accepts the Offer to Disclose a copy of the Model.
3. The Defendant will as soon as reasonably practicable reconsider the FADs in the light of such representations on the Model as the Claimant and/or consultees and/or commentators who have accepted the Offer to Disclose have made within 8 weeks of their receipt of the Model.
4. The Defendant will permit the Claimant and/or consultees and/or commentators who have made representations on the Model to appeal against the FADs (whether they have been modified or not) on any issue arising out of the representations made on the Model.

IT IS ORDERED that:

1. Permission to apply for judicial review is granted in relation to grounds (a), (c) and (e).
2. The application for judicial review is granted in relation to ground (a) and refused in relation to grounds (c) and (e).
3. No order as to costs.
4. Permission to appeal is refused to the Claimant on ground (c) and in relation to relief.

AND IT IS ORDERED AND DECLARED that:

1. The Defendant acted unlawfully in failing to take all reasonable steps to seek permission from Professor Kanis for NICE to be released from its obligations of confidentiality in

respect of the data which he had provided for the purposes of the Appraisal, so as to enable it to supply the Model to consultees and commentators (if necessary on appropriate undertakings as to confidentiality).

Neil Clarke

(COUNSEL FOR THE CLAIMANT)

Dan Galt

(JUNIOR COUNSEL FOR
THE DEFENDANT)

James Holman, J.

Appendix A

CONFIDENTIALITY UNDERTAKING TO BE GIVEN BY ANY CONSULTEE OR COMMENTATOR WISHING TO RECEIVE CONFIDENTIAL MATERIAL CONTAINED WITHIN THE NICE OSTEOPOROSIS MODEL

1. This Undertaking is given to Professor John Kanis of Rue de la Vallée, 41, Brussels 1000, Belgium ("Professor Kanis") by **[insert name and address of recipient]** (the "Recipient"). All communications with Professor Kanis in connection with this Undertaking should be sent by email to his secretary at the following address: w.j.pontefract@sheffield.ac.uk.
2. The Recipient wishes to receive a fully executable version of the economic model used in appraisals TA 160 and 161 (the "Model").
3. The Recipient acknowledges that the Model contains confidential material belonging to Professor Kanis (the "Confidential Material"). In consideration of being permitted access to the Confidential Material, the Recipient agrees to be bound by the provisions of this Undertaking.
4. The Recipient shall use the Model solely for the purposes of analysing, assessing and commenting upon the Model and its use in connection with appraisals TA 160 and 161 and any reconsideration of those appraisals (including participation in any appeal and/or proceedings arising out of that reconsideration), (together the "Purpose") and for no other purpose, including without limitation the development of other economic models.
5. The Recipient shall not disclose the Model in whole or part to any third party except that
 - a. the Recipient and/or any individual named in any Schedule to this Undertaking may, in support of the Purpose, disclose minor extracts from the Model provided that these extracts do not include or describe the co-efficients used in the Model; and
 - b. the Recipient and/or any individual named in any Schedule to this Undertaking may disclose extracts from the Model to individuals at a third party that Professor Kanis has informed the Recipient in writing are authorised to receive Confidential Material..
6. The Confidential Material contained in the Model is provided "as is". All conditions, representations, warranties or other terms (express or implied) in relation to it are excluded.
7. The Recipient shall ensure that only the individuals named in the schedule to this Undertaking have sight of, access to or use of the Model. The Recipient shall ensure that each of those individuals is provided with a copy of this Undertaking and agrees in writing signed by the individual to abide by its requirements before being allowed sight of, access to or use of the Model. The Recipient shall ensure that all individuals who receive sight of, access to or use of the Model via the Recipient shall comply with the confidentiality obligations and restrictions on use set out in this Undertaking as if they were a party to it.
8. The Recipient shall take reasonable steps to secure the confidentiality of the Model. Those steps shall include as a minimum:
 - a. Any electronic copy of the Model shall be password protected.

- b. No more copies of the Model shall be made than are strictly necessary for the Purpose.
 - c. Any copy of the Model which is no longer needed for the Purpose shall be promptly and permanently deleted.
 - d. All copies of the Model shall be clearly marked as confidential.
9. This Undertaking shall not prevent the Recipient and/or any individual named in any Schedule to this Undertaking from disclosing any output from the Model for the Purpose provided that the Recipient and any individuals named in any Schedule to this Undertaking do not directly or indirectly disclose all or any of the co-efficients contained in the Model.
10. The Recipient acknowledges that damages are unlikely to be an adequate remedy for any breach of this Undertaking, and that accordingly remedies for breach shall include, but not be limited to, injunctive relief.
11. This Undertaking is subject to English law and the exclusive jurisdiction of the English Courts.

Schedule

The individuals authorised to have sight of, access to, or use of the Model are:

	Full Name	Job title	Employer	Address and contact details
1.				
2.				
3.				

The terms of this Undertaking are agreed by the Recipient. This Undertaking is signed by the signatory identified below for and on behalf of the Recipient:

Print full name of Recipient:

Signature:

Print full name of signatory:

Job title of signatory:

Date:

Appendix B

CONFIDENTIALITY UNDERTAKING TO BE GIVEN BY AN INDIVIDUAL COMMENTATOR WISHING TO RECEIVE CONFIDENTIAL MATERIAL CONTAINED WITHIN THE NICE OSTEOPOROSIS MODEL

1. This Undertaking is given to Professor John Kanis of Rue de la Vallée, 41, Brussels 1000, Belgium ("Professor Kanis") by **[insert name and address of recipient]** (the "Recipient"). All communications with Professor Kanis in connection with this Undertaking should be sent by email to his secretary at the following address: w.j.pontefract@sheffield.ac.uk.
2. The Recipient wishes to receive a fully executable version of the economic model used in appraisals TA 160 and 161 (the "Model").
3. The Recipient acknowledges that the Model contains confidential material belonging to Professor Kanis (the "Confidential Material"). In consideration of being permitted access to the Confidential Material, the Recipient agrees to be bound by the provisions of this Undertaking.
4. The Recipient shall use the Model solely for the purposes of analysing, assessing and commenting upon the Model and its use in connection with appraisals TA 160 and 161 and any reconsideration of those appraisals (including participation in any appeal and/or proceedings arising out of that reconsideration), (together the "Purpose") and for no other purpose, including without limitation the development of other economic models.
5. The Recipient shall not disclose the Model in whole or part to any third party except that
 - a. the Recipient may, in support of the Purpose, disclose minor extracts from the Model provided that these extracts do not include or describe the co-efficients used in the Model; and
 - b. the Recipient may disclose extracts from the Model to individuals at a third party that Professor Kanis has informed the Recipient in writing are authorised to receive Confidential Material..
6. The Confidential Material contained in the Model is provided "as is". All conditions, representations, warranties or other terms (express or implied) in relation to it are excluded.
7. The Recipient shall take reasonable steps to secure the confidentiality of the Model. Those steps shall include as a minimum:
 - a. Any electronic copy of the Model shall be password protected.
 - b. No more copies of the Model shall be made than are strictly necessary for the Purpose.
 - c. Any copy of the Model which is no longer needed for the Purpose shall be promptly and permanently deleted.
 - d. All copies of the Model shall be clearly marked as confidential.
8. This Undertaking shall not prevent the Recipient from disclosing any output from the Model for the Purpose provided that the Recipient does not directly or indirectly disclose all or any of the co-efficients contained in the Model.

9. The Recipient acknowledges that damages are unlikely to be an adequate remedy for any breach of this Undertaking, and that accordingly remedies for breach shall include, but not be limited to, injunctive relief.

10. This Undertaking is subject to English law and the exclusive jurisdiction of the English Courts.

The terms of this Undertaking are agreed by the Recipient:

Print full name of Recipient:

Signature:

Date: