

1263

FIXED CONTRIBUTION CONTRACT

between

THE EUROPEAN ECONOMIC COMMUNITY

and

UNIVERSIDAD DE LA REPUBLICA

CII.0120.U (H)

The European Economic Community (hereinafter referred to as "the Community") represented by the Commission of the European Communities (hereinafter referred to as "the Commission") represented for the purpose of the signature of this contract by the Director General for Science, Research and Development, or its authorized representative,

of the one part,

and

the Universidad de la Republica (hereinafter referred to as "the Contractor") whose principal office is situated at General Fiores 2124, Montevideo, Uruguay, represented for the purpose of the signature of this contract by S. Lichtensztejn, its Rector, and Professor C.P. MacColl, its Dean of its Faculty of Chemistry, or its authorized representative,

of the other part,

have, in the framework of cooperation in the field of science and technology,

AGREED TO THE FOLLOWING:

Article 1 - Definitions

For the purpose of this contract

"the Research" means the research, development, process or project set out in Annex IV to this contract,

"the Standard Conditions" means the provisions and conditions specified in Annexes I to III inclusive to this contract,

other expressions shall have the same meaning as specified in the Standard Conditions.

Article 2 - Execution of the Research

2.1. The Contractor shall perform the Research in accordance with the Standard Conditions subject to any modifications hereinafter.

2.2. For the purposes of the Standard Conditions, the following shall apply to the Research:

- (a) title: Preparation and characterization of an experimental antidiotype vaccine against *Echicococcus granulosus*.
- (b) duration: 36 months from the first day of the month following the signature of this contract by both parties.
- (c) place of work: Montevideo
- (d) total estimated costs: 433,000 ECU (four hundred and thirty-three thousand European Currency Units)
- (e) financial contribution of the Commission: 126,500 ECU (one hundred and twenty-six thousand five hundred European Currency Units)
- (f) advance payment: 40% of the contribution of the Commission
- (g) percentage reimbursement for reports:
 - 30% on receipt and approval by the Commission of the periodic report at the end of 12 months;
 - 20% on receipt and approval by the Commission of the periodic report at the end of 24 months;
 - 10% on receipt of the final report in its definitive form, and the report and Confidential Declaration referred to in Article 4.2(c) of Annex I.

- (h) number and type of reports: As Article 4 of Annex I subject to the periodic reports being submitted each 12 months.
- (i) applicable law: Belgium
- (j) the following special conditions shall apply:

- (1) The Commission shall bear the fixed amount, inclusive of all taxes, of the costs of the Research specified in this contract in accordance with Annex III to this contract.
- (2) Articles 3.2, 3.3, 3.6 and 3.7 of, and all references to allowable costs and Annex III in, Annex I shall not apply to this contract.
- (3) The Republic of Uruguay shall be added to the states listed in Article 4 (Travel and Subsistence) of Annex III.
- (4) the following Articles of the Standard Conditions shall be modified as follows:

- Articles 11.1, 11.2 and 11.3 of Annex I shall be substituted by the following:

"11.1 Each contracting party shall absolve the other contracting party from all liability for any damage suffered by it or by its personnel as a result of performance of this contract, insofar as such damage is not due to gross negligence or intention on the part of the other contracting party or its personnel.

11.2 The Contractor shall assume all liability in respect of any action for damages brought against the Commission or its personnel by third parties, including the Contractor's personnel, arising out of performance of this Contract, insofar as such damage is not due to gross negligence or intention on the part of the Commission or its personnel.

11.3 The Commission shall notify the Contractor of any claim, action or demand being made against the Community in respect of any matter for which the Contractor is or may be liable hereunder, and, subject to Article 11.2 of this Annex, afford it assistance."

- in Article 12.2(b) of Annex I the words "of the Contractor or" shall be inserted after the words "ownership or control";
- in Article 12.3 of Annex I and Article 4.1(c) of Annex II the words "the London Money Market ECU linked deposit interest rate for deposits of 3 months" shall be substituted for "the market interest rate of the member state of the Community of the Contractor, or if there is none, of Belgium, for borrowing ECU for 3 months".
- in Article 12.6 of Annex I the phrase "the Commission may, wherever possible and appropriate" shall be substituted by "the Commission, after consultation with the other Contractors, may, wherever possible and appropriate".
- notwithstanding Article 2.6 of Annex II the Commission may, subject to Article 2.4 of the said Annex, communicate Foreground Information and Reports to developing countries, including not only those with which the Community has concluded association or cooperation agreements and those non-associated developing countries which benefit from financial and technical assistance from the Community, but also all developing countries which urgently require it and are able to use it.
- the phrase "in conformity with the interests of the Community" in Article 4.1 (a) and (b) of Annex II shall be substituted by "in conformity with the

interests of the Community and developing countries, but without prejudice to the interests of the Community".

- there shall be added after the words "the Community" in Article 4.1 (d) of Annex II, the words "and the developing countries".
- there shall be added after the words "Community Undertaking" in Articles 2.4 (b) and 6 of Annex II, the words "or similar Undertakings in developing countries".
- in Article 5.4.1 of Annex II the final words shall read "of which this Annex forms a part".

Article 3 - Annexes

Subject to any amendments or exclusions by the preceding Articles the following annexes shall form an integral part of this contract:

- Annex I : General Terms and Conditions (XII.154.1.84-E)
- Annex II : Utilisation of Results (XII.966.84-E)
- Annex III : Payment Requests and Reimbursements
- Annex IV : Research

Done at Brussels,
in triplicate,
in English.

For the Contractor,

PROF. CARLOS RODRIGUEZ

For the Commission,

SAMUEL LICHTENSZTEJN
RECTOR

ANNEX I

GENERAL TERMS AND CONDITIONS

Article 1 — DEFINITIONS

'allowable costs' means the costs allowable, in accordance with the principles specified in Annex III to the Contract, of carrying out the Research.

'the Contract' means the contract concluded between the Community and the Contractor of which this Annex forms a part.

'exclusive of all taxes' means exclusive of all taxes arising from the Contract which are directly recoverable by the Contractor from a member state of the Community, or, if not, are recoverable by the Commission in accordance with arrangements arising from the Protocol referred to in Article 6 of this Annex.

'recoverable taxes' means all taxes arising from the Contract and which are not directly recoverable by the Contractor from a member state of the Community but are recoverable by the Commission from a member state in accordance with arrangements arising from the Protocol referred to in Article 6 of this Annex.

'service' means the provision of any necessary service which is incidental to or calculated to facilitate the execution of the Research but not fundamental to the objective of the Research.

'subcontract' means work which is fundamental to the objective of the Research and in respect of which the Contractor is wholly or partially dependent upon the input of the third party carrying out the work.

Other expressions shall have the same meaning as specified in the Contract.

Article 2 — EXECUTION OF THE RESEARCH

- 2.1 The Contractor shall use its reasonable endeavours to achieve the objectives of the Research, the title of which shall be specified in Article 2.2(a) of the Contract, and shall exercise all reasonable skill, care and diligence in the performance of the Research.
 - 2.2 The duration of the Research shall be the period specified in Article 2.2(b) of the Contract.
 - 2.3 The Research shall be carried out principally at the place or places specified in Article 2.2(c) of the Contract.
 - 2.4 The Contractor shall inform the Commission without delay of the completion or the cessation of the Research or of any circumstance liable to prejudice the performance of the Contract.
 - 2.5 The Contractor shall notify the Commission in writing at least two months before the expiry of the period specified by Article 2.2 of this Annex of any need for an extension in time to complete the Research. The notification shall specify the duration of, and the reason for, the proposed extension. The Commission shall consider any such request but may reject it on reasonable grounds.
 - 2.6 The Contractor shall provide the personnel, facilities, equipment and materials reasonably and practically necessary for the proper performance of the Contract.
 - 2.7 The Contractor shall liaise with and consult any other contractor carrying out a complementary contract as specified in Annex II, the name of which may be specified in the Research or otherwise by the Commission with the agreement of the Contractor.
 - 2.8 The Contractor shall notify the Commission of the name of the person designated to be in direct charge of the performance of the Research and if the Contractor replaces this person, it shall notify the Commission thereof in writing and, if requested, submit all relevant information relating to the qualifications held by the replacement.
- 2.9 The Commission may, with the agreement of the Contractor which shall not unreasonably be withheld having due regard to reasonable and appropriate industrial and commercial interests of the Contractor, assign to the Contractor, officials and other servants of the Community and other personnel for the purpose of assisting in the performance of the Research. Details of the procedure governing such assignment and its effects upon the performance of the Contract shall be determined by the agreement between the contracting parties.

Article 3 — FINANCIAL PROVISIONS

- 3.1 The total estimated costs of the Research shall, if necessary, be the amount specified in Article 2.2 of the Contract exclusive of all taxes.
- 3.2 The Commission shall, as specified in Article 2.2(d) of the Contract, financially contribute the percentage of the actual allowable marginal costs of the Research accepted by the Commission up to the maximum amount specified, exclusive of all taxes.
- 3.3 The Commission shall, in addition to the amount specified by Article 3.2 of this Annex, financially contribute the recoverable taxes.
- 3.4 In exceptional cases where, for budgetary reasons, the Commission can specify in the Contract only a provisional maximum financial contribution which is less than its desired financial contribution to the Research, the Commission may specify in Article 2.2 of the Contract that it will increase its financial contribution up to a revised maximum amount, exclusive of all taxes, if sufficient funds are allocated by the appropriate budgetary authorities of the Community in the final budget for the year specified in the Contract. The Contractor may terminate the Contract after the date specified in the Contract if the said provisional maximum financial contribution of the Commission has been reached and has not been increased in accordance with this sub Article. This sub Article shall not apply unless specified in Article 2.2 of the Contract.
- 3.5 A single sum specified in Article 2.2(e) of the Contract shall be paid by the Commission as an advance payment towards its financial contribution of the allowable costs of the Research. The Commission may, without necessarily terminating the Contract, require the reimbursement of this advance if it considers that the Research has not effectively been commenced within six months of the payment of the advance and the provisions of Article 12.3 of this Annex regarding interest shall apply to any such requirement for reimbursement.
- 3.6 Unless otherwise specified in Article 2.2 of the Contract, the Contractor shall submit periodic statements of expenditure in accordance with Annex III covering the period of each periodic report and the reimbursement of the financial contribution of the Commission shall be in accordance with that Annex.
- 3.7 If on completion or cessation of the Research the total financial contribution of the Commission calculated in accordance with Article 3.2 of this Annex is less than the financial contribution paid by the Commission, the Contractor shall reimburse the difference to the Commission.
- 3.8 Subject to Article 15 of Annex III all periodic payments made towards allowable costs shall be considered as advances until acceptance of the final report and any other item to be supplied in accordance with the provisions of the Contract. Where the Contract requires a review to be made of the Research at specified stages or phases it may provide for the aforesaid payments to be considered as advances only until completion of such review and the acceptance of any documents connected therewith.

Article 4 — REPORTS

- 4.1 Unless otherwise specified in Article 2.2 of the Contract, the Contractor shall submit, in the English language, the

number of copies and types of reports specified in Article 4.2 of this Annex and shall observe, with regard to the layout of such reports, any rules set out by the Commission and supplied to the Contractor. An original version of each report shall be submitted or each report shall be of an appropriate quality to enable its reproduction.

4.2 The following reports shall be submitted in five copies:

- (a) periodic reports at six-monthly intervals from the date specified in the Contract for the commencement of the Research subject to the last periodic report or the last report for any period of less than six months being incorporated within the final report.

Periodic reports shall describe, in respect of each period, the Research carried out and the results obtained during that period and shall contain details of any deviations from the work plan during the reporting period and modifications to the work plan for the succeeding period. Such reports shall be submitted to the Commission within one month of the termination of each period.

- (b) a final report which shall describe in detail the whole of the Research carried out and the results obtained in the performance of the Contract. It shall contain a summary outlining the objectives, the work performed, the results obtained, and the conclusions of the Contractor.

A draft shall be submitted to the Commission within two months of the actual completion of the Research or the date specified by Article 2.2 of this Annex by which the Research is to be completed, whichever is the earlier. The Commission shall submit its observations on the draft to the Contractor within two months of receiving the draft failing which it shall be deemed to have no formal observations on the draft and to accept the draft.

The Contractor shall submit the report in its definitive form within one month of the receipt of the observations of the Commission or the expiry of the aforesaid two-month period and shall take the observations of the Commission into account or, where appropriate, set out any differing opinions.

- (c) together with the Confidential Declaration specified in Article 3.3 of Annex II, a report specifying how the Contractor intends to exploit the results of the Research and providing particulars of processes, techniques, methodologies and similar developments, and details of all industrial and intellectual property rights in the said results, including, but not limited to, patents applied for or obtained, registered designs and similar statutory rights in the results.

4.3 The following reports shall only be required if specified in the Contract or by agreement between the parties:

- (a) work programmes which shall describe the work projected for the succeeding period and shall indicate projected expenditure for that period. They shall be forwarded to the Commission on the dates specified in the Contract.

- (b) supplementary reports which shall describe in detail well defined and specific areas of the Research and shall supplement information on such areas contained in the other reports.

- (c) special reports which shall describe the Research which constitutes an important unit.

Article 5 — INSPECTIONS AND PARTICIPATION IN MEETINGS

5.1 The Commission, and persons authorized by the Commission unless the Contractor raises an objection to such persons for reasonable and appropriate industrial and commercial reasons, shall be entitled, after giving reasonable notice, to have reasonable access during the progress of the Research to sites or premises of the Research.

5.2 The Contractor shall prepare and keep at the disposal of the Commission, and of persons authorized by the Commission subject to the same qualification as in Article 5.1 of this Annex, such documents as indicate the progress of the Research.

5.3 The Contractor undertakes during the performance of, and at the end of, the Research to take part to a reasonable

extent in meetings called by the Commission for the purpose of reviewing the Research or incidental to or connected with the Research. The Contractor shall give such appropriate assistance as is reasonable in the organisation of these meetings and shall be represented at such meetings by the scientific personnel responsible for the various matters on the agenda. At the discretion of the Commission other contractors and experts may also take part at such meetings subject to the same qualification as in Article 5.1 of this Annex.

Article 6 — PROVISIONS RELATING TO TAXATION AND CUSTOMS DUTIES

6.1 General provisions

- (a) The Contractor shall carry out the formalities specified hereinafter in this Article and Article 12.4 of Annex III to enable the Community to benefit under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities which, as regards its financial contribution to the Research, provides that the Governments of the member states of the Community shall, wherever possible, take the appropriate measures to remit or refund the amount of indirect taxes or sales taxes in the price of movable or immovable property for the official use of the Community and that the Community is exempt from all customs duties, prohibitions and restrictions on imports and exports in respect of articles intended for its official use.

- (b) The Contractor shall, prior to any importation from a State not belonging to the Community, contact the relevant Commission departments, which will provide it with all relevant information.

- (c) Except with the approval of the Commission, goods purchased or imported under the provisions of the aforesaid Protocol may not be disposed of, assigned or used for purposes other than those laid down in the Contract. To enable the necessary taxation and customs formalities to be carried out, the relevant Commission departments shall be informed where such approval is given for such disposal, assignment or other use.

6.2 Special provisions

In Belgium

- (a) Where the Contractor is liable to pay Value Added Tax, invoices relating to exempted transactions shall be marked 'Exonération de la TVA — Article 42 paragraphe 2.2 du Code Circulaire No. 67/1970'.

- (b) Where the Contractor is not liable to pay Value Added Tax, it shall contact the 'Administration Centrale de la TVA, de l'Enregistrement et des Domaines', to secure exemption from VAT in respect of the provision of goods and services necessary for the performance of the Contract.

In France

By order of the Minister of Economy and Finance of 29 July 1980 (Bull. Off. note number 201 of 18 November 1980), the provision of services subject Article 259B of the Code Général des Impôts for 'Community institution outside France', is exempt from Value Added Tax.

In Italy

Goods and services supplied in Italy for official use by the Community are directly exempt from taxation by virtue of Presidential Decrees No. 687 of 23 December 1974 (Italian Official Gazette No. 338 of 28 December 1974) and No. 288 of 2 July 1975 (Italian Official Gazette No. 183 of 11 July 1975).

In the Grand Duchy of Luxembourg

Goods and services supplied within the country for official use by the Community are exempt from Value Added Tax by virtue of Articles 8 and 9 of the Règlement Grand Ducal of 19 December 1969 published in the Journal Officiel du Grand Duché de Luxembourg — Recueil de Législation A — No. 66 of 24 December 1969.

In all the other member states of the Community

The Contractor shall, at the request of the Commission, place at its disposal all such supporting documents as it may reasonably require to enable it to apply, where appropriate, to the taxation authorities for reimbursement of dues and taxes paid in connection with the performance of the Contract.

Article 7 — SUBCONTRACTS AND SERVICES

- 7.1 Subject to the provisions hereinafter in this Article the Contractor shall not, without the prior written authorization of the Commission, assign the rights and obligations arising under the Contract, in whole or in part, subcontract the Research or cause third parties to replace it. The Commission shall respond formally to any written request submitted to it within two months of its receipt failing which it shall be deemed to have approved the request.
- 7.2 The Contractor is authorized to enter into subcontracts without the written authorization of the Commission if:
- the details of the subcontracts or the names of the subcontractors and the estimated cost have been included in the Contract, or
 - after the commencement of the Contract and during the course of the Research the value of each individual subcontract does not exceed 20,000 ECU, the total collective value of all subcontracts does not exceed 20% of the estimated total allowable costs of the Research and the grant of such subcontracts does not fundamentally affect the Research.
- 7.3 This Article shall not apply to orders for materials, equipment and a specific industrial or technical support service placed in the normal course of business in accordance with the internal procedures and rules of the Contractor.
- 7.4 The Contractor shall remain bound by its obligations to the Community under the Contract even where subcontracts are authorized.
- 7.5 Unless the Commission authorizes the contrary in writing, the Contractor shall include in any subcontract provisions imposing such obligations upon the subcontractor as apply to it and enabling the Community to exercise its rights under the Contract.
- 7.6 Where the Contractor subcontracts a part of the Research or places orders for a service in connection with the performance of the Contract, it shall obtain from subcontractors and suppliers all customary trade benefits (in particular discounts, special prices, reductions and rebates) and shall endeavour to secure any other benefits. All benefits actually obtained shall be deducted in calculating the allowable costs.
- 7.7 The Contractor shall, wherever practical, give preference in granting subcontracts or the provision of a service to legal entities situated within member states of the Community and developing countries having concluded association or cooperation agreements with the Community.

Article 8 — PERMITS AND LICENCES

- 8.1 The Contractor shall bear sole responsibility for taking the necessary steps to obtain any permit or licence required for the performance of the Contract by any laws and regulations in force at the place or places where the Research is to be carried out.
- 8.2 The Contractor shall inform the Commission immediately if it is unable to obtain any such permit or licence. The contracting parties shall jointly review the effect of this situation on the performance of the Research and shall, if necessary, take appropriate measures after consulting one another.

Article 9 — PUBLICATION OF GENERAL INFORMATION ON THE RESEARCH

The Commission shall be entitled to publish information by any means in respect of the title and objective of the Research, the total estimated allowable costs, the financial contribution of the Commission, the duration of the Research and the name of the project leader of the Contractor unless the Contractor,

at the time of the signature of the Contract, raises an objection for reasonable and appropriate industrial and commercial reasons.

Article 10 — SECRECY AND CONFIDENTIALITY

- 10.1 Subject to Article 9, the provisions of Annex II, and the right of the Commission to communicate and transmit documents and information on a confidential basis to experts appointed by the Commission for the purpose of giving advice thereon, the contracting parties undertake to keep secret facts, information, knowledge, documents or other matters communicated as confidential to them or which come into their possession in the performance of the Contract, the disclosure of which may be prejudicial to the other party. This sub Article shall not apply to such facts, information, knowledge, documents or other matters which a party can show:
- were at the time of the receipt published or otherwise generally available to the public,
 - have after receipt by the receiving party been published or become generally available to the public otherwise than through any act or omission on the part of the receiving party,
 - were already in the possession of the disclosing party at the time of receipt and were not acquired directly or indirectly from the other party,
 - were rightfully acquired from others without any undertaking of confidentiality by the disclosing party,
 - were developed independently of the Research by the disclosing party.
- 10.2 The Commission shall take all practical steps to ensure that Article 10.1 of this Annex shall apply in respect of such facts, information, knowledge, documents or other matters communicated to or which come into the possession of persons authorized by the Commission to have access to these matters.

Article 11 — LIABILITY

- 11.1 The Community shall not be liable for any loss, damage, or injury, (including sickness and death), of any nature, to any property or person, whether total or partial, and howsoever arising, in or in connection with, or resulting from, the performance of the Research except where such loss, damage or injury is the direct result of any negligent or reckless act or omission, of the officials or servants of the Commission, and the Contractor, save for the aforesaid exceptions, shall bear all liability for the aforesaid loss, damage or injury suffered by or caused to any property or person.
- 11.2 Subject to Article 11.1 of this Annex the Contractor shall, in respect of the legal liability of the Contractor, indemnify the Community against:
- all costs, claims, actions, liabilities and demands arising from any said loss, damage or injury specified in Article 11.1 of this Annex or any award of damages and costs made against it in favour of any person who claims to have or has suffered any such loss, damage or injury or any person claiming on his behalf.
 - any infringement or alleged infringement of any copyright or other statutory protection in respect of any report or other material supplied by that Contractor pursuant to the Contract.
- 11.3 The Commission shall notify the Contractor of any claim, action or demand being made against the Community in respect of any matter for which the Contractor is or may be liable hereunder, and, subject to Article 11.2 of this Annex, afford it assistance and a reasonable opportunity to take over and thereafter conduct any defence of, or negotiations for the settlement of, the same. The Commission shall not make any admissions prejudicial to the interests of the Contractor except where the Contractor refuses the assistance or the said opportunity, or fails to respond within a reasonable time.
- 11.4 Where any claim is made or administrative or other proceedings are brought against the Contractor as a result of a dispute arising out of or resulting from or in connec-

tion with the performance of the Contract, it shall as soon as reasonably practical inform the Commission thereof in writing. The parties shall in all such cases endeavour to reach mutual agreement as to the course of action to be followed, failing which agreement the Contractor shall have the conduct of the proceedings provided that it shall not make any admissions prejudicial to the Commission.

Article 12 — TERMINATION OF THE CONTRACT

12.1 The Commission or a Contractor may terminate the Contract by giving written notice of two months by recorded delivery or registered post to the other party where it considers termination justified on the grounds that no further purpose would be served by continuing the Research because of technical reasons or a change in the exploitation potential of the results of the Research. Where the Research is being executed jointly by more than one contractor, termination by a Contractor shall require the agreement of all the other Contractors.

From the date of the receipt of the letter of the Commission, or the date of the letter of the Contractor, terminating the Contract, the Contractor shall not place any more orders or enter into any further contract for the supply of goods or services and shall terminate or cancel as soon as reasonably practical after the date specified in the letter all work being undertaken or to be undertaken for the Research unless the Contractor intends to continue the Research at its expense. In the event of the termination of the Research the Commission shall only be liable to reimburse the Contractor within the terms and provisions of the Contract for allowable costs already incurred and expenditure arising from the Research which has already been committed and which cannot reasonably be cancelled or terminated. The Contractor shall endeavour to ensure that it enters into no contractual commitments which may conflict with this sub Article.

12.2 The Commission may terminate the Contract:

- (a) forthwith if the Contractor becomes bankrupt, or concerned in an arrangement with its creditors, or has a winding up order made against it, or except for the purposes of reconstruction, has a resolution for voluntary winding up passed in respect of it, or has a liquidator or receiver appointed over it. Notwithstanding any termination, the Contractor shall deliver to the Commission all foreground information and results, if any, obtained up to the date of termination and the Commission shall have the right to transfer this information to other contractors which it might select to complete the Research.
- (b) forthwith if the ownership or control of a company directly controlling or under the same control as the Contractor or directly controlled by the Contractor is changed and the said change affects or threatens to affect the conditions under which the Contract was concluded.

The financial consequences of the termination shall be those specified in Article 12.1 of this Annex.

12.3 The Commission may terminate the Contract

- (a) in the event of non performance by the Contractor, except for reasonable and justifiable technical or economic reasons, of any of its obligations arising out of the Contract after giving notice in writing by registered post to the Contractor requiring performance of the Contract within one month of the receipt thereof and the Contractor is still in breach of its obligations after this time.

- (b) forthwith if, in order to obtain the financial contribution of the Commission, the Contractor has made false statements for which it may properly be held responsible.

The Commission may require the reimbursement of all or part of its financial contribution having regard to the nature and amount of the Research undertaken before the date of the termination and its value to the Commission, together with interest at the Market interest rate of the member state of the Community of the Contractor, or, if there is none, of Belgium, for borrowing ECU for 3 months, in the month the financial contributions to be reimbursed were received by the Contractor. Any reimbursement shall be made within two months of notice in writing by recorded delivery or registered post to the Contractor specifying the amount failing which a further 2% shall be added to the interest rate of the reimbursement.

12.4 The Commission may, where the duration of the Contract exceeds the research programme adopted on the basis of the decision of the Council, specify in the Contract that the financial contribution of the Commission may be terminated at any time after a date specified in the Contract, by the Commission giving written notice of three months by recorded delivery or registered post to the Contractor. The financial consequences of the termination shall be those specified in Article 12.1 of this Annex and the Contractor shall ensure that any sub-contract or service in accordance with the terms of the Contract contains a clause of similar effect to this sub Article as the Commission shall not be liable for any expenditure to be borne by the Contractor as a result of the non observance of this requirement. This sub Article shall not apply unless specified in Article 2.2 of the Contract.

12.5 The following provisions of the Contract shall continue to apply notwithstanding any termination of the Contract by the Commission or the Contractor:

- (a) Articles 4, 5.3, 6, 9, 10 and 11 of this Annex,
- (b) Part B of Annex III hereof subject to the statements of expenditure covering the period to the date of termination.

12.6 Where the Research is being executed jointly by more than one Contractor and the action of a Contractor enables the Commission to terminate the Contract the Commission may, wherever possible and appropriate, having regard to all the circumstances, determine not to terminate the Contract but solely the participation in the Research of the said Contractor in default of the Contract upon such terms and conditions for the said Contractor as the Commission may consider to be reasonable in accordance with the Contract.

Article 13 — APPLICABLE LAW AND COMPETENT COURT

13.1 The Contract shall be governed by the law specified in Article 2.2 of the Contract.

13.2 The Court of Justice of the European Communities shall have sole jurisdiction in regard to any dispute between the contracting parties concerning the Contract.

Article 14 — AMENDMENTS OR ADDITIONS TO THE CONTRACT

The provisions of the Contract and the annexes thereto may be amended or supplemented only by means of a supplementary agreement duly signed by the contracting parties.

ANNEX II

Rules governing the utilisation of results

Article 1 — DEFINITIONS

For the purposes of this Annex:

'Foreground Information' means information including all kinds of results generated by the Contractor in the execution of the research programme specified in Annex IV.

'Reports' means the reports specified by Article 4 of Annex I.

'Foreground Patents' means patent applications or patents, utility models, industrial designs, plant variety rights, copyrights and other similar rights for Foreground Information.

'Background Information' means technical information and know how owned or controlled by contractors in the same or related fields to the research programme specified in Annex IV and necessary for the execution of the contract or the exploitation or commercialisation of Foreground Information, but which have not been generated in the execution of the research programme specified in Annex IV.

'Background Patents' means patent applications or patents, models, industrial designs, plant variety rights, copyrights and other similar rights, other than Foreground Patents, owned or controlled by Contractors in the same or related fields to the research programme specified in Annex IV and necessary for the execution of this contract or the exploitation or commercialisation of Foreground Information.

'Proprietary Information' means trade secrets or technical or commercial or financial information which is known only to the owner or which the owner has transmitted or is disposed to transmit to third parties only under confidentiality obligations by the recipient.

'Community Research Programme' means the programme adopted by a specific decision of the Council or the Commission and from which this contract emanates.

'Community Undertaking' means a natural or legal person established and operating in the Community.

'Contractor' or a signatory of this contract means each natural or legal person which has concluded this contract with the Commission in the framework of the Community Research Programme, but including only if this contract expressly provides any affiliated company, defined by or specified in this contract, which is directly or indirectly controlled by the Contractor or is directly or indirectly controlling or under the same control as the Contractor.

'Complementary Contract' means a contract where the work covered has technical interdependence with the research programme specified in Annex IV to this contract and is agreed to be such by the Commission and the Contractors.

Article 2 — DISSEMINATION OF INFORMATION

- 2.1 The Commission and the Contractor shall refrain from any dissemination or publication which might prejudice the protection, exploitation or secrecy of the Foreground Information and the major business interests of the Contractor.
- 2.2 Subject to any cooperation agreement concluded under Article 5 of this Annex the Contractor may:
 - (a) itself use the Foreground Information and Reports;
 - (b) provided that it notifies the Commission in advance, disseminate or publish its Foreground Information or Reports or agree to publication of the same by third parties, but it shall delay or refrain from any communication or publication if the Commission so requests in the interest of the Community within two months

of the receipt of the advance notification, failing which it shall be deemed to have no objection. Any dissemination or publication must mention that the research has been undertaken in the framework of the Community Research Programme unless the Commission requests that this should not be indicated.

- 2.3 The Commission may use the Foreground Information and Reports for its own purposes and those of other Community institutions subject to their confidential status being preserved, where required.
 - 2.4 The Commission may publish the periodic or final reports of the Contractor. The Commission shall delay or refrain from any publication opposed by the Contractor at the time of their submission provided that in such circumstances the Contractor may not publish them itself and:
 - (a) it shall submit to the Commission for its approval copies of suitably edited versions of the final report and, if requested by the Commission, of the periodic reports, for publication.
 - (b) it shall agree with the Commission, having regard to the major business interests of the Contractor, a policy for restricted transmission of the full reports, or suitably edited versions of such reports, for confidential communication to member states of the Community or to Community Undertakings where it is necessary or useful for the execution of research work under a Community research programme.
 - 2.5 The Commission shall state in every distribution or publication of a report in accordance with Article 2.3, or 2.4, hereof that it relates to research carried out by the Contractor in the framework of the Community Research Programme, unless the Contractor has requested that its name should not be mentioned.
 - 2.6 The Commission shall not transmit Foreground Information and Reports to a non Community State or an international organisation in the framework of agreements and conventions for the exchange of information concluded by the Community unless the Contractor has been informed in writing of such agreement or convention and has accepted such transmission at the conclusion of the Contract.
- The Contractor shall be associated with the exchange if it so desires.

Article 3 — DECLARATION AND PROTECTION

- 3.1 This Article shall be subject to any cooperation agreement concluded under Article 5 of this Annex.
- 3.2 Foreground Information shall belong to the Contractor generating such Information and the said Contractor may apply for and obtain in its name the Foreground Patents necessary for its protection.
- 3.3 The Contractor shall submit to the Commission the Confidential Declaration annexed to this Annex, duly completed and signed, when any exploitable technological Foreground Information is generated, or at the latest with the last report to be submitted in accordance with this contract.
- 3.4 If a Contractor refrains, in one or more countries, from applying for the Patents referred to in Article 3.2, the Commission may, at the request of the Contractor, apply for and obtain such Patents in the name of the Community. If such a request is made the Contractor shall notify the Commission of its intentions in good time in order that the Commission may make a valid application for such Patents. The Commission shall grant a non exclusive royalty-free licence to the Contractor for its own purposes.

3.5 A Contractor which has applied for and obtained a Foreground Patent, or the Commission if it has applied for or obtained a Foreground Patent in pursuance of Article 3.4, may assign it to a third party or abandon it only with the agreement of the Commission, or in the case of the Commission having acted in pursuance of Article 3.4, with the agreement of the Contractor which requested the Commission to act under that Article, and such other party shall respond formally to any written request submitted to it within two months of its receipt, failing which it shall be deemed to have approved the request. No party may oppose assignment if the assignee is situated in the Community and agrees to discharge the obligations of the assignor arising from this annex, or abandonment, if it does not accept the assignment of the Patent in its name.

Article 4 — EXPLOITATION OF RESULTS

4.1 The Contractor shall, except for duly motivated technical or economic reasons accepted by the Commission, not later than 3 years from the date of termination of this contract or such other reasonable period as may be agreed within such period, either:

- (a) commence exploitation or commercialisation of, or additional work necessary for the exploitation or commercialisation of, the Foreground Information in conformity with the interests of the Community, or,
- (b) have the Foreground Information exploited or commercialised, or be prepared to have the Foreground Information exploited or commercialised, by third parties of its choice or which the Commission will endeavour to find for it, in conformity with the interests of the Community, or,
- (c) choose to reimburse the finance provided by the Commission together with interest thereon, following which it shall be discharged from its aforesaid obligations. Such repayment shall not annul the provisions of Articles 5.3 and 6.1 hereof which will continue to apply.

The rate of interest shall be the market interest rate of the member state of the Community of the Contractor, or, if there is none, of Belgium, for borrowing ECU for 3 months, on the first day on which the obligation of reimbursement becomes effective, or,

- (d) conclude an agreement with the Commission replacing the conditions of the present Article and specifying in particular, the extent of the obligation to exploit, the timetable for the exploitation, the rules governing the granting of licences, the possible assistance of the Commission, and the needs of the Community in respect of new products and processes applying the Foreground Information.

The Commission may also propose to contractors which have carried out related research in the framework of a Community programme to conclude an agreement on the joint exploitation of Foreground Information arising from all such research.

4.2 Where the Contractor has not exploited or commercialised the Foreground Information or taken any other action pursuant to Article 4.1 hereof for the aforesaid duly motivated technical or economic reasons, all Community Undertakings, other than the signatories of this contract and Complementary Contracts, may apply for non-exclusive licences and user rights of Foreground Information and Foreground Patents for their exploitation or commercialisation. The licences shall not be unreasonably withheld and shall be granted on reasonable commercial financial and other conditions. The withholding of the licences shall not be deemed to be unreasonable if any major business interests of the Contractor oppose the grant.

4.3 The Contractor shall keep at the disposal of, and if required make available to, the Commission and persons authorized by the Commission information and documents permitting the latter to verify if the required undertaking in Article 4.1 hereof to exploit or commercialise the Foreground Information has been complied with. The Contractor may withhold its agreement for authorized persons only on reasonable grounds having due regard to the general interests of the Community and to reasonable and appropriate industrial and commercial interests of the Contractor.

4.4 The Commission may request the Contractor to receive, at appropriate times and to a reasonable extent, visitors or trainees originating from the member states of the Community for the promotion of the use in the Community of products or equipment incorporating the Foreground Information. The said visitors or trainees shall be chosen in mutual agreement between the Commission and the Contractor having due regard both to the general interests of the Community and to the industrial and commercial interests of the Contractor, in particular the needs of protection, exploitation, and secrecy of the Foreground Information. The Contractor may withhold its agreement only on reasonable grounds.

4.5 The Commission may request the Contractor to take part at appropriate times and to a reasonable extent in seminars of a scientific, technical or commercial nature for the promotion of the use in the Community of products or equipment incorporating the Foreground Information. To that effect, the Contractor shall give such appropriate assistance as is possible in the organisation of these seminars.

Article 5 — EXCHANGE OF INFORMATION AND LICENCES BETWEEN CONTRACTORS IN CASES OF COOPERATION

5.1 Contractors cooperating in the research programme specified in Annex IV shall arrange between themselves an exchange of Foreground and Background Information and the granting of licences and user rights for Foreground and Background Patents. This exchange shall be subject to the fundamental rules specified by this Article. They shall apply:

- (a) between contractors which are signatories of this contract;
- (b) between the signatory or signatories of this contract and signatories of Complementary Contracts;
- (c) only if, and to the extent, specified in this contract of which this annex forms a part, between the signatory or signatories of this contract and their subcontractors. In such cases references in Articles 5.2 and 5.3 hereof shall be deemed to include a reference to the subcontracts and the signatories of the subcontracts.

5.2 Access to information for the execution of a research programme

5.2.1 Foreground Information and Foreground Patents or licences or user rights for the same, shall be made freely available to other signatories of this contract, and to signatories of Complementary Contracts where and to the extent that such Information and Patents are necessary or useful for the execution of research work under this contract or the Complementary Contracts.

5.2.2 Background Information and Background Patents, or licences or user rights for the same, which the Contractor is free to disclose and the use of which it may authorize, shall upon request, and at appropriate non-discriminatory conditions, be made available to other signatories of this contract and to signatories of Complementary Contracts where and to the extent that such Information and Patents are necessary for the execution of research work under their contracts.

5.2.3 The communication of Proprietary Information may be subject to an arrangement guaranteeing its confidentiality and the documents containing such information shall be duly marked so as to notify the recipient to preserve its confidential character.

5.3 Exploitation of Results of the Research

5.3.1 The signatories of this contract and the signatories of Complementary Contracts shall grant each other the right to exploit and to commercialise the Foreground Information arising from the execution of such contracts, as well as any necessary non-exclusive licences and user rights. If the payment of any royalties is proposed the principles of such payment shall be specified in this contract.

5.3.2 The signatories of this contract and the signatories of Complementary Contracts shall be entitled to be granted non-exclusive licences and user rights, at appropriate non-discriminatory conditions, for any Background

Patents and Background Information to the extent necessary for the exploitation or commercialisation of Foreground Information provided that

- (a) the contractor concerned is free to disclose and license the use of such Patents and Information,
- (b) no major business interests of the said contractor oppose this
- (c) the licences or user rights do not relate to products or the manufacture of products which are or are about to become commercially available.

5.4 Cooperation Agreements between Contractors

5.4.1 The parties to which Article 5 applies shall not modify the fundamental rules specified in that Article unless the modifications are expressly set out in the contract of which it is Annex forms a part.

5.4.2 If the parties to which Article 5 applies propose to modify the fundamental rules specified in Article 5 after the conclusion of any cooperation agreement they shall also submit the proposed modification to the Commission for its approval. The Commission shall respond formally within two months of the receipt of the proposal failing which it shall be deemed to have approved the proposal. If the Commission considers that the proposal modifies to an inappropriate extent the rights and obligations specified by Article 5, it shall notify the contractors. If the latter refuse to amend their proposals the research contracts shall be regarded as null and void.

5.4.3 Article 5.4.1 shall also apply in respect of a Complementary Contract where it is agreed to be such after the conclusion of this contract. If the Commission considers that any proposal modifies to an inappropriate extent the rights and obligations specified by Article 5, it shall notify the contractors. If the latter refuse to amend their proposals the research contracts shall be regarded as null and void.

Article 6 — LICENCES FOR THE COMMUNITY AND THIRD PARTIES

6.1 The Community shall be granted, for the needs of its Joint Research Centre and Joint Undertakings established under the Treaty establishing the European Atomic Energy Community, a non-exclusive, royalty-free, irrevocable licence to use the Foreground Information for research purposes, but shall not have the right to grant sublicences.

6.2 All contractors, other than the signatories of this contract and Complementary Contracts, which are Community Undertakings and are participating in the Community Research Programme:

- (a) shall have access to the Foreground Information and Foreground Patents, or licences or user rights for the same, against reasonable conditions, where and to the extent it is necessary for the execution of their research work under their contracts.

(b) may apply for non exclusive licences and user rights of:

- (i) Foreground Information and Foreground Patents necessary for:
 - the exploitation or commercialisation of the results of their research work under their contracts, or,
 - for the execution of their research undertaken outside the Community Research Programme but relating to the same technical field, or exploitation or commercialisation of such research
- (ii) Background Patents or other intellectual property rights protecting the use of the Background Information necessary for the execution of their research work under their contracts.

Such licences and user rights under (b) shall be granted on reasonable conditions and shall not be unreasonably withheld. The withholding of licences or user rights shall not be deemed unreasonable if:

- (1) the contractor concerned is not free to disclose and license the use of such Patents and Information,
- (2) major business interests of the said contractor oppose this
- (3) the licences or user rights relate to products or the manufacture of products which are or are about to become commercially available.

6.3 All contractors, other than the signatories of this contract and Complementary Contracts, which are Community Undertakings participating in a Community programme other than the Community Research Programme may apply for non exclusive licences and other user rights of Foreground Information and Foreground Patents which are necessary for the execution of research work under their contracts with the Commission. The licences shall not be unreasonably withheld and shall be granted on reasonable financial and other conditions. The withholding of the licences shall not be deemed to be unreasonable if any major business interests of the Contractor oppose the grant.

Article 7 — DURATION

The rights and obligations of the contracting parties resulting from this Annex, with the exception of those in Articles 4 and 6.1 which shall apply without any time limit, shall continue to exist for a period of 5 years after the expiration of this contract, provided that the cessation of the rights and obligations shall not affect the continuance of any licences or user rights in respect of Foreground or Background Information or Patents granted in accordance with this Annex to any other contractor or third party nor the rights of such persons to such licences or user rights where they were duly requested prior to such cessation.

CONFIDENTIAL DECLARATION (1)

concerning the information and other results, patentable or not,
arising from a cost-sharing research contract
concluded with the Commission of the European Communities
(application of Article 3.3 of Annex II)

1. *Name and Address of Contractor:*

2. *Title of the R&D Programme, Reference Number and Title of Contract:*

3. The Contractor declares that, to his knowledge, in the execution of the research programme specified in the contract:

- no exploitable technological result, patentable or not, has been obtained (2)
- the following exploitable technological results have been obtained (2)

Title or purpose of the result

- (a)
- (b)
- (c)

Application for Patents relating to the results

- (a) already submitted/foreseen/not foreseen (2)
- (b) already submitted/foreseen/not foreseen (2)
- (c) already submitted/foreseen/not foreseen (2)

(1) This confidential declaration duly completed must be returned to the Commission Service with which the contract has been concluded as soon as an invention is made or at the latest with the last periodic report, the final report or any other report required.
(2) Delete as appropriate.

4. In respect of the above results for which no application for a patent has yet been submitted, the Contractor requests/does not request⁽²⁾ the Commission to examine the possibility of submitting the application for the patent.

5. The Contractor has undertaken/intends to undertake/does not intend to undertake⁽²⁾ the exploitation of its results.

If applicable, the stage reached by the works:

6. The Contractor requests/does not request⁽²⁾ the Commission to assist it in the exploitation of its results, e.g., by some market studies, expositions, search for licensees, etc. Where appropriate an agreement on the exploitation of results will be concluded with the Commission (see Article 4.1(d) of the Annex governing the utilisation of results).

7. *Signature of the person authorized to sign on behalf of the Contractor*

Name (in capital letters)

Position (in capital letters)

.....
Date

Signature

ANNEX IV

Research

A lipoprotein fraction of hydatid fluid has been isolated and characterized as antigen for diagnostic purposes. This fraction is composed, at least, by two lipoproteins (antigens A and B) that have been partially separated using gel-filtration by Oriol et al (1971).

The monoclonal antibody A6 that we have described (Munoz et al, 1985) has been assayed by Oriol using immunofluorescence and it reacts with germinal membrane, brood capsules basis and scolex corpuscles. According to Oriol the fluorescence pattern is similar to that expressed by his lipoprotein fraction (personal communication). As this antigen is expressed in scoleces and also in germinal membrane cells that are likely to be similar to oncosphere germinal cells it should be useful to test its protective activity.

For these reasons we will try to purify the antigen recognized by A6 monoclonal antibody and test its protective activity in mice by challenge experiments. A6 bound to Sepharose will be used to affinity purify the antigen that will be characterized using SDS-PAGE / immunoblotting and immunoelectrophoresis.

Challenge experiments will be performed as follows: two groups of BALB/c mice will be treated with the antigen and afterwards one of them will be intraperitoneally infected with scoleces while the other will be orally infected with oncospheres. Another 2 non-treated groups will be similarly challenged and used as controls. The concentration and class of antibodies against the immunizing antigen and against the challenger parasite will be determined weekly by ELISA and immunofluorescence and correlated with parasite evolution, in all the experimental groups. Hydatid infection is a slow process, for this reason 6 to 12 months will be used to perform a challenge experiment.

Monoclonal antibodies against oncospheres and protoscoleces will be prepared according to Craig et al (1986). Cross-reactions between protoscolex and oncospherical antigens will be analyzed with those antibodies using inhibition ELISA and immunoblotting. Common antigens will be fractionated by affinity chromatography using corresponding monoclonal antibodies bound to Sepharose. Antigens will be characterized with the same techniques and tested for protective activity in mice by a challenge experiment similar to that described for lipoprotein antigen. The purified protective antigens will also be used to produce polyclonal antibodies that can be used as alternative probes in cDNA screening.

Antigen cloning from a cDNA library and its characterization for immunodiagnostic purposes will be performed in the Laboratory of Pure and Applied Biology (Imperial College of Science and Technology, London). One researcher from Uruguay will go to the English laboratory to work in this subject and will perform, after returning Uruguay, the trials to assay both the protective and diagnostic value of those antigens.

Those monoclonal antibodies that react against antigens with protective activity will be used to immunize rabbits and produce anti-idiotypic polyclonal antisera. These will be prepared by absorption of rabbit antisera with mouse immunoglobulins bound to Sepharose until no reaction of anti-idiotypic sera with normal mouse immunoglobulin could be detected by ELISA.

The presence of internal-image anti-idiotypes will be tested in these polyclonal antisera before vaccinating assay is performed. This test will consist of the analysis of cross reactions between those antisera and a pannel of human and murine individual anti-hydatid sera. This analysis will be done by inhibition-ELISA using antigen or anti-hydatid antibodies in the solid phase. If cross-reactions between human and murine idiootype repertoires are detected with an anti-idiotypic sera, it is likely to contain the desired internal-image reagent. The selected anti-idiotypic sera will be tested in challenge experiments in mice to assay its protective activity.

Phase 1: Purification, characterization and assay of protective activity of antigen recognized by A6 MoAb. Assay of passive protective activity of A6 MoAb. If immunization assays were successful: a) preparation of an anti-idiotypic serum against A6, assay of its cross reactivity and of its protective activity and b) preparation of rabbit antiserum against the antigen.

Phase 2: Preparation and characterization of new MoAbs and assay of its passive protective activity. Purification of antigens recognized by those MoAbs exhibiting passive protection activity. Assay of protective activity of those antigens and preparation of antisera against them. Preparation of anti-idiotypic antisera against the protective MoAbs, assay of its cross reactivity and protective activity.

Phase 3: Preparation of anti-human-idiotypic serum and analysis of its cross-reactivity and its protective activity.

Phase 4: Preparation of cDNA expression library and cloning of antigens of protective and diagnostic value.

1) Craig P.S., Macpherson C.N.L. and Nelson O.S. (1986) The identification of eggs of *Echinococcus* by immunofluorescence using a specific anti-oncospherical MoAb, *Am.J.Trop.Med.Hyg.* 35: 152.

2) Munoz C., Nieto A., Borche L., Gaya A., Portus M. and Prats G. (1985), Characterization of an anti-hydatid specific monoclonal antibody, X National Microbiology Congress, Sept. 30, Valencia (Spain).

3) Oriol R., Williams J.F., Perez Esandi M.V. and Oriol C. (1971), Purification of lipoprotein antigens of *Echinococcus granulosus* from sheep hydatid fluid. *Am.J.Trop.Med.Hyg.* 20: 569.

First year:

Phase 1: Purification and characterization of antigen recognized by A6 MoAb and beginning of its protective activity assay. Preparation of rabbit antiserum against the antigen.

Phase 2: Beginning of the MoAbs preparation.

Phase 3: Preparation of rabbit anti-human-idiotype serum and analysis of its cross reactivity.

Phase 4: Beginning of the cDNA library preparation.

Second year:

Phase 1: Completion of protective activity assay and preparation of an anti-A6 -idiotype if protection assay for its antigen was successful.

Phase 2: Continuation of MoAb production and beginning of passive immunization assays with the MoAbs produced.

Phase 3: Beginning of the protective assay with the anti-human-idiotype serum if it exhibited cross reactivity.

Phase 4:
Continuation of cDNA cloning work.

Third year:

Phase 1: Beginning of the protective assay with the anti-A6 -idiotype.

Phase 2: Completion of the passive immunization assays with the MoAbs. Purification of the antigens recognized by those exhibiting passive protective activity and preparation of rabbit antisera against them. Beginning of the preparation of anti-idiotypic sera against those MoAbs exhibiting passive protective activity.

Phase 3: Completion of the protective assay with the anti-human-idiotype serum.

Phase 4: Completion of the cDNA cloning work

For the following years:

Phase 1: Completion of the protective assay with anti-A6 Id.

Phase 2: Completion of the preparation of anti-Id sera and of the protective immunization assays with them.

Phase 4: Assay of cloned antigens in protective and diagnostic assays

Phase 5: Selection of the best candidate as vaccination agent according to the results obtained and design trials to assay adjuvants and vaccination protocols in mice and sheep.