Project no : FOOD-CT-2004-506416

EADGENE

"European Animal Disease Genomics Network of Excellence for Animal Health and Food Safety"

NETWORK OF EXCELLENCE (NoE)

Priority 5: Food Quality and Safety

D10.1.5 Do's and Don'ts Protocol Technology Transfer

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EFFAB (lead contractor for this deliverable)

Revision: N°1

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006) Dissemination Level		
PU	Public	
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	×
CO	Confidential, only for members of the consortium (including the Commission Services)	

Preface

The purpose of patenting any innovations produced by (EU-funded) research, licensing them and sharing the advantages with the inventor, is to motivate research bodies to disseminate the fruits of their research. Based on these developments, a new world of activities emerged related to patenting. The application of patenting soon proved twofold: the main objectives were certainly achieved but a lot of unintended consequences arose too, necessitating drastic measures to confront them. The problem of free dissemination of basic knowledge with practical and industrial application diminished, thus distorting the mission of universities. There is a view that scientific research has been held back due to the academic world's reluctance to share materials and knowledge with others unless such sharing is accompanied by legal agreements about royalties on potential findings and the right to restrict the publication of results. There is also a risk that industries protest about the excessively business-oriented mentality of research institutes' managers.

There is a need to create the right spirit and atmosphere to encourage dissemination, while simultanously defending the interests of research institutes and industry/cooperatives and, above all, the EU's intention to support research. Besides patents, other agreements between research and industry are important, e.g. contracts. Simple, sound procedures that do justice to all and avoid administrative burden are important. This is especially the case when Small and Medium Enterprises are involved,

Taking these manifold problems into account, there is a need to establish a guide for research institutes, scientists, and industries with the objective to avoid problems, establish really efficient research activities and better drive scientific investigations in the framework of current legislation.

To fulfil this deliverable several actions took place. A lot of actions were necessary and very useful to eventually reach the final documents gathered in this deliverable. To reflect some of the actions undertaken, not clearly visible in the deliverable a short summary of the most important ones:

- Contact IPUDC (Intellectual Property Use and Dissemination Committee)
- Setting up a forum for issues regarding knowledge and property
- Gathering and highlighting most important issues
- Guide des rechercheurs – pending

This deliverable is meant as a reference report for people (Industry as well as research representatives) working with patents. In the contents the included documents are summarised, documents of importance for the reader can be picked out.

The report is assembled and delivered by the Knowledge Management Working Group. The Group will continue to cooperate in the 'background' for consultancy and as industry forum regarding knowledge property issues.

The partnering for projects in EADGENE will be the practical 'test case' for these matters. For industry it is important that there are an industry forum and a Intellectual Property Use and Dissemination Committee (IPUDC)

(Research organisations, which both can assist with solving potential future issues/questions)

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Contents

The individual pages will be published and updated on the website www.eadgene.org

1 Publication Industrial Ownership

Contents

Agenae (Analyse du GENome des Animeax d'Elevage) part of INRA (Institut National de la Recherche Agronomique) is acknowledged for making available this research contract example.

The articles published in this chapter are only part of the Publication Industrial Ownership.

This document will function as a first set up document. In the course of time it will be expanded and improvements will be carried through. The latest updated version will be available at the website www.eadgene.org.

1.1 Article 1 – Confidentiality and publications

1.1.1 Confidentiality

Subject to the provisions of article 1.2., each member undertakes, both for himself and for his staff, unless there is prior agreement in writing from the other members to:

- Consider as strictly confidential the information indicated as such, hereafter called the "information", constituted by all the elements of confidential information received orally or in writing from another member or persons authorised by this other member with a view to carrying out the research, or about which he might have had knowledge during visits to the laboratories of the other members:

- Not to use the information for other purposes than successfully to complete the research and the use of the results;

- Not to divulge information to third parties. By third party is meant any person, company or body that does not participate in add name of project, with the exception of members of add name of project and their affiliated companies and bodies as defined in article 20[1] below;

- To pass on the information for which he is responsible only to those members of his staff who are directly concerned in the add name of project programme.

Will not be considered as confidential any information about which the member receiving it can prove:

- That it was part of the public domain at the time of its communication by one or more members, or that it subsequently came into the public domain other than by a failure to observe the present obligation of secrecy, or

- That he already had this information before its communication by one or more members or by any person authorised by these members, or

- That he received it freely from a third party authorised to divulge it,

- That he is legally required to communicate it.

It is moreover agreed that fundamental knowledge of universal import and information with a bearing on materials with a generic purpose acquired during generic research programmes, will not be considered as confidential.

[1] Not available

1.1.2 Publications

Publications or oral and written communications from members on the results obtained will be subject to the following conditions:

Before any publication or communication, written or oral, relative to the work of "add name of project", the laboratories participating in this work must obtain authorisation from the Operational Directorate. For this purpose, the laboratory concerned will submit a written draft of the publication or communication to the Operational Directorate, with a copy to the CPIV (Comité de Propriété Intellectuelle et Valorisation - Committee on Intellectual Property and Valorisation). Nevertheless, this obligation should not be an obstacle either to taking the patent in compliance with the provisions of this contract, or to any possible commercial use.

- The Operational Directorate will have a time limit of six weeks from its submission by the laboratory to give a ruling. Beyond this time limit, this agreement will be supposed to have been granted.

Consequently:

1.1.2.1 Content

Before any viva, the content of theses must be submitted to the Operational Directorate who will check that it does not contain any information of a confidential nature and /or likely to be the subject of a certificate of industrial ownership. If need be, a patent will be applied for before the viva, or else, in the case of confidential know-how, the viva of the theses will be held in camera.

1.1.2.2 Application for a patent

In the event of the results being likely to lead to the application for a patent, the confidentiality will be kept by the parties involved until the date of the patent application, or at the latest, until its publication date.

1.1.2.3 Confidential technical file

In the event of the results being the subject of industrial use on a Confidential Technical File (know-how), the Industrial Ownership Committee in liaison with the Operational Directorate will determine within a maximum time limit of 6 months which part of the results will constitute the aforesaid Confidential Technical File and which can in no circumstances be published during the time the corresponding know-how is being used.

1.1.2.4 Publication or communication

The results that do not come under a Confidential Technical File and/or a patent application may be the subject of a publication or communication to third parties. This publication or communication can be carried out in any case within a maximum time limit of one year after the decision of the Operational Directorate.

1.1.2.5 Mention the help

Publications and communications must mention the help contributed by the different parties to the results and make reference to add name of project.

1.1.2.6 Provisions

The provisions of the present article cannot obstruct the obligation which is incumbent on researchers or teacher-researchers of public bodies to produce an activity report for their evaluation

authorities, insofar as this communication does not constitute disclosure in the meaning of the laws on industrial ownership and where confidentiality is guaranteed.

1.1.2.7 Publication scientific knowledge

The publication of basic scientific knowledge and international scientific discussions will be favoured to the maximum in respect for the above provisions.

The results which have spin-offs in terms of public health and environmental protection are in principle intended to be published freely, after information and investigation by the CPIV.

1.1.2.8 Implementation present article

For the implementation of the present article, the Operational Directorate will be supported – as indicated in article 7[2] – by the CPIV. In the event of disagreement between the two committees, it will referred to the Strategic Committee – if need be in writing – who must make a ruling within a maximum time limit of 2 months.

1.1.3 Transfer of materials agreements

In the case of transfer of materials, notably biological, without any particular contract, between two or more members of the Group, a "transfer of materials agreement INTRA" aimed at ensuring the traceability of the results must be signed between the members concerned.

In the same way, all transfer of material to a third party outside the Group, in the scientific field of the group, must also be the subject of a "transfer of materials agreement OUT".

In the same logic, very special attention must be paid to the "materials transfer INTRA" agreements, which may be signed by the members in the field of the programme.

It is moreover agreed that any "transfer agreement" as mentioned in the paragraphs above must be subject, before its signature, to the agreement of the Operational Directorate. The Operational Directorate will have a deadline of six weeks from its submission by the laboratory to make a ruling. Beyond this time limit, this agreement will be considered to have been given.

The model for this "INTRA and OUT" agreement is appended.

1.1.4 Duration of commitments

The commitments of the present article are valid for the 10 (ten) years that follow the reception of the information or the obtaining of the results concerned.

1.2 Article 2 – Ownerschip of results

1.2.1 Content

Previous results or results obtained and acquired outside the add name of project programmes.
A review of the results previously acquired, as well as research data and materials available from the members of add name of project, will be carried out for each research programme. The Operational Directorate will draw up the corresponding inventories.

[2] Not available

The members of add name of project, remain the owners of their genetic resources and previous results placed at the disposal of the add name of project programmes.

The add name of project members undertake to place at the disposal of the add name of project programme concerned all technology, know-how or genetic resource (hereafter called "Enabling Technology" and in abbreviation E.T.) of which they have free possession of the rights and which will be necessary for the creation of add name of project programmes.

As far as the genetic resources are concerned, this availability will concern the add name of project programmes in which the member concerned is participating. Subject to their being freely available, the resources will be made available in the form of a research license and a commercial license.

The research license will be non exclusive and free; on the other hand, the commercial use of the products including the licensed E.T. will entail the payment of royalties. The license will be granted in a non exclusive manner to the interested partner and will not permit the E.T. to be out-sourced as such.

Moreover, the add name of projectmembers undertake to use their best efforts to make available to add name of projectany E.T. belonging to a third party and necessary for carrying out the work of add name of project. It will be made available in the same way as above. Nevertheless, in the event of the E.T. being acquired by one of the members on behalf of add name of project, and only for implementing the add name of project programmes, any possible rights of access will be taken into account according to modalities to be defined by the Strategic Committee in the framework of the programmes concerned.

1.2.2 Application of documents

For the application of the present documents, "industrial ownership" of the "Results" means all the rights of ownership whatever their legal nature (patents, software, databases, know-how…).

1.2.3 Industrial ownership

Industrial ownership of results obtained in the framework of the add name of project programme:
The Strategic Committee will be informed of the results by the CPIV and/or the Operational Directorate as they are obtained, at the level of both the generic research programmes and the finalised research programmes.

1.2.3.1 Ownership results generic research programmes

Industrial ownership of the results of the generic research programmes. The public research bodies will be the owners of the results of the generic research programmes and therefore holders or co-holders, at the level of their respective intellectual and financial inputs, of the rights of industrial ownership relating to the inventions they have obtained or contributed to obtaining.

The basic knowledge of universal application and the generic materials acquired during the generic research programmes, as well as their characterisation elements, as specified by the Strategic Committee, are intended to be placed in the public domain and will therefore be freely available to be disseminated and used.

The results that may need protection by patent will be subject to the following provisions:

a) Results obtained by a single public member of the Group

The results are the property of the public party who obtains them. It is he who will make the decision to submit an application for patent. Nevertheless, before any submission, he must inform the CPIV and the Operational Directorate of his decision.

If he decides not to patent, he will warn the CPIV in good time. The CPIV will inform the Operational Directorate which can invite the other public members to substitute for him if they so wish.
In this hypothesis, the party abandoning the claim undertakes to provide the interested member(s) with all the necessary technical or administrative items they might need to obtain the patents. The costs ensuing from the patent applications will in this case be the sole responsibility of the applicant(s), as indicated below.

b) Results obtained by several public members of the Group.

The results obtained in common will be a co-ownership of the members who have obtained them, pro rata of their respective inputs, both intellectual and financial. It will be up to them to take any decision about the submission of patents.

It is understood that in the event of a submission of patent, regulations of co-ownership will be established between the members concerned, prior to the submission of this application, as in the case of the use of a Confidential Technical File, in particular to determine the shares and conditions for managing their rights and obligations.

It is here and now agreed that the rights of industrial ownership will be managed by the add name of company on behalf of all the co-holder public research bodies, then possibly by the "simplified shares Company" which will be set up in conformity with the provisions of article 10[3] above.

c) The expenses of industrial ownership (deposit, maintenance, defence, procedures…), unless there are stipulations to the contrary from the Strategic Committee, will be the sole responsibility of the applicant(s).

Any member who refuses or ceases to participate in the costs of application and maintenance relating to a patent in a country, will lose all right over this patent in the country under consideration, unless there is a different agreement from the scientific committee.

d) Submission of patent applications outside France.

At the latest nine (9) months after the submission of the priority application, the CPIV, which will have discussed it with the applicant or applicants, will make proposals to the Operational Directorate which will decide about the submission of the patent requests abroad.

In the event of the public partners not wishing to extend a patent application into a given country, the private partners will have the possibility of proceeding to this extension in the name(s) of the public partners and at the expense of the private partners wishing to participate in this extension.

[3] Not available

1.2.3.2 Ownership results finalised research programmes

Industrial ownership of results from finalised research programmes. Unless there are contractual provisions to the contrary decided in the framework of a given programme and figuring in the particular corresponding contract (cf. article 11.2[4].), the results from a specific programme executed in a finalised research programme will be the property of the one who obtains them.

Nevertheless, if several partners have contributed to obtaining the results, they will be co-holders of the corresponding rights of industrial ownership, according to their respective inputs, both intellectual and financial.

In conformity with the previous provisions (article 2.3.1.b), co-ownership regulations will be established in particular to determine the co-ownership shares and designate the party who will manage their rights and obligations. A model of a co-ownership contract is appended.

It is here and now agreed that there is one exception to this rule:

If the results of a finalised research programme were to apply to other species than that of the programme, the programme manager will delegate to the add name of company the management of the rights for the applications concerned.

1.2.4 Results

The results from subsequent work by each of the add name of project members from add name of project results will be the property of the member who has worked on them and obtained them. This provision applies in particular to subsequent work of genetic improvement.

If the commercial use of these subsequent results requires an exploitation licence of the add name of project "Results", the provisions of article 3 below are applicable.

1.2.5 Provisions

The provisions, the subject of the present article 2, can if required be developed in the special agreements provided for in article 11.2[5].

1.3 Article 3 – Management of industrial ownership and licences

1.3.1 Ownership rights

As long as a joint company for using add name of project results has not been created, the industrial ownership rights and the corresponding licences will be managed by the holder of the rights (or his representative), as defined in article 2 in respect for the provisions provided for in the present document.

[4,5] Not available

1.3.2 Results framework generic programmes

As far as the results obtained in the framework of generic programmes are concerned, the management mission of industrial ownership rights conferred on the add name of company by the public members will include in particular:

- Ø Decision and management of industrial ownership with a view to ensuring the protection of the results in association with the CPIV and in agreement with the other authorities of the group (implementation of procedures necessary for the submission and obtaining of industrial ownership certificates: preparation of texts for patent applications, procedures with the Patent Office, inventors and representative councils, follow-up of procedures);

- Ø Negotiation and signature of exploitation licences or agreements with the members of add name of project and possibly with third parties, according to the rules defined in article 5.
- Ø Tax collection and payment of fees and various receipts to the co-ownership public members of add name of project and of corresponding royalties according to the provisions mentioned in article 5 below.

- Ø It is clearly understood that any proposal, decision or agreement in the matter, will be subject to the prior approval of members who are co-holders of the rights of industrial ownership.

- Ø Nevertheless, concerning the defence of the rights of industrial ownership (objection procedures started or undergone, actions for counterfeiting,…), the decisions will be taken by the Strategic Committee and the costs entailed by these decisions will be shared among the public and private members according to a share to be defined by the aforesaid committee.

1.3.3 Results framework finalised research

As far as the results obtained in the framework of finalised research are concerned, the management methods of industrial ownership and use of the said results will be determined in the terms of the special agreements as mentioned in article 11.2[6] and/or in the terms of the co-ownership regulations as provided for in article 2.4.

1.4 Article 4 – Use of the results for the exclusive requirements of research and animal selection

The add name of project results will be placed at the disposal of the members for purposes of research, in respect for articles 1 to 3.

Each of the members can freely and at no cost use them for their own research requirements, to the exclusion of all commercial use subject to the provisions of article 5 below.

[6] Not available

1.5 Article 5 – Commercial use of the results

1.5.1 Members

The members of add name of project will benefit from a non exclusive option of commercial use of results from generic programmes, as well as a co-exclusive option of use of results from finalised research programmes in which they have participated. The list of members concerned by this co-exclusive option as well as the time limit during which this co-exclusivity will be applicable will be established for each species or group of species either by the special agreement provided in article 11.2[7], or failing that, by the Strategic Committee at the proposal of the Operational Directorate.

add name of project members who have not participated in a finalised research programme can nevertheless benefit from this co-exclusive exploitation licence of results from this programme, in return for the payment of a right of access which will be determined either by special contract or failing that by the Strategic Committee, at the proposal of the Operational Directorate.

Access of third parties to the results of the finalised programmes for commercial ends, will be subject either to the provisions of the special contract as stated in article 11.2[8], or failing that to the Strategic Committee, taking particular account of the following:

- The current uses in the activity concerned, the size of the market and the competition;
- The priority of use consented to the members as defined above;
- The relevance and the state of protection of the results considered;
- The fields of application and geographical area where the members concerned invest in the development and commercialisation of the results;
- The economic situation of the destination country and the legal personality of the third party beneficiary.

To take account of the specific cooperation research mandate for development assigned to the CIRAD, the holder(s) of rights of industrial ownership, or the joint development Company, as provided for in article 3, will concede to the local producers of animal species, the subject of the present documents, licences for use in very privileged conditions, which can go as far as granting free use, thus ensuring that the least favoured farmers, whose gross annual income is less than € xxxxx, have sufficient food resources. The right to any sub-licence will be subject to the same conditions.

1.5.2 Licence contract

If the option of use stated in article 5.1 is lifted, each professional member or affiliated company concerned must take out a licence contract or commercial exploitation agreement with the holder(s) of the rights (or their representative).

This contract will in particular specify the technical and geographical extents of the rights of use, their duration, and the sub-licence methods and the provisions concerning improvements, the

[7,8] Not available

settling of differences, etc… This contract will guarantee the holders of rights a fair payment that will be determined by common agreement:

- Ø At a reasonable level compared with the process or product of the same type existing on the market,

- Ø Taking account of the intellectual and financial inputs of the add name of project members and of third parties in obtaining the results considered, their development, their industrialisation, their launch and their commercialisation,
- Ø Taking account of the existence or not of a certificate of industrial ownership or confidential know-how and corresponding costs, as well as of the period of exclusivity stated in article 5.1.

1.5.3 Results

As far as the results mentioned in article 2.3.1. are concerned, the add name of company will act on behalf of all the public bodies who are co-holders of the aforesaid results, for the implementation of the present article 5.

1.5.4 Implementation articles 4 and 5

For the implementation of articles 4 and 5, it is specified that in the case of results patented or not, that can be implemented for purposes of animal selection, access to the patented results will be free for the duration of the selection work, whoever is the holder of the aforesaid patents by virtue of article 2. On the other hand, the commercial use of blood lines or breeding animals that come from this selection work, but implementing protected results or being the subject of confidential know-how, will have to be the subject of a licence of the patent(s) considered and /or of the confidential know-how, in compliance with the provisions of the present article5.

2 Negotiating a collaborative research contract: DO's and DON'Ts

The Knowledge Management Working Group is acknowledge for putting together this list of do's and don'ts.

	DO's		DON'Ts
	Starters		
1.	**C** Check the "Lambert Review" for a set of standard agreements/contracts. [http://www.innovation.gov.uk/lambertagreements/]. **C** Read the EC Regulation No. 2321/2002. [http://europa.eu.int/comm/research/fp6/documents_en.html, click on rules for participation]. **C** Read the EC-contract for the General Conditions. **C** Do specify a time frame for draft consortium agreements (or contracts) to be discussed by all possible partners, to allow a speedy process.	**1.**	**D** Do not underestimate the effect of the General Conditions in the EC-contract of Cooperative Research and Network of Excellence on the possibilities of the consortium agreements. **D** Do not allow possible partners to exceed the times given in the time frame
	Personnel		
2.	**C** Check if the personnel can, by contract, claim rights to the know-how generated in this project. **C** Define in the consortium agreement, the conditions on which personnel can claim rights. **C** Define all rights in agreement with the contracts of personnel and EC Regulations.	**2.**	**D** Do not set up agreements or contracts with partners or with personnel if these are in conflict with existing agreements or with possible future project agreements.
	Ownership of the generated knowledge		
3.	**C** Agree in the Consortium agreement the future ownership of the generated knowledge in as much detail as possible with the other contractors of the project. **C** Ask permission from the other contractors and the Commission before transferring ownership of generated knowledge.	**3.**	**D** Do not forget to include the management of generated knowledge in the Consortium agreement. **D** Do not forget that the Consortium agreement should be in accordance with the provisions of the EC Regulation No. 2321/2002.

	DO's		DON'Ts
	Protection of the generated knowledge		
4.	**C** Specify the protection of the generated knowledge in the plan for its use and dissemination. **C** Agree in the consortium agreement on a specific time span (e.g. 30 days) for objections to **F** granting access to pre-existing know how **F** dissemination of generated knowledge **F** publication of generated knowledge. **C** Protect the generated knowledge in a sensible way, fair to all involved. **C** Inform the Commission if you are not interested in protecting the generated knowledge in a particular country. **C** Specify in the Consortium agreement, what should happen to the rights of acquired knowledge, if a company changes its name or splits up.	**4.**	**D** Do not forget to include the management of generated knowledge in the Consortium agreement. **D** Do not protect the newly generated knowledge without considering the legitimate interests of the concerned participants. **D** Do not refuse to protect the generated knowledge in a particular country specifically decided by the Commission, unless this protection will damage your legitimate interests significantly.
	Dissemination of generated knowledge		
5.	**C** Agree with the other participants on the terms of use and dissemination of the generated knowledge. **C** Include a specific time span for objections. **C** Specify the management of knowledge dissemination in the Consortium agreement. **C** Disseminate the acquired knowledge, unless it clearly infringes with its protection rights. **C** Set out the terms of use of acquired knowledge in a detailed manner.	**5.**	**D** Do not object to the request of a contractor to transfer of ownership, unless it unfavourably affects your company access rights. **D** Do not request the Commission for transfer of the rights, if the granting of such transfer is inconsistent with ethical or with commons principles that are accepted policies in EU. **D** Do not disseminate information of knowledge if one or more contrators and/or the Commission has objected against it within the time span specified in the consortium agreement. Do not use the acquired knowledge, relative to the project, if this has a known negative impact on the interests of the other contractors, now or in future.
	Publication		
6.	**C** Include a well defined time period to object to each proposed publication in the Consortium agreement.	**6.**	**D** Do not object with the request of publication of results and data unless this will explicitly affect your rights.

	DO's		DON'Ts

Access of third parties			
7.	**C** Include the possibility to grant more favourable access rights to specific (specified) third parties, such as interested enterprises, in the Consortium agreement. **C** Prepare a detailed plan to facilitate the dissemination of knowledge to contractors and third parties.	**7.**	**D** Do not provide favourable access rights to third parties (industries, research groups, or societies), if this contradicts the applicable competition rules. **D** Do not provide favourable access rights if this contradicts the developments of the knowledge-based European economy. **D** Do not provide favourable access rights if this contradicts existing ethical principles. **D** Do not facilitate the dissemination of knowledge when it contradicts the contract or the Consortium agreement.
Pre-existing know how			
8.	**C** Agree, in a written document, as a part of the consortium agreement, the exclusion of the use of the possible pre-existing know-how before the beginning of the project. **C** Clarify in the agreement which describes the use of the pre-existing knowledge, which pre-existing know-how should be considered to facilitate the project. **C** Specify in the agreement which are the pre-existing know-how giving on a royalty-free basis and which are not. **C** Use fair and not discriminatory conditions to define the granting of access rights to pre-existing know-how. **C** Understand that the list of pre-existing know-how can be increased by know-how generated by a contractor out side this consortium agreement.	**8.**	**D** Do not start the research activities before signing the agreement which describes the use of the pre-existing knowledge. **D** Do not grant the access to pre-existing know-how if you are not free to grant them. **D** Do not deny the access to your pre-existing know-how if this will impair the legitimate interests of a contractor or if this pre-existing know-how is needed to carry out the work defined in the project.

3 Quick first set up of a contract

Contents

If it is of importance to start a collaboration as soon as possible and/or to set up a contract only with a short meeting, the following documents are of interest.

The Knowledge Management Working Group is acknowledge for making available these examples for a first set up of a contract.

3.1 Entering into a (research) contract Quick reference card

Step 1: Initial meeting to determine the goals of the project.

Step 2: Draft a Term Sheet (maximum 3 pages)

Use the do's and don'ts to check if all main aspects are determined before sending the term sheet to a lawyer.

Step 3: Sign Term Sheet.

Step 4: Send Term Sheet to legal advice (lawyer) to draft and official contract.
Or
Use an example contract

Check the draft contract using the list of frequently asked questions

Step 5: Sign contract

Step 6: Initiate project

3.2 Term sheet

Term sheet for a [development / research / production / etc] agreement between [PARTY 1] and [PARTY 2]

Party 1 [address details], legally represented by [contact person]

Party 2 [address details], legally represented by [contact person]

N.B.: This document is not a complete binding agreement between the parties and is intended for evaluating the final terms and conditions for a binding agreement. After signing of this term sheet, a legal document will be drafted by the lawyer of [PARTY 1 / PARTY 2].

1) [OBJECTIVE 1]

2) [OBJECTIVE 2]

3) [OBJECTIVE 3]

4) [OBJECTIVE 4]

Etc.

This document has been prepared in two-fold with one original for each party.

Party 1	Party 2
Signature	Signature

4 Letter of intent

Name of organisation LETTER OF INTENT

This agreement is executed on by and between : .....

Add name coordinating organisation
having its registered address add address, place, street postal code, Country
represented by : add name presenter, as add function presented
hereafter called add coordinator's short name.

and

(**add your organisation's official name**
having its registered address at add your organisation's official address
represented by add name of the person signing
hereafter called add your organisation's short name

Whereas add coordinator's short name, add your organisation's short name and the members of the Consortium listed in annex 1 hereto referred individually "Party" or collectively "Parties" are aware that an international research project benefits from a written and clear commitment;

Whereas for the purpose of the proposal preparation ("Proposal Preparation"), the Parties will supply each other with necessary information, which may be confidential;

The Parties agree upon the following:

CONFIDENTIALITY

1. For the purpose of enabling the Parties to perform the Proposal Preparation, which is not-committing to each individual Party, Parties will supply, so far as free to do so, each other with all relevant information necessary, hereinafter called " Information".

2. The receiving Parties shall keep the Information received from a disclosing Party confidential during the term of this agreement and after the deposit of the Proposal for 5 years and use it strictly for the purpose of performing the Proposal Preparation and for no other purpose whatsoever.

3. The confidential Information, all copies thereof and all rights thereto shall remain the exclusive property of the disclosing Party.

All original or copies enclosing the confidential Information shall be promptly returned to the disclosing Party on receipt of the disclosing Party's written request.
4. The obligation mentioned above shall not apply to any Information which:

(a) was in the possession of the receiving Party prior to disclosure by the disclosing Party and which was not previously obtained, either directly or indirectly, from the disclosing Party under confidentiality restrictions;

(b) was at the time of its disclosure to the receiving Party, part of the public domain by publication or otherwise; or hereafter becomes generally available to the public through no act or failure to act of the receiving Party;

(c) was furnished to the receiving Party by any third party as a matter of right without restriction on disclosure.

(d) is to be disclosed pursuant to the order or requirement of a court, administrative agency or other government body, provided that each Party shall provide the other Party with prompt notice of such order or related proceeding to afford the other Party an opportunity to intervene and prevent the disclosure.

5. The Parties shall keep confidential and shall not disclose in any manner to any third party the facts, contents and objectives of this Letter of Intent, except to the Name of funding body.

6. The receiving Party shall limit access to the Information disclosed by the disclosing Party only to its personnel who are directly involved and necessary for the Proposal Preparation hereunder and the receiving party shall ensure that such personnel are fully aware of and comply with the obligations of confidentiality under this letter of intent.

7. For a period up to add date, the Parties shall jointly conduct the proposal Preparation, hereafter called "the Proposal Preparation Period"

PROPOSAL PREPARATION

8. The Parties hereby appoint add coordinator's short name to act as the coordinator ("Coordinator"). The Coordinator's initial representative shall be add name coordinator's initial representative.

9. The Parties undertake to not disclose any material exchanged in the course of the Proposal Preparation to third parties.

10. Each Party shall, within its respective scope of supplies and services for the Project, make its necessary and reasonable efforts to concur in a competitive Proposal through the preparation of all needed documents.

11. The Parties designate add coordinator's short name as a coordinator ("Coordinator") to represent the interest of the Parties vis-à-vis the Commission.

12. Each Party shall support and assist the Coordinator ("Coordinator") in finalising the Proposal, in the form and according to the schedule agreed by the Parties as necessary for the Co-ordinator to submit the Proposal in due time to the add name of funding body.

Each Party shall provide the Co-ordinator with all pertinent technical and cost data, which they deem necessary for the Proposal Preparation as well as all technical support or such other support as may be mutually agreed upon.

The Co-ordinator shall not modify the technical and cost data supplied by the other Parties without their respective prior consent.

The Co-ordinator shall make available to each Party a copy of all significant letters, emails, faxes or documents relating to the Proposal sent to or received from the add name of funding body before the submission of the Proposal.

13. Each Party is fully aware that the funding programme covers only a part of the expenses that have to be expended during the course of the Project. Each Party will find its own ways to cover the non-funded part of the expenses.

It is understood that each Party will respectively bear its own costs involved in the Proposal Preparation.

14. These basic engagements will be defined more in details during the preparation of the Project, which could be divided in sub projects and/or workpackages, and in the Consortium Agreement. These documents will follow recommendations established by the add name of funding body.

NEGOTIATION WITH THE COMMISSION

15. The Co-ordinator shall be responsible for the submission of the Proposal and the conduct of negotiations of the Proposal with the add name of funding body.

16. Each Party shall be kept fully informed of the progress of any negotiations and, as far as its Sub Project and/or Work Package is concerned, shall attend and participate in the Contract negotiations only upon request from the Co-ordinator.

The Co-ordinator shall put at the disposal of the Parties, all significant letters, emails, faxes or documents relating to the negotiations and shall also keep each Party informed of everything relevant to its Sub Project and/or Work Package until the signature of the Contract.

17. The Co-ordinator shall not, without the prior written agreement of each relevant Party, propose or accept any deviation or variation to the conditions or scope of said party's Sub Project and/or Work Package.

In case the negotiations with the Commission result in conditions in the add name of funding body Contract which substantially deviate from these letter of intention or from the future Consortium Agreement, the Parties shall in good faith negotiate in view of adapting the conditions of Consortium Agreement to those of the add name of funding body Contract.

CONSORTIUM AGREEMENT NEGOTIATION

18. In the perspective of the success of the proposal, the Parties will enter into good faith negotiations to agree the terms of a Consortium Agreement and each party shall use reasonable endeavours to sign a Consortium Agreement before the signature of the contract between the Co-ordinator and the add name of funding body.

19. Each Party shall provide the Co-ordinator with all pertinent documents, which it deems necessary for the negotiation of the Consortium Agreement, and at least:

- legal form of the party and its control by any parent company;
- affiliates the party wants to grant access to knowledge which will be yielded by the Project;

- means the Party brings to the Project (equipment, real estate infrastructures, human resources, animal populations and biological materials…);
- the Pre Existing Know-How the Party want to explicitly exclude from the obligation to grant access rights;
- number and identity of researchers and doctoral students who may be involved in the Integrated project;
- cost model used by the Party;
- documents giving details of Party's bank account.

20. The Parties undertake to negotiate a Consortium Agreement. This Consortium Agreement shall be signed before the signature of the contract related to the Project between the Coordinator and the add name of funding body.

GENERAL PROVISIONS

21. This letter of intent shall come into force on the date of its signature and shall remain in force for a six-months period. The obligations of confidentiality herein stated shall remain in force for a period of add number of years (also in number) years after the date of expiration or termination of this letter of intent.

22. The disclosure of Information shall not be construed as granting to others, agency or any other rights (except for the Proposal Preparation hereunder).

23. Disputes that might arise concerning this Letter of Intent shall be settled amicably. In case of disputes for which no amicable solution is possible, settlement will exclusively take place according to add country law.

24. This Letter of Intent and its effects are subject to and shall be construed and enforced in accordance with the laws of add country.

Signature page follows.

Signed on this ..... day of ..... 200..

Establishment **represented by**

.....
Name add name of organisation
Function : add function add name oordinator

.....
Name add name
Function add function .....

ANNEX 1 Members of the Consortium

Participant no.	Participant Name
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5 Example consortium agreement

Contents

Source: http://www.earto.org/!PCA/MU.htm (UNITE and EARTO)

Warning
If ever you are asked to sign what someone describes as the E_U-CA Model Consortium Agreement, check the version on this web-site before signing to ensure that you have not been presented with a modified version. This warning is based on experience. Unscrupulous people have done such things in the past!

This Model is offered for use at the sole discretion and on the sole responsibility of the using party. Neither EARTO nor UNITE nor the authors of this Model can accept any responsibility or liability for the use made of this Model or for any consequences arising therefrom.
Directions on how to use the model
[to be provided later]

5.1 PART I

This Model is offered for use at the sole discretion and on the sole responsibility of the using party. Neither EARTO nor UNITE nor the authors of this Model can accept any responsibility or liability for the use made of this Model or for any consequences arising therefrom.

EARTO-UNITE Consortium agreement for integrated projects

This agreement is made on <DD-MMM-YY>

Between

(1) <PARTY 1 = *Co-ordinator*>

(2) <PARTY 2>

(3) <PARTY 3>

(4) <PARTY 4>

(5) <PARTY 5>

(6) <PARTY 6>

(7) <PARTY 7>

(8) <PARTY 8>

etc.

Relating to the Project entitled " <NAME OF PROJECT>

WHEREAS:

(a) The Parties, having considerable experience in the field concerned, have submitted or intend to submit a Proposal for a Project entitled " <NAME OF PROJECT> " to the Commission in the Sixth Research And Technological Development Framework Programme

(b) The Parties wish to specify or supplement, between themselves, the provisions of the EU Contract in line with Article II.3.1(b) of the EU Contract and wish to lay down general rules related to the management of the Project and their agreements with respect to, including but not limited to, liability.

[Optional:

(c) the parties have entered into a memorandum of understanding, dated <INSERT DATE OF MEMORANDUM OF UNDERSTANDING>, concerning the project. Complete or delete as appropriate]

Now therefore it is hereby agreed as follows:

1. This Consortium Agreement shall come into force as of the date of its signature by the Parties but shall have retroactive effect as from < day-month-year: > and, in case of Parties signing a Declaration of Accession from the date of the Declaration of Accession, and shall continue in full force and effect until terminated in accordance with Section VI.3 of Part II of this Integrated Projects' Consortium Agreement (hereinafter called "IPCA Part II") or complete discharge of all obligations for the carrying out of the Project undertaken by the Parties under the EU Contract and under this Consortium Agreement, whichever is the earlier.

2. This Consortium Agreement consists of this Integrated Projects' Consortium Agreement: Part I, Part II, Part III and Part IV (hereinafter respectively called IPCA Part I, IPCA Part II, IPCA Part III and IPCA Part IV).

3. The Governance Model applicable for this Project is <select either L1, L2 or L3>.

4. The Co-ordinator (IPCA Part II Section III.1) for the Project is <insert the name of the Co-ordinator>.

5. The Project may have Sub-Projects as listed in IPCA Part III , which may be amended from time to time and which is included herein by reference, in which IPCA Part III the Sub-Projects and the names of the Sub-Project Co-ordinators are listed.

6. The General Assembly (IPCA Part II Section III.3) shall meet <define here the frequency for General Assembly meetings, e.g. quarterly>.

7. [Applicable only in case of Model L3:

The minimum number of Board members (excluding the Co-ordinator representative) for the purposes of IPCA Part II Section III.5.1.1 is……..

The maximum number of Board members (excluding the Co-ordinator representative) for the purposes of IPCA Part II Section III.5.1.1 is ……..

For the avoidance of doubt the Co-opted Board members in accordance with IPCA Part II Section III.5.1.1 are not included in the minimum and maximum number of Board members referred to herein.

The Project Share required for IPCA Part II Section III.5.1.1 third paragraph is …….

8. [Applicable only if limitations with respect to access rights to pre-existing know-how (Article II.19 (c) or (d) of the EU contract are invoked! Complete or delete as appropriate! Limitations with respect to Access Rights to Pre-Existing Know-How (Article II.19 (c) or (d) of the EU Contract: <identify here the Party not granting the Access Rights and identify the Pre-Existing Know-How explicitly excluded from the obligation to grant Access Rights>].

9. The option applicable with respect to the Have Made Rights (IPCA Part II Section IV) is <select one of the options 1, 2 or 3>.

10. The Parties agree that option (IPCA Part II Section VI.4) <insert either: "1 Arbitration" or "2 Appropriate national court"> shall be applied with respect to the settlement of disputes relating to the Project.

11. Any notice to be given under this Consortium Agreement shall be in writing to the following addresses and recipients.

(1) < Insert name and address of each party, tohether with fax numbers and email addresses, and name/position of person for whose attention notices are to be addressed >

(2)

(3)

(4)

(5)

(6)

(7)

(8)

Or to such other address and recipient as a Party may designate in respect of that Party by written notice to the others.

As witness the Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives the day and year first above written.

Authorised to sign on behalf of <INSERT NAME OF COORDINATOR>

Signature

Name
<INSERT NAME>

Title
<INSERT TITLE>

Authorised to sign on behalf of <INSERT NAME OF *PARTY* ...>

Signature

Name
<INSERT NAME>

Title
<INSERT TITLE>

5.2 PART II

This Model is offered for use at the sole discretion and on the sole responsibility of the using party. Neither EARTO nor UNITE nor the authors of this Model can accept any responsibility or liability for the use made of this Model or for any consequences arising therefrom.

EARTO-UNITE Consortium agreement for integrated projects

5.2.1 Definitions

5.2.1.1 Contract Definitions

Words defined in the EU Contract have the same meaning in this Consortium Agreement and appear in italics.

5.2.1.2 Additional Definitions

Accession Date means the date of the signature of the Declaration of Accession by Contractors joining the Project in accordance with the provisions of Sections III.3.2.4(d), III.3.2.9(d), III.3.2.14(d) and/or III.4.2.4(b), as applicable, and Section VI.3.1 hereof.

Affiliate of a Party means:

(a) any legal entity directly or indirectly controlling, controlled by, or under common control with a Party, for so long as such control lasts and provided that the said Affiliate or the ultimate controlling entity is incorporated and resident in, and subject to the law of, a Member State of the Community, or an Associated State.

Control of an entity shall exist through the direct or indirect:

- Ø Control of 50% or more of the nominal value of the issued equity share capital of the entity or of 50% or more of the equity's shares entitling the holders to vote for the election of directors or persons performing similar functions, or

- Ø Right by any other means to elect or appoint directors of the entity (or persons performing similar functions) who have a majority vote,

(b) Any other organisation specified in the agreed Schedule to this Consortium Agreement to be an Affiliate of the Party.

Common control through government does not, in itself, create affiliated status unless otherwise specified in accordance with paragraph (b) above.

Board means the body established in accordance with Section III.5.1 hereof.

Common Fund means a fund established in accordance with Section V.2 hereof.

Commission means the Commission of the European Communities

Declaration of Accession means a declaration, in the form as provided for in IPCA Part IV, signed by a participant wishing to join the Project.

Defaulting Party means a Party which the General Assembly has, in accordance with its procedures, or the other Parties acting jointly, have determined to be in breach of any of its obligations under the EU Contract and/or this Consortium Agreement in accordance with Section VI.3.3.2 hereof.

EU Contract means (i) after its signature by all Contractors, the contract (including its Annexes) for the Project identified in IPCA Part I, for the undertaking by the Parties of the Project; (ii) before such signature, the model contract proposed by the Commission at the date of this Consortium Agreement for integrated projects in the sixth research and development framework programme for which the Proposal has been or is to be submitted. EU Contract shall as applicable also mean any EU Contract amendment.

General Assembly means the body established in accordance with Section III.3.1 hereof.

Joint Fund(s) means:
a) advance payments made by the Commission to the Co-ordinator for the benefit of the Consortium and not directly allocated to a Party; and
b) a Common Fund .

Party or Parties means a party or the parties to this Consortium Agreement.

Project Deliverables mean the deliverables required under the EU Contract and this Consortium Agreement (including, but nor limited to, the reports and cost statements that have to be delivered to the Co-ordinator, Sub-Project Co-ordinator(s), and/or the Commission).

Project Share means for each Party, that Party's share of the total cost of the Project as initially set out in the EU Contract, unless otherwise agreed by all Parties.

Proposal means the proposal for the Project submitted or intended to be submitted (as the case may be) by the Parties to the Commission. Proposal shall as applicable also mean any amendment to a Proposal.

Sub-Project means any sub-project listed in IPCA Part III which can be amended from time to time by decision of the General Assembly in accordance with the provisions of this Consortium Agreement.

Sub-Project Committee means the body established in accordance with Section III.4.1 hereof.

Sub-Project Co-ordinator means the Party who will carry out the co-ordination tasks provided for in Section III.2.1 hereof. The Sub-Project Co-ordinators are listed in IPCA Part III.

5.2.2 Purpose and general provisions

The purpose of this Consortium Agreement is to specify the organisation of the work between the Parties, organize the management of the Project, to define rights and obligations of the Parties, including, but not limited to, their liability and indemnification, and to supplement the provisions of the EU Contract concerning Access Rights and to set out rights and obligations of the Parties supplementing but not conflicting with those of the EU Contract.
Participation in any meetings provided for in the EU Contract or in this Consortium Agreement is not allowed without signing of this Consortium Agreement.

5.2.3 Governing bodies, roles and responsibilities

5.2.3.1 Co-ordinator

5.2.3.1.1 Responsibilities of the Co-ordinator

1. In addition to the Co-ordinator's functions pursuant to the EU Contract, the Co-ordinator shall have the following functions only:

- Ø Administration, preparation of minutes and provision of the chairman of the General Assembly and the Board, and follow-up of its decisions;
- Ø Transmission of any documents and information connected with the Project between the Parties concerned; and
- Ø Withholding payments for, constituting and administration of the Joint Fund including but not limited to the Common Fund as provided for in Section V.2 hereof.

2. Except for the capacity as representative of the Parties described in the EU Contract, the Co-ordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party.

3. If one or more of the Parties is late in submission of Project Deliverables, the Co-ordinator may submit the other Parties' Project Deliverables to the Commission.

4. The Co-ordinator undertakes to keep advance payments allocated by the EU Contract, Section V.2 hereof or by budget allocation in accordance with a decision of the General Assembly to a Joint Fund on an account separated from his normal business accounts and his own assets and property. Such separation shall be made by means of a notary public deposit or similar deposit provided for in the national laws and regulations of the country, where the money is deposited and which means have been decided upon by the General Assembly.

The General Assembly shall designate two Parties, which shall act together with the Co-ordinator as signatories (hereinafter including the Co-ordinator referred to as "Signatories") for the Joint Funds. Any disposition concerning Joint Funds shall require authorisation of at least two Signatories who shall act together in accordance with this Consortium Agreement and/or with any specific decision of the General Assembly. Any transaction costs relating to the handling of Joint Funds shall, if not reimbursed as management costs by the Commission, be born by the Parties in accordance with their Project Share. The Co-ordinator may withhold from advance payments to a Party the share of such costs to be born by such Party.

Subject to withholding of advance payments for the Joint Funds and transaction costs (as provided for in this Section III.1.1.4 and Section V.2 hereof), the Co-ordinator undertakes to transfer, in accordance with the EU Contract and the budget allocation decided by the General Assembly, the appropriate sums to the respective Parties with minimum delay, but not later than thirty (30) days from its receipt thereof from the Commission, and the Co-ordinator will notify each other Party promptly of the date and amount transferred to its respective bank account and shall give the relevant references.

5.2.3.2 Sub-Project Co-ordinator

5.2.3.2.1 Responsibilities of the Sub-Project Co-ordinator

1. The Sub-Project Co-ordinator shall have the following functions only:

- Ø Administration, preparation of minutes and provision of the chairman of the Sub-Project Committee, and follow-up of its decisions;
- Ø Transmission of any documents and information connected with the Sub-Project between the Parties concerned;
- Ø Transmission of any documents and information connected with the Sub–Project to the Co-ordinator; and
- Ø Transmission of the Project Deliverables of the Parties within the Sub-Project to the Co-ordinator.

2. The Sub-Project Co-ordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party.

3. If one or more of the Parties is late in submission of Project Deliverables for the Sub-Project, the Sub-Project Co-ordinator may submit the other Parties' Project Deliverables for the Sub-Project to the Co-ordinator.

5.2.3.3 General Assembly

5.2.3.3.1 Composition of the General Assembly

The Parties shall establish, within thirty (30) days after the date of this Consortium Agreement, the General Assembly composed of one duly authorised representative of each of them.

After having informed the others in writing, each Party shall have the right to replace its representative and/or to appoint a proxy although it shall use all reasonable endeavours to maintain the continuity of its representation.
Each representative shall have a deputy.

5.2.3.3.2 Decision Making in the General Assembly

1. The General Assembly shall be chaired by the Co-ordinator's representative.
The General Assembly shall meet at frequency defined in IPCA Part I in principle at the request of its chairman or at any other time when necessary at the request of one of the Parties. Meetings shall be convened by the chairman with at least fifteen (15) calendar days prior notice. This notice shall be accompanied by an agenda. The agenda shall be proposed by the chairman. The agenda shall be deemed to be accepted unless one of the Parties notifies the chairman and the other Parties in writing of additional points to the agenda, at the latest two (2) working days before the date of the meeting.

Minutes of the meetings of the General Assembly shall be transmitted to the Parties within thirty (30) calendar days after the date of the meeting.

The minutes shall be considered as accepted by the other Parties if, within fifteen (15) calendar days from receipt, no Party has objected in a traceable form to the Co-ordinator.

2. Any decision requiring a vote at a General Assembly meeting must be identified as such on the pre-meeting agenda, unless there is unanimous agreement to vote on a decision at that meeting and all Parties are present or represented.

3. However, any decision required or permitted to be taken by the General Assembly may be taken in accordance with the above (i) in meetings via teleconference and/or via email; (ii) without a meeting with prior notice of at least seven (7) days and without a vote, if, in any such case, a consent in writing, setting forth the decision so taken, is signed by the representatives of the Parties having not less than the minimum number of votes that would be necessary to take such decision at a meeting at which all Parties entitled to vote on such decision were represented and were voting, and provided the consent has been delivered for signature to all Parties' representatives.

Option 1 (for MODEL "L1") [for small projects]

4. The General Assembly shall be responsible for the overall direction of the Project. To that end, the General Assembly shall have the following powers:

(a) Deciding upon the allocation of the Project's budget in accordance with the EU Contract, reviewing and proposing to the Parties budget reallocations and deciding upon the creation, modalities of use, management and release of Joint Funds;

(b) Making proposals to the Parties for the review and/or amendment of the terms of the EU Contract, however excluding the entering into the EU Contract of new Contractors as referred to in Section III.3.2.4 d) hereto and excluding Annex I of the EU Contract as referred to in Section III.3.2.4 j) hereto;

(c) Deciding or making proposals to the Parties (other than the Defaulting Party) to service of notices on a Defaulting Party in accordance with Section VI.3.3.2 hereof and to assign the Defaulting Party's tasks to specific entity(ies) (preferably chosen from the remaining Parties);

(d) Deciding upon the entering into the EU Contract and the Consortium Agreement of new Contractors;

(e) Without prejudice to Section IV, agreeing procedures and policies in accordance with Article II.2.5 of the EU Contract for the management of the Knowledge such as but not limited to measures for Dissemination of Knowledge from the Project which is not to be Used by the Parties;

(f) Implementing Article II.15.1 of the EU Contract and deciding upon press releases and (without prejudice to Section IV.4) joint publications by the Parties with regard to the Project;

(g) Deciding upon the technical roadmaps with regard to the Project;

(h) Deciding upon the designation of a third party in charge of part of the management of the Project;

(i) Deciding upon the launch of Sub-Projects within the Project;

(j) Deciding upon the change of technical specifications in Annex 1 of the EU Contract and exchange of work packages between the Parties;

(k) Deciding upon measures in the framework of controls and audit procedures to ensure the effective day-to day co-ordination and monitoring of the progress of the technical work under the Project;

(l) Approving of the proposals for nominations of Subcontractors by one or more Parties

(m) Deciding upon the designation of the Signatories in accordance with Section III.1.1.4 hereof; and

(n) Management of the Project.

5. The General Assembly shall not deliberate and decide validly unless a majority of two-thirds (2/3) of its members are present or represented. Where decisions are to be taken unanimously, all Parties must be represented at the meeting.

In voting each Party shall have a number of votes equalling the percentage of its Project Share in the total cost of the Project.

6. In the cases of Section III.3.2.4 (a) and (b), decisions shall be taken unanimously by all of the Parties. In the case of Section III.3.2.4 (c), the decision shall be taken unanimously by all of the non-Defaulting Parties.

7. In the cases of Section III.3.2.4 (d), (e), (f), (g), (h), (i), (j) and (m) decisions shall be taken by a majority of 75% of the votes of Parties present or represented by proxy at a quorate meeting, provided always that in cases of Section III 3.2.4 (g), (i) and (j) a Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions.

8. In the cases of Section III.3.2.4 (k) and (l) and in other cases not referred to above in Section III.3.2.6 or III.3.2.7, decisions shall be taken by the majority of the votes of the Parties present or represented by proxy at a quorate meeting.

Option 2 (for MODEL "L2") [for medium sized projects]

9. The General Assembly shall be responsible for the overall direction of the Project. To that end, the General Assembly shall have the following powers:

(a) Deciding upon the allocation of the Project's budget in accordance with the EU Contract, reviewing and proposing to the Parties budget reallocations and deciding upon the creation, modalities of use, management and release of Joint Funds;

(b) Making proposals to the Parties for the review and/or amendment of the terms of the EU Contract, however excluding the entering into the EU Contract of new Contractors as referred to in Section III.3.2.9 d) hereto and excluding Annex I of the EU Contract as referred to in Section III.3.2.9 j) hereto;

(c) Deciding or making proposals to the Parties (other than the Defaulting Party) to service of notices on a Defaulting Party in accordance with Section VI.3.3.2 and to assign the Defaulting Party's tasks to specific entity(ies) (preferably chosen from the remaining Parties);

(d) Agreeing upon the proposal made by the Sub-Project Committee for the entering into the EU Contract and the Consortium Agreement of new Contractors for participation in the Sub-Project;

(e) Without prejudice to Section IV, agreeing procedures and policies in accordance with Article II.2.5 of the EU Contract for the management of the Knowledge such as but not limited too measures for Dissemination of Knowledge from the Project which is not to be Used by the Parties;

(f) Implementing Article II.15.1 of the EU Contract and deciding upon press releases and (without prejudice to Section IV) joint publications by the Parties with regard to the Project;

(g) Deciding upon the technical roadmaps with regard to the Project;

(h) Deciding upon the designation of a third party in charge of part of the management of the Project;

(i) Deciding upon the launch of Sub-Projects within the Project;

(j) Deciding upon the change of technical specifications in Annex 1 of the EU Contract and exchange of work packages between the Parties, in the event that this exchange has an impact which goes beyond the scope of the Sub-Project;

(k) Deciding upon measures in the framework of controls and audit procedures to ensure the effective day-to-day co-ordination and monitoring of the progress of the technical work affecting the Project as a whole; and

(l) Deciding upon the designation of the Signatories in accordance with Section III.1.1.4 hereof.

10. The General Assembly shall not deliberate and decide validly unless a majority of two-thirds (2/3) of its members are present or represented. Where decisions are to be taken unanimously, all Parties must be represented at the meeting.
In voting each Party shall have a number of votes equalling the percentage of its Project Share in the total cost of the Project.

11. In the cases of Section III.3.2.9 (a) and (b), decisions shall be taken unanimously by all of the Parties. In the case of Section III.3.2.9 (c), the decision shall be taken unanimously by all of the non-Defaulting Parties.

12. In the cases of Section III.3.2.9 (d), (e), (f), (g), (h), (i), (j) and (l) decisions shall be taken by a majority of 75% of the votes of Parties present or represented by proxy at a quorate meeting, provided always that in cases of Section III.3.2.9 (g), (i) and (j) a Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions.

13. In the cases of Section III.3.2.9 (k) and in other cases not referred to above in Section III.3.2.11 or III.3.2.12, decisions shall be taken by the majority of the votes of the Parties present or represented by proxy at a quorate meeting.

Option 3 (for MODEL "L3") [for large projects]

14. The General Assembly shall be responsible for the overall direction of the Project. To that end, the General Assembly shall have the following powers:

(a) Agreeing upon the proposal made by the Board for the allocation of the Project's budget in accordance with the EU Contract, reviewing and proposing to the Parties budget reallocations and deciding upon the creation, modalities of use, management and release of Joint Funds;

(b) Making proposals to the Parties for the review and/or amendment of the terms of the EU Contract, however excluding the entering into the EU Contract of new Contractors as referred to in Section III.3.2.14 d) hereto and excluding Annex I of the EU Contract as referred to in Section III.3.2.14 f) hereto;

(c) Agreeing upon proposals made by the Board for decisions on or proposals to the Parties (other than the Defaulting Party) to service of notices on a Defaulting Party in accordance with Section VI.3.3.2 and proposals to assign the Defaulting Party's tasks to specific entity(ies) (preferably chosen from the remaining Parties);

(d) Agreeing upon the proposal made by the Sub-Project Committee for the entering into the EU Contract and the Consortium Agreement of new Contractors for participation in the Sub-Project;

(e) Deciding upon the launch of Sub-Projects within the Project;

(f) Deciding upon the change of technical specifications in Annex 1 of the EU Contract and exchange of work packages between the Parties, in the event that this exchange has an impact which goes beyond the scope of the Sub-Project; and

(g) Deciding upon the designation of the Signatories in accordance with Section III.1.1.4 hereof.

15. The General Assembly shall not deliberate and decide validly unless a majority of two-thirds (2/3) of its members are present or represented. Where decisions are to be taken unanimously, all Parties must be represented at the meeting.

In voting each Party shall have a number of votes equalling the percentage of its Project Share in the total cost of the Project.

16. In the cases of Section III.3.2.14 (a) and (b), decisions shall be taken unanimously by all of the Parties. In the case of Section III.3.2.14 (c), the decision shall be taken unanimously by all of the non-Defaulting Parties.

17. In the cases of Section III.3.2.14 (d), (e), (f) and (g) decisions shall be taken by a majority of 75% of the votes of Parties present or represented by proxy at a quorate meeting, provided always that a Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions.

18. In the other cases not referred to above in Section III.3.2.16 or III.3.2.17, decisions shall be taken by the majority of the votes of the Parties present or represented by proxy at a quorate meeting, provided always that any Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions.

5.2.3.4 Project Committee

5.2.3.4.1 Composition of the Sub-Project Committee

1. The Parties participating in the same Sub-Project shall establish, within thirty (30) days after the date of this Consortium Agreement, a Sub-Project Committee composed of one duly authorised representative of each of them.

After having informed the others in writing, each Party participating in the same Sub-Project shall have the right to replace its representative and/or to appoint a proxy although it shall use all reasonable endeavours to maintain the continuity of its representation.
Each representative shall have a deputy.

5.2.3.4.2 Decision Making in the Sub-Project Committee

1. The Sub-Project Committee shall be chaired by the Sub-Project Co-ordinator's representative.

The Sub-Project Committee shall meet at least twice a year in principle at the request of its chairman or at any other time when necessary at the request of one of the Parties participating in the same Sub-Project. Meetings shall be convened by the chairman with at least fifteen (15) calendar days prior notice. This notice shall be accompanied by an agenda. The agenda shall be proposed by the chairman. The agenda shall be deemed to be accepted unless one of the Parties participating in the same Sub-Project notifies the chairman and the other Parties participating in the same Sub-Project in writing of additional points to the agenda, at the latest two (2) working days before the date of the meeting.

Minutes of the meetings of the Sub-Project Committee shall be transmitted to the Parties participating in the same Sub-Project within thirty (30) calendar days after the date of the meeting. The minutes shall be considered as accepted by the other Parties participating in the same Sub-Project if, within fifteen (15) calendar days from receipt, no Party participating in the same Sub-Project has objected in a traceable form to the Sub-Project's Co-ordinator.

2. Any decision requiring a vote at a Sub-Project Committee meeting must be identified as such on the pre-meeting agenda, unless there is unanimous agreement to vote on a decision at that meeting and all Parties participating in the same Sub-Project are present or represented.

3. However, any decision required or permitted to be taken by the Sub-Project Committee may be taken in accordance with the above (i) in meetings via teleconference and/or via email; (ii) without a meeting with prior notice and/or (iii) without a vote, if, in any such case, a consent in writing, setting forth the decision so taken, is signed by the representatives of the Parties participating in the same Sub-Project having not less than the minimum number of votes that would be necessary to take such decision at a meeting at which all Parties participating in the same Sub-Project entitled to vote on such decision were represented and were voting, and provided the consent has been delivered for signature to all Parties' representatives participating in the same Sub-Project.

4. The Sub-Project Committee shall be responsible for the direction of the Sub-Project. To that end, the Sub-Project Committee shall have the following powers:

(a) Deciding upon the allocation of the Sub-Project's budget in accordance with the EU Contract and reviewing and proposing to the Parties participating in the same Sub-Project budget reallocations within the limits of the budget for the Sub-Project;

(b) Making proposals to the General Assembly for the entering into the EU Contract and the Consortium Agreement of new Contractors for participation in the Sub-Project;

(c) Deciding upon the change of technical specifications in Annex 1 of the EU Contract and exchange of work packages between the Parties participating in the same Sub-Project, in the event that this exchange has an impact which does not go beyond the scope of the Sub-Project;

(d) Management of the Sub-Project;

(e) Co-ordinating on a day to day basis the progress of the technical work under the Sub-Project;

(f) Deciding upon measures in the framework of controls and audit procedures affecting the Sub-Project, without affecting the Project as a whole; and

(g) Agreeing upon proposals for nominations of Subcontractors by one or more Parties participating in the Sub-Project;

5. The Sub-Project Committee shall not deliberate and decide validly unless a majority of two-thirds (2/3) of the Parties participating in the same Sub-Project are present or represented. Where decisions are to be taken unanimously, all Parties participating in the same Sub-Project must be represented at the meeting.
In voting each Party participating in the same Sub-Project shall have one (1) vote.

6. In the cases of Section III.4.2.4 (a) and (b) decisions shall be taken unanimously by all of the Parties represented in the Sub-Project Committee.

7. In the case of Section (c) decisions shall be taken by a majority of 75% of the votes of

Parties present or represented by proxy at a quorate meeting, provided always that any Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions.

8. In the cases of Section III.4.2.4 (d), (e), (f) and (g) and in other cases not referred to above, decisions shall be taken by the majority of the votes of the Parties present or represented by proxy at a quorate meeting, provided always that any Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions.

5.2.3.5 Board

5.2.3.5.1 Composition of the Board

1. The composition of the Board for the Project shall reflect the Parties' Project Share and respective responsibilities in the Project and an appropriate mixture in respect of balance of competencies and fields of activities, while staying at a count level compatible with effective decision-making processes.

The Board shall consist of the following members:

- The representative of the Co-ordinator; and
- A number of representatives of other Parties, within the limits specified in IPCA Part I; and
- The co-opted Board members, if any.

Only Parties with a Project Share equal to or greater than the share specified in IPCA Part I shall be entitled to determine the number of Board members within the limits specified in IPCA Part I and to appoint the members of the Board and only representatives of said Parties are entitled to present candidates eligible for Board membership. However, the Board as constituted in accordance with this paragraph, hereinafter referred to as the "core Board", may co-opt one or more additional Board members, hereinafter referred to as the "co-opted Board members", provided that if more than one additional Board member is co-opted the total number of co-opted Board members shall not exceed 25% of the core Board. The core Board shall act unanimously in nominating and determining the period of office of co-opted Board members. For the avoidance of doubt, the co-opted Board members shall have the same rights as the core Board members to receive notice or to participate in discussions and to vote on all matters considered by the Board, excepting only the nomination and period of office of co-opted Board members.

2. Any Board member may resign by delivering written notice to the chairman of the Board. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

Any Board member having resigned shall hold office until his successor shall have been appointed in accordance with Section III.5.1.1.

5.2.3.5.2 Decision Making in the BoardThe Board will be chaired by the Coordinator's representative.

1. The Board shall be chaired by the Co-ordinator's representative.
The Board shall meet at least quarterly in principle at the request of its chairman or at any other time when necessary at the request of one of the Board members. Meetings shall be convened by the chairman with at least fifteen (15) calendar days prior notice. This notice shall be accompanied by an agenda. The agenda shall be proposed by the chairman. The agenda shall be deemed to have been accepted unless one of the Parties notifies the chairman and the other Parties in writing of additional points to the agenda, at the latest two (2) working days before the date of the meeting.

Minutes of the meetings of the Board shall be transmitted to the Board members within thirty (30) calendar days after the date of the meeting. The minutes shall be considered as accepted if, within fifteen (15) calendar days from receipt, no Board member has objected in a traceable form to the Co-ordinator.

2. Any decision requiring a vote at a Board meeting must be identified as such on the pre-meeting agenda, unless there is unanimous agreement to vote on a decision at that meeting and all Board members are present or represented.

3. However, any decision required or permitted to be taken by the Board may be taken in accordance with the above (i) in meetings via teleconference and/or via email; (ii) without a meeting with prior notice and/or (iii) without a vote, if, in any such case, a consent in writing, setting forth the decision so taken, is signed by the representatives of the Board members having not less than the minimum number of votes that would be necessary to take such decision at a meeting at which all Board members entitled to vote on such decision were represented and were voting, and provided the consent has been delivered for signature to all Board members.

4. The Board shall be responsible and have the powers for the following:

(a) Making proposals to the General Assembly for the allocation of the Project's budget in accordance with the EU Contract for reviewing and proposing to the Parties budget reallocations and making proposals to the General Assembly for the creation, modalities of use, management and release of Joint Funds;

(b) Making proposals to the General Assembly for decisions on or proposals to the Parties (other than the Defaulting Party) to service of notices on a Defaulting Party in accordance with Section VI.3.3.2 and to assign the Defaulting Party's tasks to specific entity(ies) (preferably chosen from the remaining Parties;

(c) Without prejudice to Section IV, agreeing procedures and policies in accordance with Article II.2.5 of the EU Contract for the management of the Knowledge such as but not limited too measures for Dissemination of Knowledge from the Project which is not to be Used by the Parties;

(d) Deciding upon the technical roadmaps with regard to the Project;

(e) Implementing Article II.15.1 of the EU Contract and deciding upon press releases and (without prejudice to Section IV.4) joint publications by the Parties with regard to the Project;

(f) Deciding upon the designation of a third party in charge of part of the management of the Project;

(g) Deciding upon measures in the framework of controls and audit procedures to ensure the effective day-to-day co-ordination and monitoring of the progress of the technical work affecting the Project as a whole;

(h) Management of the Project; and

(i) Deciding upon the nomination and period of office of the co-opted Board members in accordance with Section III.5.1.1 hereof.

5. The Board shall not deliberate and decide validly unless a majority of two-thirds (2/3) of its members are present or represented. Where decisions are to be taken unanimously, all Board members must be represented at the meeting.
In voting each Board member shall have one (1) vote.

6. In the cases of Section III.5.2.4 (i) decisions shall be taken unanimously by all of the Board members, in accordance with the provisions of Section III.5.1.1 hereof (i.e. co-opted Board members shall be excluded from participating in decisions on nomination and period of office of co-opted Board members).

7. In the cases of Section III.5.2.4 (a), (c), (d), (e) and (f) decisions shall be taken by a majority of 75% of the votes of the Board members present or represented by proxy at a quorate meeting, provided always that in case of Section III.5.4 (d) a Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions. In case of Section III.5.4.(b) the decision shall be taken by the Board members representing the non-Defaulting Parties.

8. In the cases of Section III.5.2.4 (g) and (h) and in other cases not referred to above, decisions shall be taken by the majority of the votes of the Board members present or represented by proxy at a quorate meeting, provided always that any Party whose scope of work, time for performance, costs or liabilities are changed or whose information is to be published, may veto such decisions.

5.2.3.6 Responsibilities of each Party

5.2.3.6.1 General Responsibilities

1. Each Party undertakes to each other Party to use reasonable endeavours to perform and fulfil, promptly, actively and on time, all of its obligations under the EU Contract and this Consortium Agreement.

2. Each Party shall bear its own costs in connection with the making of the Proposal, the negotiation of the EU Contract and the carrying out of the Project.

5.2.3.6.2 Responsibilities towards the Co-ordinator, the Sub-Project Co-ordinator, the Board and the General Assembly

1. Each Party hereby undertakes to use reasonable endeavours to supply promptly to the Co-ordinator or to the Sub-Project Co-ordinator, as the case may be, all such information or documents as the Co-ordinator (if appropriate, acting on behalf of the Board or the

General Assembly) or the Sub-Project Co-ordinator (if appropriate, acting on behalf of Sub-Project Committee), need to fulfil obligations pursuant to this Consortium Agreement and the EU Contract.

5.2.3.6.3 Responsibilities towards Each Other

1. Each Party undertakes to use reasonable endeavours:

(a) To notify each of the Parties in the same Sub-Project, or in the event no Sub-projects exist, in the Project promptly of any significant delay in performance; and

(b) To inform other Parties in the same Sub-Project, or in the event no Sub-Projects exist, in the Project of relevant communications it receives from third parties in relation to the Sub-Project or the Project.

2. Each Party shall use reasonable endeavours to ensure the accuracy of any information or materials it supplies hereunder or under the EU Contract and promptly to correct any error therein of which it is notified. The recipient Party shall be entirely responsible for the use to which it puts such information and materials.

3. In addition to the obligations specified in Article II.20 of the EU Contract, each Party agrees not to use knowingly, as part of a deliverable or in the design of such deliverable or in any information supplied hereunder or under the EU Contract, any proprietary rights of a third party for which such Party has not acquired the right to grant licences and user rights to the other Parties in accordance with the EU Contract, unless all of the other Parties have accepted such use in writing, such acceptance not to be unreasonably withheld.

4. Each Party shall be fully responsible for the supervision of its Subcontractors and shall enter into appropriate arrangements for such purpose with its Subcontractors. These arrangements shall as appropriate require the obligations in this Consortium Agreement also apply to, and (where they apply) be fulfilled by, such Subcontractor.

5.2.4 IPR & Access Rights [EARTO/UNITE version]

[Note: This Section IV is not part of the IPCA Model agreed upon between EARTO-EICTA-TNOGT-UNITE]

5.2.4.1 Additional Definitions

API or **Application Programming Interface** means an interface or other means provided for by a Software application, component or library for the purpose of interfacing or interaction of other Software with such application, component or library including, but not limited to, data types and -structures, constant and macro definitions, function and procedure definitions including their name, parameters, parameter count and parameter data type(s) and any data type of function results thereof, as set forth in header files, specifications and related documentation.

Preferential Conditions means non-discriminatory and reasonable conditions, which are when taken as a whole more favourable to a Party being granted Access Rights than would be the case in an equivalent arm's length transaction under normal market conditions.

Object Code means Software in machine-readable, compiled and/or executable form including, but not limited to, byte code form and in form of machine-readable libraries used for linking procedures and functions to other Software including the necessary Software Documentation.

Software means software programs being sequences of instructions to carry out a process in, or convertible into, a form executable by a computer or similar device or hardware and fixed in any tangible medium of expression.

Software Documentation means Software information being technical information used or, useful in, or relating to the design, development, use or maintenance of any version of a Software program.

Source Code means Software in human readable form normally used to make modifications to it including, but not limited to, comments and procedural code such as job control language and scripts to control compilation and installation including the necessary Software Documentation.

5.2.4.2 Intellectual Property Rights

5.2.4.2.1 Joint Ownership

1. If, in the course of carrying out work on the Project, a joint invention, design or work is made (and more than oneParty is contributor to it), and if the features of such joint invention design or work are such that it is not possible to separate them for the purpose of applying for, obtaining and/or maintaining the relevant patent protection or any other intellectual property right, the Parties concerned agree that they may jointly apply to obtain and/or maintain the relevant right.

The Parties concerned shall seek to agree between them arrangements for applying for, obtaining and/or maintaining such right on a case-by-case basis. Unless otherwise agreed during the period any such right is in force, the Parties concerned shall be entitled to use and to license such right without any financial compensation to or the consent of the other Parties concerned.

2. For the avoidance of doubt, joint ownership of an invention, design or work shall not affect the obligations arising under this Consortium Agreement or the EU Contract.

5.2.4.2.2 Transfer of Employees' Rights

In addition to the obligations pursuant to the Article II.16.3 of the EU Contract, each Party shall ensure that it can grant Access Rights and fulfil the obligations under the EU Contract and this Consortium Agreement notwithstanding any rights of its employees, or persons it engages to perform part of its share of the Project, in the Knowledge or Pre-existing Know-how they create after the effective date of this Consortium Agreement as identified in IPCA Part I .

5.2.4.3 Access Rights

5.2.4.3.1 General Principles relating to Access Rights

1. All Access Rights granted in accordance with this Section IV.3 are granted on a non-exclusive basis, expressly exclude any rights to sub-license unless otherwise agreed herein, and save in exceptional circumstances shall be made free of any transfer costs.

2. Except as provided in this Section IV.3, Access Rights shall be granted in accordance with and subject to the EU Contract. Knowledge and Pre-Existing Know-How shall be used only for the purposes for which Access Rights to it have been granted and only for so long as is necessary for those purposes.

3. In relation to the grant of Access Rights "needed" or "need" shall mean that, without the grant of such Access Rights:

(a) In the case of Access Rights granted for the execution of the Project, carrying out the tasks assigned to the recipient Party would be impossible, significantly delayed, or require significant additional financial or human resources.

(b) In the case of Access Rights granted for Use, the Use of a defined and material element of the recipient Party´s own Knowledge would be technically or legally impossible.

4.

(a) The burden of proof in relation to a claimed need for Access Rights shall be on the receiving Party. Where Access Rights are deemed to have been granted, the receiving Party shall provide such proof to the granting Party within 30 days of receipt of a written request. Subject to the receiving Party acting in good faith, Access Rights for execution of the Project shall remain in force pending the resolution of any dispute between the Parties over the need for Access Rights.

(b) Any grant of Access Rights not covered by this Section shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties.

5.

(a) In the event of a dispute between Parties with respect to the need for Access Rights for execution of the Project, the decision of the Board shall be final and binding on all Parties. A member of the Board who is associated with any of the Parties in dispute shall not participate in its deliberations or vote on its decision. The power of decision may be delegated to a Panel convened for that purpose, the membership of which shall be determined by the Board and shall be acceptable to all Parties concerned.

(b) In the event of a dispute between Parties with respect to the need for Access Rights for Use, a Panel shall be appointed in the manner aforesaid whose decision shall be final and binding on all Parties.

(c) Where no Board has been appointed, the powers of the Board under this section shall be exercised by the General Assembly. If this Consortium Agreement has already been terminated and the Board and/or General Assembly have been dissolved, the Parties shall have recourse to the settlement of disputes procedures provided in Section VI of this Consortium Agreement. [NOTE: Check against surviving provisions clause].

5.2.4.3.2 Access Rights for the execution of the Project

1. Access Rights for Parties participating in the same Sub-Project. Access Rights to Knowledge and Pre-Existing Know-How needed for the execution of the Sub-Project shall be deemed granted, as of the date set out in the Contract on a royalty-free basis to and by all Parties participating in the same Sub-Project.

2. Access Rights for Parties participating in different Sub-Projects. Access Rights to Knowledge and to Pre-Existing Know-How needed for the execution of a different Sub-Project shall be granted upon written request on a royalty-free basis to and by all Parties.

5.2.4.3.3 Access Rights for Use

1. Access Rights for Parties participating in the same Sub-Project. Access Rights to Knowledge resulting from a Sub-Project needed for Use shall be granted upon written request on a royalty-free basis subject to Section IV.3.1. to and by all Parties participating in that same Sub-Project.

Access Rights to Pre-Existing Know-How needed for Use shall be granted on Preferential Conditions to and by all Parties participating in the same Sub-Project subject to a bilateral agreement between the Parties concerned.

2. Access Rights for Parties participating in different Sub-Projects. Access Rights to Knowledge needed for Use shall be granted on Preferential Conditions to and by all Parties in different Sub-Projects subject to a bilateral agreement between the Parties concerned.

Access Rights to Pre-Existing Know-How needed for Use shall be granted on market conditions to and by all Parties in different Sub-Projects subject to a bilateral agreement between the Parties concerned.

5.2.4.3.4 Fair use

A Party which, having received royalty-free Access Rights for Use of the Knowledge of another Party, and which over the period up to ten years after the Contract Completion Date has derived substantial commercial benefit from the exploitation of such Access Rights shall, without prejudice to the rights and obligations of the Parties concerned, make a payment or payments to the granting Party reflecting the royalties that would have been payable had the grant of Access Rights been on Preferential Conditions.

5.2.4.3.5 Research

1. Recognizing the Parties' obligations to act in good faith, the Parties agree that, to the extent such Access Rights are not already provided for by law, Access Rights for direct or indirect utilisation of Knowledge in research activities are deemed to have been granted on a royalty-free basis as of the date set out in the Contract

2. Where research is carried out in collaboration with and/or for a third party and it appears to the researching Party that the third party will require direct access to the Knowledge of another Party, Access Rights to the said Knowledge of another Party shall be granted to the third party on written request subject to the following:

(a) The researching Party shall in a traceable form (before starting or committing to start the research) inform the third party of such requirement, and shall use reasonable endeavors to inform the owner of that Knowledge of such requirement in a traceable form.

(b) The owner having been so informed, shall:

- Ø Not unreasonably delay his decision on whether or not to grant the required third party Access Rights and
- Ø Not unreasonably refuse to grant such rights on fair and reasonable terms but may, in good faith, so refuse on the grounds of business interest.

(c) If despite reasonable efforts on behalf of the researching Party, the owner cannot been so informed, the researching Party may carry out the research without prejudice to the owner's rights to enforce its rights in any way it deems fit against such third party.

(d) For the avoidance of doubt, the Parties agree that where such research does not result in direct access to another Party's Knowledge by a third party (as examples - producing research results which are available to the third party but which contain hermetically-sealed Knowledge of another Party; using Knowledge of another Party for in-house testing or diagnosis purposes in doing research), no further grant of Access Rights is necessary.

5.2.4.3.6 Access Rights in Projects without Sub-Projects

In Projects where no Sub-Projects are installed Sections IV.3.2, IV.3.3 and IV.3.10 ("Access Rights for Parties participating in the same Sub-Project") shall apply to all Parties as if they all were participating in the same Sub-Project.

5.2.4.3.7 Inability to grant *Access Rights* due to Third Party Rights

When due to the existence of third party rights a Party is unable to grant Access Rights which it reasonably believes that another Party will require, it will promptly notify such other Party and in particular where possible shall do so before submission of the Proposal to the Commission or entering into the EU Contract.

5.2.4.3.8 *Access Rights* to third parties

Notwithstanding the provisions of Section IV.3 of this Consortium Agreement and the provisions as set out in Article II.19 of the EU Contract, each Party may enter into a technical co-operation or licensing arrangement with a third party in respect of its own Knowledge even if there are minor amounts of Knowledge owned by another Party, or even Pre-Existing Know-How (associated with that other Party's Knowledge), unavoidably incorporated into or amalgamated with such own Knowledge. In such circumstances and upon request of the Party entering the co-operation or arrangement, the other Party shall grant non-exclusive rights to permit such co-operation or arrangement against terms and conditions to be agreed, provided that no Legitimate Interest of the other Party opposes the grant of such rights.

5.2.4.3.9 Access Rights for Affiliates

1. Each Party hereby grants to each other Party the power to extend the grant of Access Rights to its Affiliates on the same terms and in the same manner as if such Affiliates were Parties. A Party granting Access Rights to an Affiliate warrants that such Affiliates shall have granted Access Rights to all Parties including this same power to extend the grant to Affiliates and that, without prejudice to the Parties' obligations to carry out the Project and to provide Project Deliverables, such Affiliate has undertaken to fulfil all confidential and other obligations accepted by the Parties under the EU Contract or this Consortium Agreement as if such Affiliates were Parties.

2. Cessation of Control. Upon cessation of the control of an Affiliate any Access Rights granted to such Affiliate in respect of Knowledge or Pre-existing Know-How shall lapse, provided however that information which is Knowledge which has been incorporated into the products, processes, Software or services of such Affiliate or which has been amalgamated with such Affiliate's own information may continue to be used (in the manner it was then being used) by such Affiliate provided it is not practical to do otherwise. In such event, at the request of such Affiliate, each requested Party shall grant to such Affiliate non-exclusive licences under that Party's intellectual property rights which are Knowledge against terms and conditions to be agreed upon, provided that no Legitimate Interests of such Party oppose the grant of such licences. Upon such cessation of control, Access Rights granted by such Affiliate shall continue in full force and effect.

5.2.4.3.10 Specific Provisions for *Access Rights* to *Software*

1. General principles relating to Access Rights to Software. For the avoidance of doubt, the general provisions for Access Rights provided for in Sections IV.3.1 and IV.3.4 - IV.2.9 herein are applicable also in case of Software.

Access Rights to Software do not comprise access to Source Code but only Limited Source Code Access as defined below. Access to Source Code will be granted subject to separate agreements only, to be concluded between the Parties concerned.[9]

Limited Source Code Access comprises:

(a) Access to Object Code; and,
(b) Where normal use of such Object Code requires an API, access to Object Code and such API; and,
(c) If neither (a) nor (b) is available, access to Source Code

Access Rights to Software do not include any right to receive Source Code or Object Code ported to a certain hardware platform or any right to receive respective Software Documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

[9] It should be clear that whenever access to source code is granted, be that directly or via LSA, then this has to be subject to separate agreements.

2. Access Rights to Software for the execution of the Project

(a) Access Rights for Parties participating in the same Sub-Project. Access Rights to Software which is Knowledge or Pre-Existing Know-How, needed for the execution of the Sub-Project shall be deemed granted on the basis of Limited Source Code Access, as of the date set out in the Contract on a royalty-free basis to and by all Parties participating in the same Sub-Project.

(b) Access Rights for Parties participating in different Sub-Projects. Access Rights to Software which is Knowledge or Pre-Existing Know-How needed for the execution of a different Sub-Project shall be granted on the basis of Limited Source Code Access upon written request on a royalty-free basis to and by all Parties.

3. Access Rights to Software for Use

(a) Access Rights for Parties participating in the same Sub-Project.

- Ø Access Rights to Software which is Knowledge resulting from a Sub-Project needed for Use shall be granted on the basis of Limited Source Code Access upon written request and on a royalty-free basis subject to Section IV.2.1. to and by all Parties participating in that same Sub-Project.
- Ø Access Rights to Software which is Pre-Existing Know-How needed for Use shall be granted on Preferential Conditions to and by all Parties participating in the same Sub-Project subject to a bilateral agreement between the Parties concerned.

(b) Access Rights for Parties participating in different Sub-Projects.

- Ø Access Rights to Software which is Knowledge needed for Use shall be granted on Preferential Conditions to and by all Parties in different Sub-Projects subject to a bilateral agreement between the Parties concerned.
- Ø Access Rights to Software which is Pre-Existing Know-How needed for Use shall be granted on market conditions to and by all Parties in different Sub-Projects subject to a bilateral agreement between the Parties concerned.

4. Software license and sub-licensing rights

1. Access Rights to Object Code and/or Limited Source Code Access all granted in accordance with Section IV.3.10.1 – IV.3.10.4 shall comprise the worldwide right

(a) To use Object Code in research, or to create and market a product or process, or to create and provide a service; and

(b) To make and have made an unlimited number of copies of Object Code; and

(c) To distribute, make available, market, sell and offer for sale; even by using services of a third party, such Object Code in connection with products or services of the Party having the Access Rights.

Provided however that,

- Ø Any product, process or service has been developed by the Party having the Access Rights in accordance with its rights to use Object Code and Limited Source Code Access for its own Knowledge; and
- Ø Object Code and Limited Source Code Access represent only a minor part of the overall product, process or service; and
- Ø Object Code and Limited Source Code Access cannot be separated from and/or have been amalgamated with such product, process or service.

In addition, Access Rights to Object Code granted in accordance with the above shall comprise the worldwide right to grant in the normal course of the relevant trade to end-user customers buying/using the product/services a perpetual, irrevocable, worldwide license

(a) To use Object Code in connection with or integrated into, products and services of the Party having the Access Rights and, as technically essential,
(b) To maintain such product/service, and
(c) To create for its own end-use interacting interoperable Software in accordance with the Council Directive of 14 May 1991 on the legal protection of computer programs (91/250/EEC).

2. Where a Party has been granted access to Source Code to Knowledge according to Section IV.3.10.1 herein, the Parties concerned may further agree that the Access Rights to such Source Code can comprise a worldwide license to use, to make and have made copies, to modify and have modified, develop and have developed, to adapt and have adapted Source Code for research, or to create and market a product or process, or to create and provide a service. In addition, Access Rights can comprise the worldwide right to sub-license such Source Code, but solely for purpose of adaptation, error correction, maintenance and/or support of the Software.

3. Each sublicense granted according to the provisions of this Section IV.3.10.4 shall when reasonably possible be made by a traceable agreement specifying and protecting the proprietary rights of the Party or Parties concerned unless otherwise agreed upon in a separate agreement.

5.2.4.3.11 Standards

If one of the main explicit objectives of the Project is to contribute to the establishment of a particular European standard, the Parties hereby agree to make available to third parties, needed licences relating to Knowledge and Pre-Existing Know-How in conformance with the rules of the standards body setting such standard provided such third party similarly makes needed licences available under its intellectual property rights.

5.2.4.3.12 Access Rights for Contractors joining and leaving the Project

1. Contractors joining the Project in accordance with the provisions of Sections III.3.2.4(d), III.3.2.9(d), III.3.2.14(d)and/or III.4.2.2(b), as applicable, and Section VI.9 after the date of the Contract will be granted the Access Rights as provided for in Sections IV.3.1 - IV.2.11 hereof as from the date of their signature of the Declaration of Accession or of their accession to the Contract, whichever shall be the later.

2. For Contractors leaving the Project in accordance with the provisions of Section VI.3 hereof the following will apply :

With the exception of the cases where the participation of a Party is terminated by reason of default, the Access Rights accrued up to the date of termination and the obligations to grant Access Rights pursuant to the Contract and this Consortium Agreement shall continue to be in full force and effect.

Defaulting Parties are obliged to continue to grant Access Rights pursuant to the Contract and this Consortium Agreement, but the Access Rights granted to the Defaulting Party pursuant to this Consortium Agreement shall cease immediately upon termination of the participation of the Defaulting Party in the Contract.

3. Termination of this Consortium Agreement and/or cessation of licenses granted to the Defaulting Party in accordance with Section VI.3 shall not terminate any sublicenses granted or agreed to be granted or offered by the Defaulting Party in accordance with Section IV.2.8.2 prior to the date on which such termination of this Consortium Agreement and/or cessation of licenses becomes effective, provided that the Party or Parties which generated the Knowledge or Pre-Existing Know-How so sublicensed shall have the right to have an assignment of the Defaulting Party's rights under such sublicenses.

5.2.4.4 Confidentiality

5.2.4.4.1 Period of confidentiality

For any document, information, Knowledge, Pre-existing Know-how or other material communicated being confidential according to Article II.8 of the EU Contract, the period of confidentiality shall be at least 5 (five) years from the date of disclosure, unless a longer period of confidentiality is provided for in the EU Contract.

5.2.4.4.2 Confidentiality obligations

For the avoidance of doubt, it is stated that the confidentiality obligations under the EU Contract and this Consortium Agreement shall not be interpreted as to prevent the communication of information

(a) As is needed to be communicated to comply with applicable laws or regulations or with a court of administrative order provided that insofar as reasonably possible the complying Party shall have informed the owner of the information of such need and shall have complied with such owner's reasonable instructions designed to protect the confidentiality of such information;

(b) Subject to Section IV.4.3., to any Affiliate or to any other third party (including the Commission) insofar as needed for the proper carrying out of the EU Contract and/or this Consortium Agreement;

(c) Subject to Section IV.4.3., to any third party (including to the public) as strictly needed for technical reasons and insofar as needed for proper Use of Knowledge from the Project.

5.2.4.4.3 Third party

As respects any permitted communication of any of the information referred to in the previous Section by the recipient Party to a third party (including but not limited to its Affiliates) such Party will use reasonable endeavours to procure due observance and performance by such third party of the undertakings referred to in the previous Section of this Consortium Agreement and all relevant undertakings in the EU Contract.

5.2.4.5 Publications, Press Releases and Reports to the Commission

5.2.4.5.1 Publications

If the Parties have agreed a Project Deliverable to be available to the public, any Party may publish information included in such Project Deliverable without any notifications to the other Parties and without any other Parties' consent.

For the avoidance of doubt it is stated that unless otherwise agreed between the Parties concerned no Party shall have the right to publish or allow the publication of data which includes Knowledge of another Party, Pre-Existing Know-How of another Party or confidential information of another Party even where such data is amalgamated with such first Party's Knowledge, Pre-existing Know-How or other information, document or material. Any use of such other Party's data justifies objection to the publication by the Party concerned in accordance with Article II.17.3 of the EU Contract.

In case a Party objects to the publication of the data in accordance with Article II.17.3 of the EU Contract, the Parties concerned shall use all reasonable endeavours to overcome such opposition (for example by amendment to the planned publication or by postponing such publication). The opposing Party shall not unreasonably continue the opposition if appropriate actions have been taken.

This Section shall not prevent the submission, examination, publication and defence of any dissertation or thesis for a degree which includes incidental and minor elements of Knowledge of another Party, Pre-Existing Know-How of another Party or confidential information of another Party in case the intention to make such dissertation or thesis has been notified to the other Parties in writing promptly as soon as such intention is foreseen.

5.2.4.5.2 Disclaimer & marking of confidential information provided to the Commission

In addition to the Article II.15,

(a) All information provided to the Commission, publications and press releases shall have a disclaimer saying "The information in this document is provided as is and no guarantee or warranty is given that the information is fit for any particular purpose. The user thereof uses the information at its sole risk and liability.";

(b) Confidential information provided to the Commission will be marked stating the information is confidential and may be used only for information purposes by Community Institutions to whom the Commission has supplied it.

5.2.5 Liability and Indemnification

5.2.5.1 Liability

5.2.5.1.1 Liability towards each other

In respect of information or materials supplied by one Party to another hereunder or under the EU Contract, the supplier Party shall be under no obligation or liability other than as stated in Section III.6.3(b) hereof and no warranty condition or representation of any kind is made, given or to be implied as to the sufficiency, accuracy or fitness for purpose of such information or materials, or, subject to Section III.6.3(c) hereof, the absence of any infringement of any proprietary rights of third parties by the use of such information and materials and the recipient Party shall in any case be entirely responsible for the use to which it puts such information and materials.

5.2.5.1.2 Liability towards third parties

Subject always to such other undertakings and warranties as are provided for in this Consortium Agreement and the EU Contract, each Party shall be solely liable for any loss, damage or injury to third parties resulting from its carrying out its parts of the Project and from its Use of Knowledge and/or Pre-existing Know How.

5.2.5.1.3 Third parties (Subcontractors)

1. Each Party shall be fully liable for the performance of any part of its share of the Project, or other EU Contract obligation, in respect of which it enters into any contract with a third party (e.g. a Subcontractor) and shall ensure:
(a) such contracts enable fulfilment of the EU Contract;
(b) the other Parties' Access Rights are the same as would have been the case had the contracting Party performed its share of the Project and/or those obligations itself; and
(c) the third party shall not have access to any other Party's Knowledge or Pre-existing Know-how without that Party's prior written consent.

2. Each Party shall in writing inform the Co-ordinator or Sub-Project Co-ordinator, as applicable, asking for decision of the General Assembly or Sub-Project Committee, as applicable, if it intends to enter into a contract referred to in Section V.1.3.1 (giving the rationale therefor) if such an event has not been detailed in the EU Contract Annex I and the contract is other than for less than 10% of its share of the Project.

5.2.5.2 Indemnification in the event of claims from the Commission

5.2.5.2.1 Common Fund

1. By decision of the General Assembly in accordance with Sections III.3.2.4(a), III.3.2.9(a), III.3.2.14(a) hereof (as applicable) the Parties can establish a Common Fund in order to secure indemnification according to Section V.2.2 in the event of application of Article II.33 of the EU Contract by the Commission. In this decision, the Parties shall:

- Ø Name the Signatories;
- Ø Determine the amounts or percentage to be withheld from advance payments by the Co-ordinator;
- Ø Determine the modalities for its use;

- Ø Detail the rules for management of the fund; and
- Ø Detail the conditions and/or time for the release of the reserves in whole or in part by the Signatories.

Subject to Article II.27 of the EU Contract, any interest accrued by the Common Fund shall be divided among all non-Defaulting Parties according to their share in the Common Fund, where such share is calculated without the share of any Defaulting Party.

5.2.5.2.2 Indemnification by the Defaulting Party

In any case where the Commission claims reimbursement in accordance with Article II.33 of the EU Contract from a Party other than the Defaulting Party (hereinafter "Compensating Party"), the Compensating Party shall be entitled to seek full indemnification by the Defaulting Party.

5.2.5.3 Indemnification in the event of claims between the Parties, without Commission claims

Each Party shall indemnify each of the other Parties in respect of the acts or omissions of itself and of its employees, agents and Subcontractors provided always that such indemnity shall not extend to claims for indirect or consequential loss or damages such as but not limited to loss of profit, revenue, contract or the like and provided that the total limit of liability of that Party to all of the other Parties collectively in respect of any and all such claims shall not exceed twice that Party's Project Share - any excess shall be apportioned between all the Parties pro rata to their Project Shares.

5.2.5.4 Force Majeure

Notwithstanding any provisions on Force Majeure provided for in the EU Contract, a failure in the performance of this Consortium Agreement cannot be imputed or assumed to a Party to the extent it is due to “Force Majeure”.

The expression "Force Majeure" shall mean any unforeseeable and insuperable event affecting the Party fulfilling its obligations hereunder.

Each Party will notify the other Parties in writing of any “Force Majeure” or Force Majeure as soon as possible. The Parties shall discuss in good faith the possibilities of a transfer of tasks affected by the event. Such discussions shall commence as soon as reasonably possible. If such Force Majeure event is not overcome within six (6) weeks after such notification, the transfer of tasks shall be carried out.

5.2.6 Miscellaneous

5.2.6.1 No partnership or agency

Nothing in this Consortium Agreement shall create a partnership or agency between the Parties or any of them.

5.2.6.2 Assignment

No Party shall, without the prior written consent of the other Parties, or Parties of its own Sub-Project, as applicable, assign or otherwise transfer partially or totally any of its rights and obligations under this Consortium Agreement. Such consent shall not be unreasonably withheld or delayed when such assignment or transfer is in favour of an Affiliate of that Party.

5.2.6.3 Term and Termination

5.2.6.3.1 Term

This Consortium Agreement shall come into force as from the date defined in IPCA Part I, provided the Parties have signed this Consortium Agreement. However, this Consortium Agreement shall come into force for Parties joining on the basis of a Declaration of Accession as from the Accession Date.

This Consortium Agreement shall continue in full force and effect until terminated in accordance with this Section or complete discharge of all obligations for the carrying out of the Project undertaken by the Parties under the EU Contract and under this Consortium Agreement, whichever is the earlier.

5.2.6.3.2 Termination before Signature of the Contract by the Co-ordinator

Before signature of the *EU Contract* by the *Co-ordinator*,

- Ø Any Party may withdraw from and terminate this Consortium Agreement in respect of itself by informing the other Parties in writing of such termination (which shall take effect as of the latest date of such notice) if at its sole option it decides it will not participate either in the submission of the Proposal or in the carrying out of the Project;

- Ø The Parties may by agreement terminate this Consortium Agreement forthwith;

- Ø This Consortium Agreement shall terminate if and on the date that
  (a) The Parties agree not to submit a Proposal to the Commission; or
  (b) The Commission rejects the Proposal.

5.2.6.3.3 Termination after Signature of the Contract by the Co-ordinator

1. After signature of the EU Contract by the Co-ordinator, no Party shall be entitled to withdraw from this Consortium Agreement and/or participation in the Project unless:

(a) subject to the approval procedures provided for in Section III.3.2.4(b), III.3.2.9(b) or III.3.2.14(b) hereof, as applicable, and always provided that the notifications set forth in Article II.7.1 of the EU Contract are complied with, that Party has obtained the prior consent of the other Contractors, and also of the Commission, to the termination of its participation in the EU Contract; or

(b) that Party's participation in the EU Contract or the EU Contract is terminated by the Commission pursuant to the provisions of Article II.7.2 of the EU Contract, provided always that a Party shall not by withdrawal or termination be relieved from

- Ø Its responsibilities under this Consortium Agreement or the EU Contract in respect of that part of that Party's work on the Project which has been carried out (or which should have been carried out) up to the date of withdrawal or termination; or
- Ø Without prejudice to the provisions of Section V hereof any of its obligations or liabilities arising out of such withdrawal or termination.

2. In the event of a substantial breach, but not in case of force majeure, by a Party of its obligations under this Consortium Agreement or under the EU Contract which is irremediable or which is not remedied within one month of written notice from the other Parties, acting jointly, or from the Co-ordinator, acting on the basis of a decision taken by the General Assembly in accordance with Section III.3.2.4 (c), or Section III.3.2.9. (c) or Section III.3.2.14 (c) hereof, as applicable, such notice requiring that the default be remedied, the other Parties or the Co-ordinator (as the case may be) may terminate this Consortium Agreement with respect to the Defaulting Party concerned by not less than fourteen (14) days written notice. Without prejudice to the provisions of Section IV such termination shall become effective with respect to such Defaulting Party as of the date of such notice.

3. If any Party's participation in the EU Contract is terminated by the Commission pursuant to the provisions of Article II.7.2 of the EU Contract, or a Party withdraws from the Project, then, without prejudice to any other rights of the other Parties the provisions of Sections V.2 and IV hereof shall apply correspondingly.

General Provisions relating to Termination

4. The provisions of Section I, III.6.3(a), IV, V, VI.4, VI.5, VI.6 and VI.7 hereof shall survive the expiration or termination of this Consortium Agreement to the extent needed to enable the Parties to pursue the remedies and benefits provided for in those Sections.

5. For the avoidance of doubt, termination or withdrawal shall not affect any rights or obligations incurred prior to the date of the termination unless otherwise agreed in the EU Contract or in this Consortium Agreement.

5.2.6.4 Settlement of Disputes

5.2.6.4.1 Option 1 (Arbitration)

All disputes or differences arising in connection with this Consortium Agreement which cannot be settled amicably shall be finally settled by arbitration in Brussels under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators to be appointed under the terms of those Rules. In any arbitration in which there are three arbitrators, the chairman shall be of juridical education.

The award of the arbitration will be final and binding upon the Parties concerned.

The Parties may instead elect to resolve by mediation a dispute or difference arising in connection with this Consortium Agreement which cannot be settled amicably.

5.2.6.4.2 Option 2 (Approproate national court)

All disputes or differences arising in connection with this Consortium Agreement which cannot be settled amicably shall be subject to the jurisdiction of the appropriate national court of the Party who would be the prospective defendant in legal action on the issue.

The Parties may instead elect to resolve by mediation a dispute or difference arising in connection with this Consortium Agreement which cannot be settled amicably.

5.2.6.5 Language

This Consortium Agreement is drawn up in English which language shall govern all documents, notices and meetings for its application and/or extension or in any other way relative thereto.

5.2.6.6 Notices

Any notice to be given under this Consortium Agreement shall be in writing to the addresses and recipients listed in Section 11 of IPCA Part I or to such other address and recipient as a Party may designate in respect of that Party by written notice to the others. Notices shall be deemed to have been served when personally delivered, or, if transmitted by telefax, electronic or digital transmission when transmitted provided that such transmission is confirmed by receipt of a successful transmission report and confirmed by mail.
Written communication by means of registered letter with acknowledgement of receipt, shall be used for notices provided for in Article II.7 of the EU Contract and for notices provided for in Sections III.3.2.3, VI.2, VI.3.2, VI.3.3 and VI.8.1.2 hereof.

5.2.6.7 Applicable Law

This Consortium Agreement shall be construed according to and governed by the law provided in Article 11 of the EU Contract.

5.2.6.8 Entire Agreement - Amendments - Severability

1. This Consortium Agreement and the EU Contract constitute the entire agreement between the Parties in respect of the Project, and supersede all previous negotiations, commitments and writings concerning the Project including any memorandum of understanding between the Parties (whether or not with others) which relate to the Project or its proposal to the Commission.

2. Amendments or changes to this Consortium Agreement shall be valid only if made in writing and signed by an authorised signatory of each of the Parties.

3. If one or more of the provisions contained in this Consortium Agreement or any documents executed in connection herewith are found by the Commission or a competent court or authority to be invalid, illegal, or unenforceable in any respect under any applicable law, including competition law, the validity, legality, and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired, provided, that in such case the Parties oblige themselves to use all reasonable efforts to achieve the purpose of the invalid provision by a new legally valid stipulation that cause the same or similar (economic) benefit or burden.

5.2.6.9 Counterparts

This Consortium Agreement shall be executed in _____ [include twice the number of Contractors] counterparts, all of which together shall constitute one and the same instrument. The Co-ordinator and every Party shall each initial and sign two counterparts.

The Co-ordinator has an obligation to send copies of all the signed counterparts to each Party within sixty (60) days of receipt of all signed counterparts.

5.3 PART III

EARTO-UNITE Consortium agreement for integrated projects

This Model is offered for use at the sole discretion and on the sole responsibility of the using party. Neither EARTO nor UNITE nor the authors of this Model can accept any responsibility or liability for the use made of this Model or for any consequences arising therefrom.

5.4 PART IV

EARTO-UNITE Consortium agreement for integrated projects

This Model is offered for use at the sole discretion and on the sole responsibility of the using party. Neither EARTO nor UNITE nor the authors of this Model can accept any responsibility or liability for the use made of this Model or for any consequences arising therefrom.

Declaration of Accession to the Consortium Agreement
(to be filled in by each participant joining the ProjectI)

[name of participant (legal entity)], represented for the purpose hereof by [name and title of person written out in full (person legally authorised to act on behalf of the legal entity)] acting as its legal authorised representative, hereby consents to become a Party to the Consortium Agreement [identification of final version of the Consortium Agreement] (relating to project [title]) and accepts all the rights and obligations of a Party.

Done in 2 copies, of which one shall be kept by the Co-ordinator and one by [name of Party (legal entity)].

Name of Legal Entity [name of participant]
Name of legally authorised representative (written out in full)
Title of legally authorised representative
Signature of legally authorised representative
Date

Name of Legal Entity [name of Co-ordinator]
Name of legally authorised representative (written out in full)
Title of legally authorised representative
Signature of legally authorised representative
Date

6 Memorandum of Understanding

Source: http://www.earto.org/!PCA/MU.htm (UNITE and EARTO)

Important notice
At the time of writing, the European Commission had not yet finalised the Model Contract. The Model Contract is the standard form of contract which the Commission will use for all FP6 projects. It is possible that the final version of the Model Contract will contain provisions which could not be anticipated when this Memorandum of Understanding was drafted. EARTO and UNITE will endeavour to update this document as soon as the final provisions of the Model Contract become known. In any event, the following disclaimer applies to all information provided on this web-site.

Disclaimer
All information published on this web-site is offered for use at the sole discretion and on the sole responsibility of the using party. Neither EARTO nor UNITE nor the authors of any document published on this web-site can accept any responsibility or liability for the use made of such document or for any consequences arising therefrom.

Integrated projects

Memorandum of Understanding

This agreement is made on <DD-MM-YY>

Between
1. <PARTY 1 = Coordinator>
   and
2. <PARTY 2 - Contractor>

and
relating to the Project entitled enter the name of the PROJECT" <NAME OF PROJECT>

Whereas:

(a) The Parties, having considerable experience in the field concerned, intend to submit a Proposal for a Project entitled enter the name of the PROGRAMME and the PROJECT" <NAME OF PROJECT> " to the Commission in the Sixth Research And Technological Development Framework Programme

(b) The Parties intend to lay down rules between them with regards to the setting up of the Consortium, the preparation of the Proposal, their support or financial contribution (if any) towards the Coordinator resulting from these activities and to any further issues as the Parties feel appropriate including but not limited to Confidentiality, Management, Pre-existing Know-how etc.

(c) The Parties acknowledge that the setting up of the Proposal requires specific efforts and expenses which cannot be expected to be incurred by the Coordinator solely.

(d) The Parties express their intent to enter into a Consortium Agreement and to consent to certain principles laid down in this Memorandum of Understanding.

(e) Terms and definitions as provided for in the Model Contract shall have the respective meaning in this Memorandum of Understanding.

Now therefore it is hereby agreed as follows:

1. This Memorandum of Understanding shall come into force as of the date of its signature by the Parties and shall continue in full force and effect until complete discharge of all obligations resulting from the setting up of the Consortium and the preparation of the Proposal or the commencement date of the Project whichever is the earlier.

2. In accordance with the Model Contract and in agreement with the other Parties the Coordinator undertakes to assume the general responsibility with regards to the setting up of the Consortium, the drafting of the Proposal, the integration of the other Parties´ support or financial contributions (if any) and the negotiation with the European Commission. The Coordinator will use reasonable efforts, however does not warrant the success or positive evaluation of the Proposal.

3. The Parties undertake to use reasonable endeavours to perform and fulfil, promptly, actively and on time all of their obligations under this Memorandum of Understanding. In particular, each Party will use reasonable endeavours to supply to the Coordinator all such information, documents or support necessary for the Coordinator to fulfil its obligations pursuant to this Memorandum of Understanding.

4. Each Party shall use reasonable endeavours to ensure the accuracy of any information or materials it supplies and promptly to correct any error therein of which it is notified. The recipient Party shall be entirely responsible for the use to which it puts such information and materials provided that the Coordinator may rely on the accuracy of any such information or material with respect to the setting up of the Consortium and/or the drafting of the Proposal.

5. Each Party undertakes to contribute to the efforts and expenses incurred by the Coordinator in the preparation of the Project as laid down in Annex 1.

6. With respect to Confidentiality the Parties agree to be bound by Annex 2 of this Memorandum of Understanding. With respect to the Management of the Project the Parties consent to the application of the Management Model as described in Annex 3 for the Project.

7. The Parties fully accept the terms and conditions of the Model Contract including its Annexes with respect to the ownership of results and the mutual granting of Access Rights. In addition, the Parties consent to a security fund which shall be established on a specific trust account separated from the normal business accounts of the Coordinator. The withheld amounts shall be retained until the decision of the responsible management body that there is no further need for precaution with regard to financial risks resulting from joint and several liability towards the European Commission.

8. The Parties which invoke their right not to grant Access Rights to the other Parties with respect to their own Pre-existing Know-how are listed in Annex 4 identifying the Pre-existing Know-how which will be explicitly excluded from the principal obligation to grant Access Rights to the other Parties.

9. This Memorandum of Understanding shall be governed by the substantive law of <to be completed> . Any dispute arising out of or in connection with this Memorandum of Understanding shall be subject to <jurisdiction alternatively arbitration>, unless settled amicably. Any modification of this Memorandum of Understanding including its Annexes shall be in writing and signed by all Parties. The attached Annexes shall become part of this Memorandum of Understanding:

Annex 1 (Work Description - Drafting the Proposal),
Annex 2 (Non-Disclosure Agreement - Agreement of the Party using this MoU),
Annex 3 (Management Model),
Annex 4 (Limitations - Pre-existing Know how)

<INSERT NAME OF COORDINATOR>
Signature
Name Title

<INSERT NAME>
Signature
Name Title

7 Tutorial on consortium agreements for participants under FP6

This document has been prepared on the Regulation establishing the Rules for Participation and for the Dissemination of results under the Sixth Framework Programme of the European Commission.
As EU funded projects are a notorious example of transnational collaboration, in which participants from different cultural backgrounds, with different working methods, communication tools, etc., work towards the same goal. These projects gather different kinds of entities e.g. multinationals, SMEs, laboratories, universities, research centres...all groups with different interests. Their management forces all of their members to make an effort towards mutual understanding and cooperation in order to solve all the difficulties relating to the differences in languages, methods and, perhaps, particular expectations.

Establishing internal rules and adequate provisions regarding intellectual property rights (IPR) management is vital in order to ensure the project's success. A strong project will demand a high level of understanding; and the consortium agreement is the instrument to try to achieve it from the very beginning.

One has to bear in mind that the contract between the consortia and the Community follows the same model issued by the Commission whatever the specific nature and purpose of the project. The same contract is used for hundreds of projects that have significant differences between them. It follows that such a contract cannot foresee all the specificities of every single project (this would be impracticable). Due to this fact, and taking into account the experience of previous Framework Programmes, the consortium agreement is envisaged as the instrument used by the consortia to develop and supplement the aspects that are particular to the specific project and that are not contemplated in the model contract.

Find document at: http://www.ipr-helpdesk.org/docs/docs.EN/tutorialCA.html

8 Protecting innovation with patents

Source: Eppic Faraday Patnerships
http://www.eppic-faraday.com (/eye.html)

There are numerous ways of protecting an innovation and the Intellectual Property (IP) surrounding it and many important points to consider when implementing a strategy of protection to get the best out of the innovation. Amongst others IP can be protected using patents.

Governments originally introduced patents to encourage innovation. Patents are granted to give inventors the right of monopoly over their inventions, for a limited period (20 years from filing), in exchange for disclosing that invention to the public. The intention is to encourage further development of ideas and technology.

When a patent is granted, that invention is registered as being the inventor's (or inventors') property and it can be used in the same way as any other property.
This document contains important points to consider before and when filing a patent.

The document is available in Enclosure 1

9 Best practice in Intellectual Property Management

Source: Eppic Faraday Patnerships
http://www.eppic-faraday.com (/eye.html)

Intellectual Property (IP) is an increasingly important aspect of business today. As we move further into the 'knowledge economy', the embodiment of knowledge in the form of IP forms a crucial part of the value of a business and IP considerations underlie many important business decisions.

IP is not, however, a 'legal'issue; it is a fundamental business issue and all aspects of IP management must be considered as important business decisions. If IP is to have value, it must be prepared into an exploitable form, protected and marketed, just as any other product.

This document describes some best practice in protection and exploitation of IP, including IP in joint developments, pricing and business models.

The document is available in Enclosure 2

10 Questions and answers concerning patentin and directive

Contents

(Last update 1 February 2006)

(Last update 1 February 2006)

Questions and answers concerning patentin and Directive 98/44/EC of the european Parliament and of the council of 6 July 1998 on the legal protection of biotechnological inventions.

The information in this chapter is focussed at the situation in Europe. The situation in amongst others, the USA might differ. A table with the most important differences is published below. As regulations changes all the time the table might not be up to date. For example in 2005 a change took place in the USA patent system: it is possible to file a protest against a patent application. This gives third parties the right to file arguments and present references as to why the pending claims should not be allowed. The disadvantage may be that the third party needs to present its 'arguments', allowing the applicant ample time to prepare a defence.

Source : http://www.effab.org. Under: publications

10.1 Why is the directive needed?

In the EU there was a 30 year old patent law, that did not fit into the new developments in biotechnology and hampered both innovation and openness in research in Europe. A new directive would finetune the demands from research, industry and society with the scientific and societal developments and remove the existing legal incertainties:

- There were no ratified harmonised laws in Europe on patent rights;
- In the case of biotechnological inventions, harmonised patent law is necessary. The science base in this field is of such a high technology nature, that very substantial amounts are invested in research and development;
- There were too many different interpretations of biotechnology patents which lead to a high risk of legal 'heterogeneity' and consequently created a block to biotechnological developments in the single European market.

In other words: what was there was unclear, unharmonised and unworkable.
Research investments need to be payed back through new products, so that new investments for future products can be made. With a workable directive, there is an equilibrium between protection of research results linked to an industrial application and openness to society about the research results. Only with a workable directive, European research investments can bring new jobs and products to European companies. If European countries depend too much on health and agricultural products from other continents, they loose influence on the direction of innovations, and they fund indirectly the research in other continents.

The first step, a European patent directive, was reached in July 1998. The second step is the implementation of this directive into the national laws of the member states. It is important that there is a European wide directive, so that the competitiveness of European scientists and companies is not hampered too much if compared to scientists and companies in America or Asia. So it is necessary to harmonise patent protection in all Member States to ensure that the general principles of patent law are applied to biotechnological inventions in the same way throughout the EU. The implementation of the directive will guarantee harmonised and reliable patent protection right across the EU. It will also provide a standard of patent protection comparable with the standard that competitors of the EU can already rely on. The directive will make Europe more attractive for

investment in biotechnology and thus help create new jobs and ensure future European input in research and the spinn-off of these investments.

10.2 What is a patent?

A patent is a right to use a certain invention exclusively for a limited period (usually 20 years). The owner of the patent does not 'own' the objects that make up the invention, like an author who has copyrights on a novel does not own the novel bought at a bookshop. Patents prevent piracy of technology in a way that copyright does for literature and music.

In return for these exclusive rights the patentee must make open the details of his invention (so detailed, that someone else is in principle able to copy the result). Others can use this knowledge for further research and, when the patent period is over, use the knowledge for commercial purposes. Without patents, scientists and companies would keep scientific information for themselves. Now they are protected somehow, they can speak out and exchange information with other scientists. This encourages research.

Before a patent can be granted to an innovation, it has to filful the conditions of patentability:

- It has to be patentable. This is called: statutory subject matter. E.g. life can not be patented. People can not be patented. Patent laws do not permit this;
- It has to be novel. Only if you are the first to invent, and if the novelty has not been published yet, you can get a patent. In e.g. the U.S. patent law is different on this aspect: there you have to be the first to file a novel thing;
- It has to be an invention and not a discovery. See question 3.
- There has to be industrial application. You have to mention the industrial applications in the patent;
- You have to open your invention to others. This is called disclosure;
- You have to be clear. You have to give such a detailed description of your invention that a person skilled in the art can conceive what you write in the patent.

10.3 What is the difference between an invention and a discovery?

A discovery is about something that is found out that was already there, but one did not know. This can be determining the existence of a substance in nature. This is not patentable.

An invention is something new; in the practice it requires human intervention of a technical nature. This is patentable, if it fulfuls the other patentability requirements. In other words, if a substance is freely occuring in nature, there is a distinction between whether it is just a discovery or whether it is subsequently isolated and then used for a techncal purpose. The latter is an invention.

For example, identifying a gene sequence occuring in nature is a discovery and not an invention. Isolating a gene or a piece of DNA, and determining its utility, is an invention and can be patented.
In the guidelines of the European Patent Office it is described as follows:

To find a substance freely occuring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable.

Moreover, if that substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters and it is 'new' in the absolute sense of having no previously recognised existence, then the substance *per se* may be patentable. An example of such a case is that of a new substance which is discovered as being produced by a micro-organism. (Artical 52(3) EPC-Discoveries. EPO guidelines for examination (Part C, Ch. IV,2).

10.4 Why are there product patents as well as process patents?

In the practive, process patents do not give enough protection. In a patent you have to give an exact description of what you patent, and the industrial applications that are going with it. Sometimes, when a product has been identified and produced, it is relatively easy to produce the product via a slightly alternative process. This does not give justice to the scientist who has invented the product. If we compare it to copyrights: a novel, with a few words changed, should not be published and sold by someone else. This does not give justice to the writer.

Take the example of the hormone relaxin. Relaxin does exist naturally in the bodies of pregnant women. The processes for producing a medicine (such as the hormone relaxin) from a DNA sequence are self-evidently patentable if they are new and involve an inventive step. The product relaxin can be patented, when and if is identified and isolated through human intervention and, a step further, the DNA sequence that codes for the hormone is used to develop a technical process for producing relaxin from the decoded DNA sequence. The DNA sequence as a product as such needs patent protection like other chemical products, but we are dealing with the sequence in combination with the technical intervention, and the industrial applications as a package. So the relaxin of pregnant women in their bodies is not patented and certainly not owned!

For future research, it is such that future applications which are within the scope of the industrial applications mentioned in the patent claim, should ask permission from the patentee to commercialise these for the period of the patent protection.

For example once a DNA sequence, information about its function, and guidance about its utility has been provided by an inventor, and this has been made available to the public, others may, entirely legally, use this information to develop further inventions based upon that knowledge. These inventions may be patentable in themselves, but they would never have come about, if it were not for the efforts of the first inventor. Such further inventions may include use of the DNA sequence for uses slightly other than those indicated by the first inventor, and it is reasonable that within the limited period of protection granted to the first inventor, subsequent inventors have to obtain his permission in order to exploit their inventions commercially – so that the first inventor gets some return as well. This is mostly done via a license that the second inventor pays to the first one.

So patents neither prohibit further research and development on patented genes, nor development of therapies or diagnosis. Only if the genes are exploited commercially a patent holder can enforce his rights.

In addition, the intellectual property agreement reached in the Uruguay Round of the General Agreement on Tariffs (TRIPS -Trade Related Intellectual Property Rights) confirms the basic premise that patents should be available for products and processes in all fields of technology. If patents were to be awarded only for biotechnology processes and not for biotechnology products

(excluding from patentability subject matter such as human genes and DNA sequences), this would be a discrimination contrary to the basic principles of TRIPS.

10.5 Does the directive give special advantages to biotechnology inventions?

No, on the contrary. The patent directive for biotechnological inventions is a provision that, once implemented also at the national levels, enables these inventions to follow the same rules of patentability as other products. They do not need more protection than other inventions, just the same rules and the same certainties.

This means that the directive will not make it easier to patent biotech products than other products. It just removes the systematic disadvantage that inventors seeking to patent biotechnology products used to face in Europe, by contrast with those elsewhere, especially in the USA.

Far from widening the range of patent law for biotech products the new directive clarifies the situation, including the limits on patentability. In doing so, it will help to make evident why some of the perceived problem areas are not in fact problems at all. The directive states that body organs, nor human beings, nor animal or plant varieties can be patented. Furthermore, in the directive it becomes clear that patents related to biological material of human origin cannot be extended to its presence in humans. In the case of the relaxin mentioned above this means: the code can be patented, and consequently the relaxin made artificially using this code, but never the relaxin in the bodies of pregnant women (' in their natural state')!

10.6 Why does genetic material need patent protection?

Key issues, which require clarification, are

- why do scientists explore the human genome and its components, and
- why does industry need patent protection for genetic material ?

The human body is made up of billions of cells, all of which contain genes composed of DNA strands of chemical building blocks called nucleotides. Such genes represent the instruction manual of an organism, containing the essential information for development and life of the organism. In humans these genes comprise sequences of about 3,000 million nucleotides amounting to some 100.000 genes. Genes are present in the human body along with very many other chemical substances. The key chemicals of living organisms: amino acids, proteins and nucleic acids are made by living cells thanks to the instructions contained in these genes. Diseases can arise, if these genes contain errors or are processed inappropriately.

Often diseases can be treated successfully using traditional therapeutic medicines. However, there are many diseases for which no satisfactory traditional medical solutions are known and for which the best prospects for successful treatments require investigation and intervention at the level of the gene or genes involved in the disease process. For such diseases the key to a therapeutic solution is to get to the root cause; namely to identify the responsible gene(s) or gene product(s), understand their role in the disease process, and take appropriate action to modify the situation, e.g. of providing a missing gene product, replacing a defective gene by a copy of the functional gene, or by rectifying the way in which the gene is processed. The responsible gene, or its association with the disease, may be previously unknown and thus its identification may provide a new target for therapeutic intervention, or indicate a new way to treat a known disease. Examples of disease candidates for such gene therapy approaches include: Alzheimer's disease, AIDS, heart diseases, cancers, multiple sclerosis, and muscular dystrophy.

To achieve these objectives and provide effective treatments for patients requires immense research and development effort and investment by industry Such effort and investment cannot be made unless effective (product) patent protection is available for the key biological chemical entities (proteins and nucleic acids). In the absence of such protection there would be no financial rationale for research as there would be little or no return on the enormous amounts of investments required.

The importance of (product) patent protection for proteins and nucleic acids has long been recognised. Patentability of these materials is essential to ensure timely and effective achievement of the fundamental objectives of curing diseases, preventing suffering and saving millions of human lives.

10.6.1 But DNA and genes occur naturally, so how can they be patentable?

DNA is existent in all living matter. For instance, in man, the 3 billion bases of DNA ('genomic DNA) comprise our genes. Over 90% of this genomic sequence is believed to be 'junk'. The junk sequences are interspersed amongst 50,000 to 100,000 individual genes which determine our genetic make-up and, in many cases, predisposition to disease. Only genes which are isolated from this tangle of genomic DNA are, in patent law, novel and thus patentable. Article 5.2 of the directive deals with this point. A patent claim to an isolated DNA sequence does never 'read on' to genes as they exist in nature.

Furthermore, the DNA in patent claims is frequently claimed as cDNA (complementary DNA). cDNA is a copy of the genomic DNA without the interspersed junk sequences ('introns'). cDNA does not occur naturally (except in rare cases where a gene is not interrupted by introns) and is novel for that reason alone**.**

Raw sequence data is NOT patentable (see Directive 5.1). However, identification of genes associated with disease is far from simple. Identifying a gene (isolated from the body!) and establishing a use or 'industrial application' for it elevates the exercise to one of invention (patentable) and not one of discovery (unpatentable). The industrial application has to be included in the patent specification (Directive 5.3). Patent office examination procedures are in place to check that only what is patentable is in fact patented and examination standards are being increasingly tightened up.

Patenting natural products has been common practice in the US and Europe for many years. Provided the compound is novel, in the sense of having no previously recognised existence, then it can be claimed (see above) - provided all the other usual criteria for patentability (e.g. inventive step, utility) are established. Examples of natural products patented in the past include daunorubicin used in the treatment of tumours, streptokinase used in myocardial infarction and cyclosporin used to prevent tissue rejection in organ transplant surgery, to name but a few.

10.7 What has the European patent office ruled on human genes?

When the European Patent Office was examining an application for a patent on fragments of a gene isolated from humans - in this case it was the gene that generates relaxin (an important hormone in the process of giving birth) opponents argued that such patenting of human genes amounted to a modern form of slavery, and that patenting genes was the same as patenting life.

The European Patent Office found that the sampling had been conducted in accordance with recognised medico-ethical procedures. It stated that the allegation of slavery was based on a fundamental misunderstanding of the effect of a patent. A patent on DNA, which contained the code for human H2-relaxin or any other human gene, did not give its holder any special right over the Individual human. There was no need for humans to be the source for the protein sought once the invention had been made, and at no stage any obligation on humans to be a source. The only point at which a woman was involved was at the beginning of the implementation of the invention, namely as a voluntary source for the relaxin mRNA.

The EPO also rejected the claim that patenting genes was the same as patenting life: DNA, the structure of a gene, is not life, but a chemical substance that carries genetic information and can be used as an intermediate in the production of proteins that may be medically useful. The patenting of a single human gene has nothing to do with the patenting of human life. Furthermore, the EPO found that there is no difference in ethical terms between patenting genes and other human substances such as proteins.

10.8 Does the directive permit the patenting of life?

No. Life itself is not a material, and as such is not patentable. However, subject to specific controls and definitions, biological material and living matter such as micro-organisms, cell lines, plants and animals, are patentable under patent laws in Europe. Like with all patents, also the other patentability requirements have to be fulfilled, and this is never the case with just naturally occuring living matter. This is already there and can only be discovered, not invented. Only if something has been changed technically, the new product or living matter, and its offspring, can be patented.

The directive does not change this situation. It merely confirms and clarifies it. It is also important to mention again, that patents do not give ownership of the patented material, only the right to exclude others from commercial use of the material. This is frequently misunderstood about the patent system. A patent is only an exclusive right - to stop others practising the patented invention absent a licence. It does not give any ownership rights. One owns the intellectual property but not the patented material itself.

Controls and definitions are necessary, since patent law and wider ethical considerations must be respected. The directive does not extend patent protection for biotechnological inventions beyond the principal rules of patent law; its main role is to bring long overdue uniformity to the existing national patent rules.

This directive is not a debate over "patenting life". The real area of debate with this directive is over the precise nature and scope of the controls and definitions to be imposed. The directive confirms that man, the human body, or parts of it are not patentable. This is based not only on ethical considerations, but it also flows from the basic principles of patent law, that is to say, that only inventions may be patented, while discoveries cannot.

The reason why an element derived from humans can be patented - such as an element isolated from the body by artificial techniques, is that this may be an invention (provided the product is new, inventive and commercially applicable). For instance, the human body produces interferon naturally; the provision of the ability to produce interferon outside the body in a non-natural fashion, combined with the know-how to use this interferon as a cancer medicine, is not merely a discovery: it is a true invention, which can lead to the patenting of that interferon and the gene that codes for it.

It is important to understand the scope of the directive. Patents do not give rights to the patentee to use their invention. Judgements on how appropriate it may be to use an invention (have to) come from the legislators who impose controls on research and on the exploitation and commercialisation of its results on behalf of society. For this reason patent law as such is not really fit for ethical provisions.

10.9 What limits should be placed on patenting interventions on the genotype?

There should be clear limits on any patenting in this area. The current proposal excludes from patentability any methods of germ line gene therapy on humans, such as any intervention on the genotype of a fertilised human egg.

However, inventions relating to somatic gene therapy (that is, intervention on defective genes in cells without changing heredity) should be patentable because otherwise, promising opportunities would be missed for using biotechnology to develop new treatments for cancer and other diseases that continue to cause considerable suffering and to kill.

A society with needs and problems, and with a vision of how to respond, will encourage research that could come up with answers. Diseases have been conquered by discovery and invention, but there are still many diseases that continue to pose problems. Finding out about the genes related to these diseases is a first step towards understanding and can accelerate the process of finding effective means of prevention and treatment.

The full potential value of mapping and sequencing the human genome cannot even be guessed at today. But a better understanding of the human genome will assist understanding of the causes of disease and offer wider opportunities for developing effective means of preventing and treating diseases.

The biotech patents directive also takes account of general ethical principles, such as in the proviso that no invention may be patented if this could breach public order or morality. In addition, the directive excludes from patentability any processes for modifying the genetic identity of animals which are likely to cause them disproportionate suffering or physical handicaps without substantial medical benefits to man or animal. It also precludes the patenting of any animals resulting from such processes.

10.9.1 But doesn't gene patenting stifle research?

If a company obtains a patent on an important gene, no one else can do research on the gene and subsequently use it, and thus important (medical) advances may be delayed.

Patent law permits non-commercial research on patented subject matter, so pure research by academic institutions is not affected by the existence of patents. Patent law has a "research exemption" rule, whose goal is precisely not to block fundamental research. Any breeder or any company has a free access to patented animals or genes and may experiment in order to develop a new application of the gene or to perfect a protected method. But as its name suggests, research exemption is only valid within the confines of research. As soon as the breeder or the company develops an invention closely related to the patented one (for ex. a new application of a patented gene) and wants to commercialize it, he may be obliged to get the authorization of the patentee. The latter is not obliged to grant a license and may prevent the second invention from being commercialized.

However, in relation to commercial research it does not necessarily follow that others are irrevocably blocked as it will often be possible to negotiate a licence under the patent – or challenge its validity. The pharmaceutical industry is opposed to any attempt to impose compulsory licensing as that would undermine the incentives that the patent system provides. A better way is to rely on voluntary licence agreements as we always have done.
Finally, it is always open to third parties to obtain 'dependent patents' - that is to say, patent a new use for an already patented gene. The original finder of the gene could not then commercialise the new use without a licence under the dependent patent. This situation, which tends to stimulate cross-licensing, is inherent in the patent system. It is frequently encountered with pharmaceuticals and is in principle no different in the genomics field.

10.10 Animal breeding

The subject of the questions 10a and 10b can be found in the article of Christine Noiville 'Farm animal breeding and the law' in the report of the EC-ELSA project Farm animal breeding and society, which can be downloaded from www.effab.org under: publications.

10.10.1 What can be the effects of broad claims in animal breeding?

Although the few wide patents found today in this field particularly concern animals used as experimental models or bioreactors, there are also some examples of wide patents regarding breeding of farm animals. For instance in aquaculture, one patent claims "all transgenic fish" expressing a growth hormone gene. Wide claims are also numerous in patents covering animal genes, such as genes encoding bovine prolactin, porcine growth hormones or salmon growth hormone, which already seem to be protected by a large number of potentially overlapping patents. A first inventor has a patent on the gene and its use, which is described in a relatively abstract manner ("the muscular growth regulation function operated by the myostatin gene"). A second inventor holds claims on a more specific part of the same gene for a more specific application ; a third one...etc.

In some of the above examples, the wide monopoly is legitimate because if the inventor was only protected for what he actually achieved - a specific transgenic salmon or a specific gene - anyone could freely carry out his invention by using a slightly different gene performing the same activity or by crossing the patented gene into a different species. The patent would therefore be commercially worthless. From a business perspective, wide claims are therefore essential to obtain effective control of breeding technology. But with regard to the future of research and development in this field, important questions must still be answered. For example, should insertion of a growth hormone gene into a pig always be a basis for claims over other farm animals, even if the effectiveness of the transformation techniques on these other strains may not be known at the time of patenting? In a similar vein, in a research sequence moving from a relatively abstract idea - for ex. "a fish gene having an antifreeze function" - to detailed implementation - a more precise description and application of this gene -, who should have what rights? As a matter of fact, excessively wide monopolies can prevent the useful improvement of inventions. Several patent-law directions should be considered by patent offices and courts, such as a strong non-obviousness principle and a reasonably limited scope of patent claims.

10.10.2 What can patents on biotechnological processes mean for farm animal breeding?

Of the numerous patents on animal breeding and reproduction inventions, many are already distributed in the form of processes and some are licensed, so that effects on the breeding sector are easier to anticipate.

Some of these patents apply to specific and quite narrow situations (cloning of bovine embryos, method of producing transgenic pigs, process of culturing avian embryos, etc.) but others are broad patents on basic processes of animal breeding. For example, several broad patents cover basic approaches to the production of transgenic animals, such as a patent on genetic transformation of zygotes. Above all, a similar situation of broad patents exists in the field of marker-assisted selection tools. Here, a growing number of patents - especially in the pig sector - protect methods of detecting genetic mutations or genetic variations in functional genes that directly influence production traits, for example pigs that are resistant to stress or more likely to produce larger litters or to develop less intramuscular fat.

As the first generation of patents with a real impact in the animal biotechnology field, such patents have sometimes caused concern in the animal selection sector. The owners of these patents are in a position to require royalties from a very large number of persons working in the pig sector and the patent may be very difficult to bypass because of the broad monopoly. For instance, a Canadian company holds a patent on a "mutant RYR1 gene" and a method of identifying said gene in a pig. Claims are drafted in such a way that any method to determine the presence of the mutation is protected by the patent. Any improved process proposed by another company would be considered counterfeiting, which is all the more inconvenient when the requested royalties seem high. In these areas, it may be necessary to support public sector research and to explore ways to develop intellectual property arrangements in order to ensure that these techniques are available to the whole breeding sector at fair commercial conditions. This is particularly important for patents on methods of detecting diseases such as mad cow disease. In such situations, it would seem necessary to make adjustments to the patent system, which could rely upon a compulsory licensing mechanism tailored to this problem of broad patents.

10.11 Does modern biotechnology really help patients?

In many cases it is only biotechnology, which can make therapy possible at all. It offers patients safe treatments, vaccines with fewer side effects, and more rapid and sensitive diagnostics. And it holds out the best hope for new treatments too, for the many diseases that still remain without any effective therapy.

Using genetic engineering techniques, naturally occurring substances that provide treatment for disease can now be produced in large quantities. Previously, many of these preparations could be obtained only from animals (in the case of insulin, for instance), or from human tissue (as in the case of factor VIII for haemophilia). Today, thanks to biotechnology, these can be produced not only more abundantly, but also to the highest level of quality so that they offer the greatest safety and efficacy with the least risk of side effects. In the past, human growth hormone, for instance for treating hereditary dwarfism, could be obtained only from the brains (pituitary glands) of human cadavers. Now a single 500 litre production run using modified micro-organisms in biotechnological processes can produce as much human growth hormone as could formerly be obtained from 35,000 corpses and without the risk of Creutzfeldt Jakobs? disease contamination.

In addition, only genetic engineering makes it possible to obtain sufficient quantities of substances such as beta-interferon, which can effectively alleviate the symptoms of a form of multiple sclerosis, or colony stimulating factor, which can reinforce the body's immune system during certain cancer treatments. Previously, thousands of litres of blood were needed to produce a few milligrams of interferons and as a result, they were so scarce that their potential could not be property explored in therapy.

Over the last decade, biotechnology has also created a new generation of vaccines against hepatitis and whooping cough with a lower potential for causing side effects.

Further breakthrough vaccines developed by modem biotechnology methods can be expected, notably to protect a growing number of patients from herpes, Lyme disease, respiratory syncitial virus, and malaria; improved vaccines against cholera and tuberculosis can also be expected. Therapeutic vaccines to cure patients suffering from diseases such as hepatitis B and certain forms of cancer are also in development.

Genetic engineering techniques make it possible to identify diseases more quickly than before. With tuberculosis, for instance, a test derived from genetic engineering can detect the disease in hours, instead of the four to six weeks previously required. These techniques make it possible to treat patients sooner, and therefore more effectively.

10.12 How is biotechnology controlled?

Biotechnology is closely controlled. It does not take place in a legal vacuum.
At European and national levels laws and guidelines provide a framework of strict obligations within which biotechnology users must operate. So researchers must, for instance, provide details of research plans and any changes must be reported to committees responsible to governments. They must also record all results. In addition, medical research in patients or healthy volunteers is covered by specific medical rules and conventions, and subject to scrutiny by ethics committees.

From an ethical point of view, it is obvious that all data on the genetic constitution of an individual - which may include information on defects or abnormalities - should be kept in absolute confidentiality. This is provided for in the new EU directive on data protection

10.13 Are there risks for human health and the environment because of biotechnology?

Biotechnology is carefully controlled through an elaborate framework of legally imposed safety measures. As regards genetically modified organisms (GMOs) more specifically, there is now more than 20 years of experience, which has allowed the identification of appropriate controls. The European Union has established specific rules covering all operations involving GMOs that are often modified and adapted in the light of scientific knowledge and experience.

At a technical level physical containment prevents accidental release of GMOs into the environment. In addition, in-built biological and safety measures reduce or remove the GMOs ability to survive outside their place of application.

The deliberate release of GMOs, such as genetically modified plants, into the environment is subject to rigorous regulations under both Community legislation and national laws.

Predictions about the behaviour of GMOs can be made with the same, if not greater, degree of accuracy as for non-modified biological entities.
Specifically, the existence of patents covering such products enhances the possible control of this, and has no influence on the granting of any permission to place GMOs into the environment.

10.14 Is the biotech directive in conflict with the biodiversity convention?

No. The directive is fully consistent with the Convention. The Parliament and the Commission legal services have carefully looked at this question, and both have stated that the rules for biotech patenting will have no adverse effect on the commitments made and aspirations expressed in the EU institutions in relation to the Biodiversity Convention.

The Convention on Biodiversity, signed in Rio de Janeiro on 5 June 1992, is based on and refers to the existence of rights of protection in the field of biotechnology.

The aim of the Convention is to conserve biological diversity and to share fairly the economic advantages derived from the use of biological materials, in particular those from developing countries. They reaffirmed "the importance they attach to transfers of technology and to biotechnology in order to ensure the conservation and sustainable use of biological diversity. The compliance with intellectual property rights constitutes an essential element for the implementation of policies for technology transfer and co-investment. The European Community and its Member States will encourage the use of the financial mechanism established by the Convention to promote the voluntary transfer of technology and intellectual property rights held by European operators, in particular through the granting of licences, through normal commercial mechanisms and decisions, while ensuring adequate and effective protection of property rights".

The EU Council of Ministers supported the final outcome of the negotiations of the Biosafety Protocol at the Biodiversity Convention.

10.15 Can animals be patented?

Only offspring of animals of which the DNA is changed due to a technological intervention, that does not happen naturally in nature, is patentable. Consequently, genetically modified animals and their offspring can be patented. However, animals selected using DNA markers or similar tools can not be patented, as they are produced by normal agricultural practices.

The offspring of genetically modified animals used for day to day agricultural practices are free from patent claims. This means that a farmer can have offspring from his animals on his farm. However, as soon as the animals or their genetic material, or e.g. eggs, semen or embryos, are used for commercial reproduction, then the farmers' privilege does not apply. The details of this exemption have to be arranged in national law. It will be important to have consistent law in the EU countries. Farm animal breeding and reproduction is operating at the international level. However, European farmers are not planning to use genetically modified animals for food production, because European consumers are not in favour of genetically modified animal products. Furthermore, technological developments are still far from commercial economically interesting application.

It is more likely that genetically modified animals will be used for the production of medicines or organs for human health. Most EU Member States' patent systems (except for e.g. The Netherlands) already provide patent protection for animals per se, as does the European Patent Convention. The directive does not extend patent protection of animals, but merely confirms what already exists.

Animals can now be bred to help the investigation of new medicines for cancer, asthma, diabetes, or cystic fibrosis. Genetically altered animals can produce substances, which they would not normally generate, such as goats, sheep or cows that secrete medicines (e.g. Factor VII for haemophiliacs) in their milk. And it is expected that genetic alterations will permit animals to produce organs suitable for transplanting into humans. Demand for human transplant organs is huge and increasing, whereas the supply is stagnant at a low level. Only biotechnology can help remedy this. Other techniques of genetic modification of an animal make possible tests of promising new cancer treatments, and at the same time they reduce the number of animals needed for specific safety and screening tests.

10.15.1 Would it be possible to get a patent on an animal with modified DNA?

If you put a piece of 'worthless' DNA next to a gene or region of the genome of economic interest in an animal, the DNA of this animal is modified. Would it be possible to get a patent on this animal, and the offspring?

The answer depends on what is claimed. For a patent several conditions should be met. Apart from novelty, inventive step, enabling disclosure, clarity and statutory subject matter, a condition is industrial applicability (see proceedings patent workshop Jaenichen page 11 and 12). The industrial applicability of the modified piece of DNA might be, that it provides breeders, producers, and retailers with an improved method of selecting the best animals for their purposes. The utility of the DNA is not the genetic merit of the DNA, but in the invention of placing this easily selected sequence next to a gene of economic importance.

10.15.2 Is a patent on a DNA marker possible?

Identifying a gene sequence freely occuring in nature (not in genetically modified animals) is a discovery and not an invention. An animal carrying this gene sequence can not be patented, just because someone can identify the gene sequence or indicate what the function of a gene sequence is, nor can his/her offspring. Isolating a gene or a piece of DNA, and determining its utility, e.g. developing a selection test based on the sequence information may be an invention and can be patented. However, animals selected using DNA markers or similar tools cannot be patented, as they are produced by normal agricultural practices (e.g. mating or artificial insemination resulting in crossing of genomes).

10.15.3 Is introgression, or the offspring of the animals bred through introgression, patentable?

The process of introgression is not patentable. Introgression is crossing of genomes, and a natural biological process. Normal crossing and selection is not patentable under the EU patent directive for the protection of biotechnological inventions, being essentially biological processes for the production of animals (article 4.1.b and article 2.2).

However, introgression may be used to move a gene inserted by genetic modification into an animal. If a certain animal is subject of a patent, than his/her offspring is also subject of the patent, both from introgression as well as from crossing.

10.15.4 Is offspring a subject of the patent?

If an animal is subject of a patent, because it is genetically modified, and it is producing offspring, such that some of the offspring do not carry the new DNA information, is this offspring a subject of the patent?

No. This offspring is not subject of the patent, because it does not have the DNA on which the patent claims are based. Article 8.1 says that the patent is valid for all the offspring 'possessing those same characteristics'.

10.15.5 If a farmer sells a genetically modified and patented cow to his neighbour, and this cow gets a calf, is this calf subject to the patent?

Farmer's privilege. A genetically modified animal can be used for normal farming purposes, but not for a commercial reproduction activity. If a farmer sells a genetically modified and patented cow to his neighbour, and this cow gets a calf, is this calf subject to the patent?

No, if the calf is used for normal farming purposes. If a genetically modified calf (carrying the patented DNA) would be used as a parent animal for breeding purposes, e.g. embryo's taken of the cow or a bull used for artificial insemination, then this offspring would be included in the patent.
The key word in this is commercial reproduction activity: acting like a breeding company, small or big, is a commercial reproduction activity. Day to day farming, e.g. a cow getting a beef calf, a cow getting a milk calf for replacement on the farm, a sow getting piglets for meat production, is not. However, a sow giving birth to piglets that will be used as a sow or a boar for sales purposes should be subject of the patent. I.e. it is not allowed to act as a breeding company with patented animals. (article 11.2).

With the farmer's privilege, which is an exemption from traditional patent law, the E.U. directive tries to establish an equitable solution whereby both the farmer and the patentee will benefit from the invention. Article 11.3 leaves the implementation of article 11.2 to national law. It is important that this will be the same or at least similar in all the EU countries.

10.15.6 Information

For information: the following on the farmers' privilege can be found in the article of Christine Noiville 'Farm animal breeding and the law' in the report of the ELSA project Farm animal breeding and society, which can be downloaded from www.effab.info under: publications

10.15.6.1 The exemption

As far as he is concerned, the farmer appears to have the legal right to mate the patented animal and to perpetuate offspring without royalties. As long as it is for an agricultural purpose (milk, slaughter...) and not for a commercial reproduction purpose, it is not an act of infringement to reproduce a patented transgenic farm animal through breeding, to use such animal in the farming operation, or to sell such animal or the offspring of such animal. Though it is still difficult to know whether this exemption will be worthwhile for the farmer - because little is known on the genetic drift of transgenic animals - such a rule will be important especially for small farmers who intentionally reproduce animals.

Acting as a breeding company, however (selling the germ cells, semen or embryos of a patented animal) is considered to be commercial reproduction and is forbidden, as it is in direct commercial competition with the patentee. The patent holder has the legal right to forbid such use of his invention or to claim royalties. Nothing is clear, however, about application of the derogation, which is left up to the different countries' responsibility.

10.15.6.2 Application of the derogation

Firstly, states will have to specify exactly what the exemption means: does "pursuing of the agricultural activity" include the reproduction, by a farmer, of a patented transgenic sheep producing a therapeutic molecule in its milk?

Does "livestock" include aquaculture fish? Secondly, states will have to take a position on a more fundamental issue: the control of transfers of genetically-modified, patented animals between farmers.

In fact, although this may vary according to the species, patented animals will be dispersed from farm to farm. For example, in the beef cattle sector, transfers between farms are frequent and types of use are varied (bulls sold for immediate slaughter, for breeding purposes, etc.). Logically, the patentee should then sell breeding stocks with a side contract specifying the requirement to indicate any transfer of semen, embryos or animals. He could then monitor each transfer of patented animals, identify transfers for "commercial reproduction", test each animal and check which ones carry the patented genetic modification, and finally ask for royalties. But such monitoring seems highly difficult: is it realistic to expect farmers to become involved in such patent enforcement?
Is a monitoring of sales and collection of royalties possible given the large volume of sales and numerous changes of ownership? Facing such difficulties, the patentee may find that policing to collect royalties is unnecessary and that marketplace solutions present the most efficient method of allocating the cost of enforcement. He may carry out no monitoring and claim no residual rights to fees but merely sell the animal for a higher price.

Today, national authorities tend to let companies and patentees find such marketplace solutions. Their first reaction is to transcribe the farmer's privilege "a minima", without any special rules, and to let things evolve as regards choice of companies commercializing G.M. animals. But such a solution may not be satisfactory, for two reasons. Firstly, a "pricing policy" could make the cost of the patent prohibitive and ruin the usefulness of the farmer's privilege, whose idea is to prevent, for practical but also for economic reasons, the payment of excessively high prices. Secondly, although patent law does not itself require any monitoring of animal transfers and uses, such monitoring may soon become mandatory since traceability requirements are emerging in the field of GMOs, in order to prevent ecological consequences or sanitary risks and to establish separate channels - genetically / non genetically modified animals and food derived from them - leaving the consumer free to choose. In the same way as it is already enforced in the bovine sector, traceability may oblige those concerned to organize the close monitoring described above, instead of simply choosing "pricing policies". For this reason, it appears necessary for States to participate, alongside breeders and farmers, in a global reflection on the articulation of patentees rights, farmer's privilege and traceability issues (which system, who pays ?...).

10.16 Ethical questions concerning the patenting of inventions in farm animal production

The questions and answers 16a, 16b, 16c and part of 16d are based on the article of Peter Sandøe ‘Ethical questions concerning the patenting of inventions in farm animal production’ in The proceedings of the Farm Animal Industrial Platform workshop on the EU patent direcive for the farm animal production sector. These can be found on www.effab.info/985proce.htm.

10.16.1 Does patenting go hand in hand with a lack of respect of nature? And do patents violate our common ownership of nature?

The argument for the first question is "in accepting patenting of inventions that include naturally occurring biological material, we sanction a view of nature as a mere resource". However, nature possesses inherent value and should be treated with respect. Michael Fox: "The genetic engineering and patenting of life forms reflect an exploitative and doministic' attitude towards living beings that denies any recognition of their inherent nature."

Against this it may be objected:

- Ø Patents are not what turn nature into a resource. It is because we already want to make use of natural resources that patents are interesting.
- Ø If patents are banned within biotechnology, this will not stop us from viewing nature as a resource. Rather, it may prevent us from making use of specific natural resources.
- Ø If these resources are of vital importance, a ban on patents may itself create an ethical problem.

Although often the first and second question are presented together, it is interesting to see that they do not sit well together. The first presupposes that we should leave nature on its own, and the second that nature is owned (by mankind). The latter view clearly implies that you are allowed to use nature for the benefit of mankind.
The patent directive permits the patenting of a range of types of biological material. However, it may be asked whether this is compatible with the view that nature is shared property of mankind as a whole. A particular problem here is the so-called "farmer's privilege".

This claim can be met, arguing that mankind has no use of a shared property if there is no incentive to realise the potentials of that property. Also, in the EU patent directive for biotechnological inventions protection of the patent holder's right is limited so as to uphold farmers' privilege'.

10.16.2 Do patents violate the property rights of people living the third world?

It is interesting to see that this claim is often used on top of the two previous ones. Nevertheless the third claim presupposes that nature may be owned by man and is therefore incompatible with the first claim. Furthermore it is also incompatible with the second claim. This claim implies that nature is owned collectively by mankind, while the third one implies that natural resources are owned by those who inhabit the area where the resources are found.

A great deal of biological material that is of commercial interest in agriculture originates from plant or animal species found in the third world. However, the inventions that are made on the basis of this material will typically be made and commercially exploited by scientists and companies in the rich countries. This - it may be argued - is a form of exploitation of people living in the third world.

Ownership to natural resources that form the basis of biotechnological inventions is clearly an important issue. However, it may be argued that this issue should not primarily be dealt within the EU patent directive. This is primarily a subject for WTO (TRIPs) and UN (Convention on Biodiversity). Of course, it could be required that an invention is only patentable if the Convention on Biodiversity and other like international agreements are complying with.

10.16.3 Will patents boost an unsustainable development in agriculture?

Patents will - allegedly - be used to accelerate agricultural developments in which pesticides and other agrochemicals play a crucial role. However, this is at a variance with the ideal of a sustainable development, an ideal which envisages the phasing out of pesticides and other agrochemicals.

There is a discussion to be had whether sustainability means no use of agrochemicals' rather than wise use'. Furthermore there is no reason to believe that agrochemicals are an essential component of future biotechnological inventions within agriculture. Finally, to deal with the challenge of feeding the growing world population in a sustainable manner, there is a huge need for progress within agricultural biotechnology.

10.16.4Do patents have an adverse effect on animal welfare?

Patenting will mean that biotechnological inventions are used more widely and with greater frequency in farm animal breeding. The farm animal breeding and reproduction industry, together with scientists, ethicists, an animal welfare organisation and sociologists, are now looking into details what are the future possibilities and constraints in animal breeding and reproduction. Together they will come with sustainable, acceptable and economically viable breeding strategies. Biotechnological developments will be an important part of this study. The EU Patent directive for biotechnological inventions does contain a specific animal welfare clause. It says that processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes ... shall be considered unpatentable (Article 6)'. Interestingly, this will mean that to animal welfare is better looked after when biotechnology is used than it is with traditional selective breeding.

The use of transgenic animals in pharmaceutical research allows for a considerable refinement of the need for trials on animals. In this way animal experiments that yield less relevant results can increasingly be avoided. And biotechnological test techniques themselves make it possible to replace altogether some tests that were previously conducted on animals, shifting from *in vivo* testing to *in vitro* testing, where no live animals need to be used.

10.17 Is patent protection for biotechnological inventions not just a way to make money out of exploiting nature?

Since mankind stopped being a hunter and moved to agriculture, he has been using nature for his own benefit, say: exploiting it. Since the industrial revolution fewer people need to provide the food for the 'citymen'. The 'first and second' world now have reached a level of wealth, which depends on this use of nature. The third world is developing and will, in the future, be in the need of food. Biotechnological and tradtional developments in agriculture will be necessary to meet this demand.

Biotechnological research is expensive, and needs patent protection to reward the inventing scientists. There is, however, an important area for debate in Europe on the appropriate ethical limits to biotechnology. That is the reason why the European Commission has set up a special committee on the ethical implications of biotechnology under the chairmanship of Mme Noelle Lenoir - a distinguished member of the French Conseil Constitutionnel. There is also a Commission unit in the Research Directorate General dealing specifically with ethical, social and legal aspects of life science research, and the European Parliament frequently examines different facets of the subject. So, setting appropriate ethical limits to biotechnology is an important task, which is being undertaken both at a European and national level. The patent directive is aimed at promoting European research, and no amount of modification to a directive on biotech patents would do anything to increase the attention given to ethics by national and European authorities.

On the contrary, ill-considered or premature interference with the draft directive on supposedly ethical grounds could actually lead to distinctly unethical consequences: European patient groups, anxious for new products for currently untreatable diseases, have warned against the risk of delaying the passage of a measure which holds out hope for many of their members.

10.18 Do patent regulations really influence the future of biotechnology in Europe?

Yes! The regulatory climate is of key influence on the investment decisions of research based companies. R&D in biotechnology is more expensive than in many traditional branches of science

and technology, and there is no guarantee of generating a product that can be marketed. Therefore, investments in biotechnology R&D must have protection. Patents offer a method of protection by granting the investor a limited period during which no-one else can make commercial use of the invention without the permission of the patentee.

In this respect, Europe is at a disadvantage vis-à-vis the United States and Japan. These countries have better intellectual property protection for biotechnological inventions and the technology meets with a wider acceptance in society and in political spheres.

In the US, about 1300 companies are investing in biotechnology today, as against 584 in Europe. Investments in the US exceed ECU 7 billion; in Europe they total only ECU 2 billion. As for the number of biotechnology patents granted, the US holds a dominant position. In fact European companies are to some extent dependent on licenses for these inventions, which obviously puts them at an economic disadvantage. Moreover, European companies contribute to the development of the biotech infrastructure in the US and Japan with investments amounting to ECU 3.5 billion. Europe is on the forefront in world animal breeding. Keeping this competitive position means being able to influence the performance of livestock in the future. For this, precompetitive research, the protection of research results, and similar regulations regarding research results in the EU member states will be essential.

To illustrate the problem, the US Office of Patents and Trademarks issued 350 genetic engineering patents in 1995, according to an analysis by the Pharmaceutical Research and Manufacturers of America (PhRMA). Of those, 150 were healthcare patents, and the vast majority 81 percent were of US origin The EC was a distant second with 7 percent and Japan third with 4 percent. US corporations received 47 percent of the 150 genetic engineering healthcare patents issued in 1995.

Table 1: Differences USA vs. Europe patent applications

	USA	Europe
Filing	Grace period 1 year	Before publication (paper or oral)
Scope	All transgenic animals	1) Farmers' privilege – farmers can use patented material on their farm, but not for resale 2) Exclusion animal breeds
Research exemption	No infringement until a late stage of clinical trials.	No infringement for research for non-commercial acts.
Ethics	-	No harm to farm animals unless strong human benefit
Inventions	Inventions and discoveries (however, no 'products of nature')	Inventions only
Filing costs	One language	Translations and national filing*
Protest	File protest when application is still penting	-
Opposition	Any time	Within 9 months when patent comes out

***** Community patent: patent law measure being debated within the European Union, which would allow individuals and companies to obtain a unitary patent throughout the European Union, and avoiding translation costs.

11 Frequently asked questions about contracts

Contents

The list with frequently asked questions about contracts is meant as a check list. As an expedient to check if the most important questions (out of this list) for your institute / company are covered in the contract.

11.1 Rights and ownership

1. Clear definition of intellectual property rights, in particular when various kind of national scientific bodies are involved.

2. Which policies and agreements for the exploitation of results should be built up when a non-profit organization and a profit organization are involved in the agreement?
   (In other words, sometimes organizations with different statutes objectives and constraints need to find an agreement that should not collide with their ruling constraints.)

3. Who is in charge to protect a generated knowledge?
   There might be particular difficult situation such as: a partner intends to protect generated knowledge in the country of another partner that has interest to keep the generated knowledge free of protection.

4. Intellectual Property (IP) ownership. What background IP will the company need to license to the University to get the project work done (if any) and who will own any new IP stemming from the project? Usually the industrial partner will want to own all new IP in return for paying full overhead costs under an industrial research contract. What are the options / rights for each partner on completion of key milestones?

5. The industrial partner will need access to the project staff / documents under an agreed protocol. Which Company staff will be used in the project and how will they be deployed?

6. How will the project be concluded and what are the final outcomes on options / ownership?

7. Access to results (royalty free licenses?) Who owns the results (depends on 'kind of research')? What are the conditions?

8. Who owns the patent in case of invention (generally, in Germany the patent is owned by the research institute)?

9. Right to use is more important than property. The industry that partly funds research projects expects the right to use the new technology developed by supported research institutes at reasonable and preferential (no) costs.

10. IP ownership: this is often an issue and it is best to try to deal with as much as possible at the outset of a collaboration. Each party should try to take a reasonable stance on value of the IP and the inputs of the parties involved (resources as well as intellectual). Industry partners are likely to want a first option to negotiate a commercial licence as a minimum.

11.2 Confidentiality

11. Diffusion of outcomes of the research to third parties, when signatories parties are bound with the use of the results, and management of confidentiality during the research period: there are some provisions about it but in general terms.

12. Confidentiality - who are we dealing with at the University and how do we keep the discussions / project confidential?

13. What information is confidential?

14. Confidentiality: The collaborations often need confidential background information (from both sides) to implement a project. It is important to make sure that confidentiality of this information, as well as foreground information generated in the project (as above re publication and disclosure) is respected.

15. Language of writing: in some situations contracts may be written and in French and in the other language: complicated, expensive etc. A possible solution is acceptance of English by anybody.

11.3 Government

16. Appointing competent court that settle up disputes (when all tentative to settle up "gently" the dispute have failed).

17. Who decides which law is the one governing the contract? How can we have a neutral law? Does a European standard or recommendation exist?

11.4 Publications

18. How can a simple standard protocol to publish the outcomes of the research in a scientific magazine be produced, avoiding to wait for long a time without being obliged of receiving signed agreements from every partner?

An issue which may be unique to some organizations is that they may have a mandatory in house publications review process which may take up to 6 weeks, involving legal council as well as scientific review, and this level of lead time is invariably alien to academic collaborators, especially when applied even to something as simple as a poster at a minor local scientific meeting.

19. Publication/disclosure: Important to recognize the importance of the academic institution to publish, but it needs to be balanced with the need to avoid eroding any potential IP. So good communication between the parties (industry and academia) is important. Both parties need to be fully involved and aware of potential publications from the collaboration and have the ability to review each others potential publications before they are submitted (this includes posters as well as papers in journals). This gives chance to avoid premature disclosure and erosion of IP. Timing is important here – contracts usually specify a reasonable period to review and respond to draft manuscripts, however, it is not unusual to receive a request on a much shorter timeframe. Sticking to agreed timetables is simply good practice that should be adhered to by all.

20. How to deal with publishing without prior consent?

21. How are publications treated (Researchers have to publish, but publications have to be reviewed by industry that no confidential information is published)

11.5 Time

22. What is a proper time span for legal objections, or for receiving permissions from other partners.

23. Failure to meet deadlines in the project - passive attitude to all except the invoice!

24. How important are go/no go moments?

11.6 Contradictions groups

25. We have evolved agreements which are usually acceptable to ourselves and both academic and research institutions but for groups new to the process, there can be quite protracted discussions

26. Difficulty in getting a contract prepared - researchers not really bothered to sort it out

27. What are the conflicts between the academic institute's requirements for staff to publish versus the industrial partner's requirements to patent? A protocol must be agreed.

28. What input comes from industry (only third party funds or material as well?)

29. Contract should reflect a real partnership.

11.7 EU funding

30. Is my contract involved in Funding from the European Union?

31. If I want information about EU-funding, whom should I contact?

11.8 Other

32. What will the research cost and how will costs be managed by the academic partner?

33. Additional issues may arise relating to staged payments if these are dependent on reaching certain milestones and if the collaboration involves animal experimentation, agreement on our requirement to inspect facilities and procedures and to have ethical review of protocols. How will any academic staff be managed to deliver on time under key milestones? What is the penalty for failure?

34. How do I know if the contact person at the university or institute is legally allowed to sign an agreement?

35. What are the costs/efforts, according to the research project, subscribed to the different parties.

36. License fee for third parties (industry that has not supported the research) should be higher than for industry partners, but at a level that allows to widely use the new technology (generate money for covering investment costs of all! partners and financing further research). Exclusive agreements that prevent wide use should be avoided.

11.9 Remarks

It would be nice to have clear guidelines what a good and fair contract should include.

Problems are:
- Lack of interest
- Lack of information
- Interaction between the two (not looking for information)

Possible solution: basic information, simply worded, drawn or whatever to create a basis for interest.

11.9.1 Problems with research contracts

Its all down to people!
With the best wil in the world, if you can't get on with the person you are dealing with no amount of contractual details is going to make it work.

Interesting sites with regard to frequently asked questions:
- http://europa.eu.int/comm/internal_market/en/indprop/patent
- http://europa.eu.int/comm/internal_market/indprop/index_en.htm

Acknowledgement: This list has been compounded by the Knowledge Management Working Group and several members of the Club of Interest.

12 List of Lawyers specialised in contracts

In this document lawyers located in several countries are listed who could be contacted in order to contact to ask for advice about contracts. If more contact details of lawyers (in other countries) come available this will be included in the information at the webpage www.eadgene.org.

Common Frame of Reference in European Contract Law (CFR)
www.eu.int/comm/consumers/cons_int/safe_shop/fair_bus_pract/cont_law/cfr_net_members_en.pdf

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