DeDrug

"They finally did it!" It is Friday, June 11 2004 and Olga is enjoying the evening sun on one of the many terraces in the University City she lives in. Waiting for Nicole -one of her colleagues at the lab and also a good friend- and sipping a cold glass of white whine, she happily relives what has happened today.

This afternoon they received the proof that they had mastered the final step in their synthetic strategy. Meaning that they were definitely able to make stable mRNA in very small quantities in an automated way. It was the last of the three crucial steps they had developed. Already 11 months ago they had filed for a patent, so the results came just in time to update the patent application.

Of course, the molecular backbone itself had been known for quite some time. But the synthetic route needed to be optimized to work in the robot. Lots of people had tried to do it before but without any success. Last week the novelty report containing the results of the search for prior art had come in. The patent attorney had called and he said that no prior art had been reported. She had been so relieved that she hardly heard his remark that there was something about an old patent. "The novelty report will be in your mail soon. Take a good look at it and you will see what I mean" he had said.

Hans had been very helpful. Hans had been a post-doc in her group until he made his move to the pharmaceutical company GrossFar AG some six months ago. Without his suggestions they probably would not have succeeded. Wonderful how he was still keeping contact and thinking along. His boss –prof dr Otto Schmidt- was very nice too, not at all the type you would expect a German professor and research director of a Big Pharma company to be. Together with Hans he had visited the laboratory last week. He was genuinely interested in the research they did and quite knowledgeable with regard to the synthetic work.

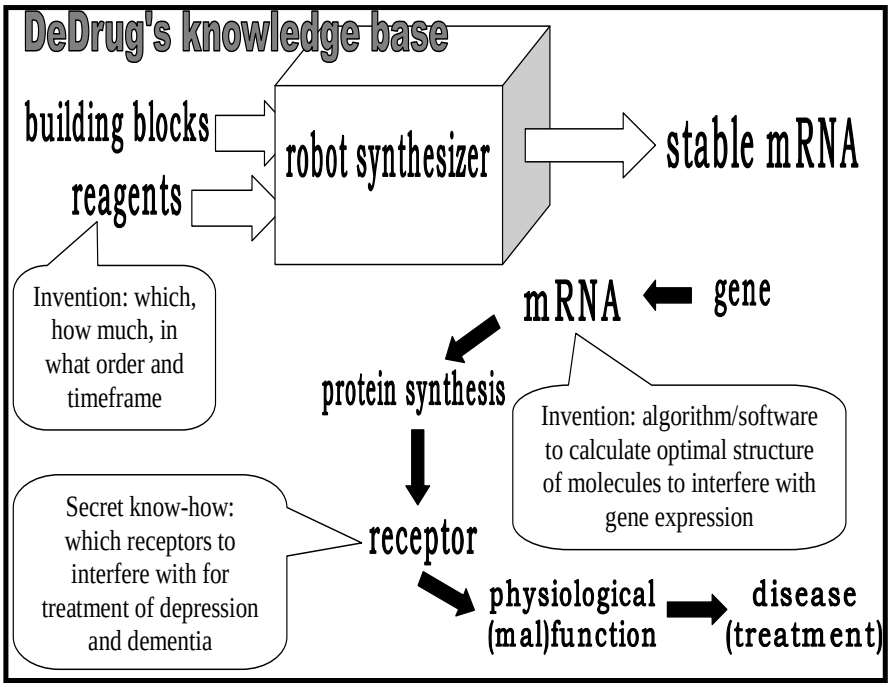
Nice was not the word she would use for Dave, a colleague from the US who two years back had spent his sabbatical in her group. Romantic summer it had been until that terrible row. On a conference, a couple of weeks back, she met Sheila, a colleague working in the same University department as Dave. For the first time since he had left in quite a hurry, his name had come up. Gossiping, Sheila told that some two years ago –just after he had returned from Holland- Dave had been very excited about patenting some algorithm. Cautiously, Olga had asked what it was about but she had no idea. Sheila had thought it quite typical of him that afterwards they had not heard about it anymore. Dave was well known for his wild and mostly not very practical ideas.

That might be so, it still got Olga very worried. Already some three years ago, she herself had developed an algorithm that she treated like a sort of trade secret. With the help of a colleague in the legal department she had even non-disclosure agreements (NDAs) set-up and signed by her co-workers. Dave hadn't been involved in the software development so she didn't let him sign the NDA. But as they had been quite close, they had talked about it and he certainly was clever and devious enough. She had always been convinced that things like algorithms and software couldn't be patented. An extensive search of patent applications had not revealed anything. If he had filed for a patent, it surely would have been published by now, so probably there was nothing to it.

She had thought it all out so carefully. Her background was in neuroscience. Trained as a biochemist she had done her Ph.D. in the neurology department of the Academic Hospital, focussing on brain disorders. She had become an expert on the role of nuclear receptors in depression and dementia. What made her extra motivated was that her brother, suffering from depression –it ran in the family- had killed himself. She was convinced that she would be able to develop new drugs against depression and dementia by better regulating the function of these receptors. That was primarily what she developed the software and new synthetic routes for. With stable mRNA, the expression and function of the nuclear receptors could be selectively altered. Based on her previous studies, she was quite sure

which receptors she should target –and how. Those were her secrets she had not shared with anybody, not even with her supervising professor. So it was a matter of doing animal studies to establish proof of principle and then claiming the mRNA-structures and all other molecules that could perform the same function. For this, she wanted to establish the company DeDrug which would also do the further design and development of the drugs for dementia and depression. She had all the right contacts for it. The heads of various clinical departments had already said they would gladly cooperate in setting up the studies with their patients.

But that was far away. First she had to establish the company, make a deal with the University, write a business plan and raise money. Although her idea was that initially she would not have to raise that much money at all. As DeDrug would focus on dementia and depression, others could use the software and synthetic pathways for different purposes. And pay for it, of course!



She knew the software would be in high demand. With the unique algorithm they had developed, it was the only tool that could effectively predict the bond strengths of molecules interacting with strings of mRNA and vice versa. And so, it was ideal for optimizing molecules that were to mediate gene expression. Three other groups had tested the software (of course she had not provided the source code!). They were extremely enthusiastic after lab experiments had proven the calculations were spot-on. Somehow, a guy from MicroDyne –a company specializing in scientific software- had got word of it. Last week, she had talked to him over lunch. Nice guy! More importantly, he had said that MicroDyne would be interested in acquiring an exclusive license for distribution of the software. He thought sales could easily reach ∈ 1 million per year and that he might convince his company to pay a 20% royalty, next to some money for after sales support. Of course, some time and money would need to be invested to professionalize the software. He had asked what kind of platform they had used for the software. As she didn't know she had dodged the question. Later, she had asked her brilliant but not so communicative programmer, who had confused her with computer jargon. Right before the conversation ended because her next appointment entered the room, he had mumbled something about a copyleft software license. No clue as to what it meant, she still had to follow-up.

Similarly, the synthetic route they had developed would be broadly applicable. Many researchers in genomics and proteomics would want to have specific strands of stable mRNA synthesized. DeDrug could develop such business itself though this could naturally be quite a burden. Perhaps it would be better to license the method to a company, e.g. to one in the business of synthesizing stabilized DNA. It would certainly fit the customer base. Or perhaps to a company that fabricates DNA-synthesizers like the one they implemented their automatic synthesis on? They could license their customers, perhaps as part of the sale of specific chemicals that were necessary to do the synthesis. Of course,

both the software and the synthetic routes were not to be used for the purpose of targeting nuclear receptors for the design of drugs against depression and dementia. However convinced she was that her secret ideas were superior to what anyone else was currently pursuing in the area, she certainly did not want to help the competition! Surely, it would be possible to restrict the use of the technology to non-nuclear receptor research?

Yesterday, she shared her ideas for establishing a business with a dear friend. She secretly hoped her friend might be interested in helping her, even joining the company in the future. Instead of being enthusiastic, her friend had frowned. Yes, she thought the scientific and technological accomplishments were great, but she had doubts about the business approach. At the end of her studies –also Biochemistry- she had followed some introductory business courses. And from the little it had taught her about patents, she had the distinct feeling that things wouldn't work this way. But what did she know? "Go talk to that patent attorney," she had said. Surely, she should have done so a long time ago but there were so many questions and there was so much to do!

Upon hat rather negative response, Olga had felt that her friend was not really open to the idea and had changed he subject. And there were so many more things she had wanted to discuss with someone. There had been this contract with a biotech company. It was about a different project, but the researcher assigned to it –and named in the contract- had in reality helped in realizing one of the synthetic steps. He might well be co-inventor. Given the good work he had done she felt obliged to name him as one of the inventors on the patent. But might that mean that this biotech company would be entitled to the invention? They probably wouldn't find out anyway, but just suppose they did?

And what about the EU-project they entered into four years ago? The software development had been part of it. As she had been told was quite common, the collaboration had not really come of the ground. There had been some meetings, which were agreeable enough, but in practice every contractor had done the research for themselves and had sent their report to the coordinator who would try to make it look like a concerted action. Some 3 months back the EU-project had ended and she had duly reported about the software, without going into too much detail though, she was not that stupid. Still, she regretted she had reported at all. Though she had not had much choice, not willing to come in the position of having to explain to the University administrator that for commercial reasons she might forfeit € 20,000 she couldn't cover out of her research budget. But soon the draft report would be distributed and one of the industry members of the consortium might actually read it. Then he or she might notice what the software could do and she wasn't all too sure that they wouldn't be entitled to some sort of license. She couldn't really remember what was in the consortium agreement; it had been made up over four years ago! She should have looked it up before letting the report be sent to the coordinator, why hadn't she?

Only once so far, Olga had given a presentation on the business opportunities her research had to offer. It had been at one of the network meetings on the science park. Her talk went really well. Coached by one of the organizers, she had skipped all detail and hardly touched upon the science. It had met with great enthusiasm. In particular Tom had shown interest. Tom was an informal investor who had made his money by developing and selling analytical equipment and software. Last year he had sold his business. Tom had introduced himself to her by saying that he looked for an opportunity to invest his time and € 500,000 in. They had discussed how DeDrug might develop. Tom seemed very motivated to help establish a drug-oriented biotech company, even though that was not really his expertise. He thought the best way forward would be to create an alliance with a big pharmaceutical company. They had discussed this at length. Finally, Tom had said: "I really think this is an interesting opportunity. Of course, if I put my money in, I would want to be CEO, you will understand that. So what do you think, would it be an idea that I sign an NDA so I can have a look at the information you have available?" Tom's direct approach had overwhelmed her. She felt she would be losing control. She feared that going into business with Tom might steer DeDrug in a totally different direction than she aimed for. So, finally she had said she would think it over and –wanting to sound business like- would let him know within two weeks time. The day before yesterday, Tom had called

to ask if she had already decided or that there was anything he could do to help her reach a decision. “No”, she had replied, “but I will let you know on Monday.”

She had made some enquiries with people at the University who knew Tom a little better. They all had been rather positive about him, said that he really had built a business from scratch. “His major problem seems to be that he can be so very pushy. I know some people who for that reason do not want to deal with him anymore”, was the most negative and not very surprising comment she had heard. She really did not know what to do. She felt that she was not ready yet, that there were still too many issues and uncertainties to be resolved. They would certainly put Tom off, would they not? She really felt like just saying “no, not now, perhaps later”. But then, Tom might find another opportunity and there would be no later. What should she do?

How on such a glorious day could she become so depressed! If that was the result of all her efforts, perhaps she should just forget about it. Perhaps she should look for another position, try to become full professor at some second rate university. She is happy to spot Nicole arriving on her bike. In spite of her gloomy thoughts, Olga greets her with a cordial “glad you are here, let’s celebrate our achievements!” Nicole has a piece of paper in her hand and a very worried face. “Good idea. But I think you’d better read this first”, she says.

The piece of paper bears a short e-mail from Hans. It reads:

Dear Olga,

I am so sorry to have to tell you this. Our legal department just informed me that my company wants to claim co-ownership to the synthesis based on the fact that I should be considered co-inventor and that the company owns rights to everything I do. Don’t know how to handle this! I’ll try to reach you by phone asap, please also try to call me.

Cheers -Hans

Attachments:

- novelty search
- patent abstracts
- contract with company who funded the researcher partaking in synthesis development
- (relevant parts of) standard EU consortium agreement

INTERNATIONAL SEARCH REPORT

International application No.
070562143.4

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : C07H 21/00C4, G06F 17/12
US CL : 536/24.5; 514/44; 435/375
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 536/24.5; 514/44; 435/375

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	**WO 020568432.6 A2 (GrossFar A.G.)15 December 1988 (15.12.1988), whole document**	1-25, 32-34, 41-45

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 November 2003 (16.11.2003)	11 June 2003
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Janet L. Epps-Ford, Ph.D. Telephone No.

Form PCT/ISA/210 (second sheet) (July 1998)

Abstract Universiteit West-Holland patent application:

(75) Inventors: Kratzky Olga, Houtdrager Hans J, Naser Rolf G, DeWit Nicole AM

(73) Assignee: Universiteit West-Holland

(21) Application number: 070562143.4

(22) Date of filing: 11.07.2003

(51) International Patent Classification: C07H 21/00C4, G06F 17/12

(54) Title: The automated synthesis of stable mRNA strands

(57) Abstract: The invention consists of a method of synthesizing stable mRNA strands in a robot synthesizer. The procedure enables the synthesis of very small quantities in a clean and highly efficient manner and involves very specific reagents and programming of the robot.

Abstract GrossFar patent:

(75) Inventors: Schmidt Otto, Simmel Wolfgang

(73) Assignee: GrossFar AG

(21) Application number: 020568432.6

(22) Date of filing: 15.06.1987

(43) Date of publication: 15.12.1988

(45) Patent assigning date: 23.11.1989

(51) International Patent Classification: C08G 79/04

(54) Title: The synthesis and structure of a stable RNA backbone

(57) Abstract: the invention provides a backbone structure and methods to synthesize the backbone structure which can be used to make stable RNA (RiboNucleic Acid). It consists of ribose units alternating with phosphate groups. The backbone is formed as the 3' hydroxyl group on the ribose connects with the phosphate, and this phosphate connects with the 5'hydroxyl group of another ribose unit. An efficient and short synthetic route has been developed to synthesize this backbone with ribose as a cheap starting material. Stable RNA is a promising tool for sequence-specific regulation of gene expression and for the preparation of gene targeted drugs

UWH/1999/086 February 10, 1999

AGREEMENT

BIOSYN Limited, Woodstreet 1-100, Woodcity, UK, hereinafter to be referred to as: BIOSYN,

and

UNIVERSITEIT WEST-HOLLAND, having a place of business at Onderzoeksweg 1, WEST-HOLLAND, the Netherlands, hereinafter to be referred to as: UWH,

considering:

- that UWH, and in particular the Department of Neurochemical Research, has expertise and know-how in the area of the strategies for designing ligands interacting with mRNA;
- that a common interest exists between BIOSYN and UWH in the applicability of mRNA ligands for developing new therapeutics for diseases of the Central Nervous System;
- that they have, subsequently, agreed to start collaboration on the evaluation of the applicability mRNA ligands.

have reached the following agreement:

1. **UWH shall carry out a study in accordance with the research proposal entitled "evaluation of the applicability of mRNA ligands" which proposal is attached to and shall be regarded as an integral part of the present agreement , hereinafter to be referred to as: the Project,.**

2. **For the execution of the Project UWH shall appoint dr. R. Naser as post-doctoral fellow, who will, on a full time basis, carry out the research under the responsibility of Prof.dr. O. Kroetjov, associate professor in the Department of Neurochemical Research. Dr. O. Kroetjov shall regularly inform Dr. H. Klein of BIOSYN of the progress made during the execution of the Project. Prof.dr. O. Kroetjov and Dr. Dr. H. Klein will, by mutual consent, make all necessary practical arrangements on intermediate reporting.**

3. In return for the execution of the Project, BIOSYN shall compensate UWH by paying the amount of Dfl. 480,000.- in five instalments, viz. Dfl.100,000.- (Euro 45,378.02) as soon as possible after the starting date of the Project, the second, third and forth instalments of Dfl. 95,000 (Euro 43,109.12) each 12, 24 and 36 months respectively after the starting date and the fifth instalment of Dfl. 95,000 (Euro 43,109.12) upon completion of the Project. The project is planned to take four years. BIOSYN shall pay each instalment upon receipt of an invoice from UWH, and within 30 days from the invoice date. In addition, BIOSYN shall furnish the UWH, free of charge, sufficient quantities of the compounds to be studied in the Project and all necessary information.

4. **UWH shall complete the Project by submitting to BIOSYN a written report containing at least the experimental data generated by dr. R. Naser during his execution of the research, hereinafter to be referred to as: the Data.**

5. It is understood that parties may, on the basis of results obtained during the execution of the Project, jointly decide to adapt the objectives, the scope and/or the time frame of the (remainder of) the Project. Parties recognise that such adaptations may affect other arrangements made under the present agreement, such as financial arrangements. Said adaptations shall only be effective if they have been made in writing, bearing the signatures of both parties.

6. Subject to paragraph 7 the parties agree to keep confidential all information produced or exchanged by either UWH or BIOSYN in connection with the Project. BIOSYN and the UWH shall as far as possible limit the number of their employees who should get access to secret information produced in connection with the Project. In addition, they shall ensure that said employees will comply with the obligations as expressed in this paragraph. These obligations shall not be effective if and as far as the secret information:
   a. is commonly known, provided the receiver of said information shall adequately substantiate with documentation that this common knowledge does not arise from any non-fulfilment on her part;
   b. has been lawfully acquired from a third party, provided the receiver of said information shall adequately substantiate this with documentation;
   c. is the lawful property of the receiver of said information at the time of disclosure by the provider of the same, provided the former party shall adequately substantiate this with documentation;
   d. Is independently developed by the receiver without the benefit of any disclosure hereunder.

7. **With respect to the use of the Data, parties agree subject to paragraphs 8 and 9 that**
   a. the right to use the Data for publications in scientific media and/or fora is granted exclusively to UWH;
   b. the right to use the Data for research, registration and commercial purposes is granted exclusively to BIOSYN.

8. In addition to paragraph 7 a above, parties agree that UWH shall submit all manuscripts or abstracts of intended publications to BIOSYN for review. Should BIOSYN substantiate that a delay is necessary to protect the right(s) meant in paragraph 7 b above, UWH shall delay an intended publication by no longer than 90 days. Should BIOSYN substantiate that a certain interpretation of Data to be published by UWH would be harmful to said right(s), UWH shall appropriately adapt that interpretation, unless UWH would substantiate that this would infringe upon its scientific integrity, in which event BIOSYN's interpretation shall be included in the publication concerned next to UWH's interpretation if parties would eventually not agree on a mutually acceptable interpretation.

9. In addition to paragraph 7 b above, parties agree that BIOSYN has a 90-day right of first refusal on applying for patents involving Data, hereinafter to be referred to as: Patents. Consequently, parties shall promptly inform each other of patentable results. Applications for Patents shall be put to the names of BIOSYN and UWH on the understanding that UWH will give a transferable, exclusive, world-wide, and everlasting licence to BIOSYN for the use, exploitation and commercialisation of the Patents. UWH shall sign all documents and support all measures necessary for obtaining Patents, for which UWH shall receive no financial compensation, unless experimental work outside the scope of the Project would be carried out by UWH. All expenses and taxes related to filing and/or sustaining and/or protecting (applications for) Patents shall be paid by BIOSYN.

10. In addition to paragraph 9 above, parties agree that
    a. UWH shall have the right to further pursue Patent rights and/or applications if BIOSYN decides to stop activities aimed at commercialisation of those Patents and/or at obtaining patents, on the understanding that all (further) expenses and taxes shall be paid by UWH;
    b. BIOSYN shall pay UWH a royalty of between 2 and 5 percent of net turnover generated by inventions commercialised under protection of Patents by BIOSYN and/or one or more licensees designated by BIOSYN, on the understanding that a definitive percentage shall be settled at an appropriate moment prior to market introduction;

c. BIOSYN shall pay UWH a suitable financial compensation in the event BIOSYN decides to sell Patents rights to a third party.

11. In further addition to paragraph 7 a above, parties agree that BIOSYN may publish the Data outside the scientific domain, on the understanding that any claims made in such publications may not be attributed to UWH, the Department of Neurochemical Research, or the investigators concerned, unless they have given their prior written consent.

12. Any liability BIOSYN may have in respect of UWH is hereby expressly excluded, with the exception of liability for any damage caused by or connected with any defect, as defined in the EEC Guidelines for Product Liability of 25 July 1985, in or of the materials which BIOSYN has furnished to UWH, on the understanding that the term "defect" shall also constitute any instance in which BIOSYN, in pursuance of its obligation to provide information as described in paragraph 3 above, has provided UWH with incomplete or inaccurate information on these materials.

13. The UWH makes no expressed or implied warranties or representation of any kind with respect to the Project and/or its results. BIOSYN hereby indemnifies and holds UWH harmless from any and all liability and/or damages resulting from the use of the which includes, but is not restricted to, liability for damage caused by or connected with BIOSYN's use of Data; non-completion, delay in the implementation, non-implementation of insufficient implementation of the Project - is hereby expressly excluded, with the exception of deliberate damage or gross negligence on the part of UWH.

14. Without prejudice to paragraph 12 above, parties agree that
    a. UWH will restitute any payments it might already have received from BIOSYN in the event of non-implementation of the Project;
    b. they will, by mutual consent, determine BIOSYN's (further) payment obligations toward UWH in the event of non-completion of the Project, thereby taking into account the potential usefulness or applicability for BIOSYN of the Data resulting from the part of the Project which UWH did carry out.

15. If one of the parties should fail to fulfil one or more of its duties under the present agreement, that party shall be warned by the other party in writing, in which case the former party shall be given the opportunity to fulfil the duty or duties concerned within a reasonable period of time. Should, subsequently, the former party still be in default, the latter party may either seek legal redress or unilaterally terminate the present agreement without prejudice to its right to indemnification.

16. The present agreement is deemed to be binding on any and all legal successors to BIOSYN and UWH.

17. The present agreement is made under Dutch law. All disputes arising in connection with the present agreement shall be finally settled by arbitration by and in accordance with the rules of the Netherlands Arbitration Institute (Nederlandse Arbitrage Instituut).

18. The present agreement shall be effective immediately upon signing by both parties, and shall expire on the day following the day of completion of the Project, unless parties should agree otherwise in writing. The obligations as expressed in paragraphs 6 through 17 above and this paragraph 18 shall survive such termination, on the understanding that paragraph 6 shall survive for a period of five years following the disclosure of secret information.

Thus done and signed at Woodcity /Westholland,

BIOSYN

By: _____

Date: _____

UWH

By: _____

Date: _____

EU-FP6-RTD Contract-Annex II: Selected definitions and articles

II.1 – Definitions

1. ***Access rights:*** means licences and user rights to *knowledge* or *pre-existing know-how*.

5. ***Consortium agreement***: means an agreement that *contractors* conclude amongst themselves for the implementation of this *contract*. Such an agreement shall not affect the *contractors*' obligations to the *Community* and/or to one another arising from this *contract*.

7. ***Contractor***: means a participant as defined in Article 2.7 of the *Rules for Participation* and a signatory to this *contract* other than the *JRC*, which signs a separate arrangement with the *Commission* with respect to its participation in the *contract*.

8. ***Dissemination:*** means the disclosure of *knowledge* by any appropriate means other than publication resulting from the formalities for protecting *knowledge*.

14. ***Knowledge:*** means the results, including information, whether or not they can be protected, arising from the *project* governed by this *contract*, as well as copyrights or rights pertaining to such results following applications for, or the issue of patents, designs, plant varieties, supplementary protection certificates or similar forms of protection.

15. ***Legitimate interest:*** means a *contractor's* interest of any kind, particularly a commercial interest which may be claimed in the cases provided for in this *contract*. To this end the *contractor* must prove that failure to take account of its interest would result in its suffering disproportionately great harm.

16. ***Own resources***: means those resources identified in the *Rules for Participation*[3] which may be contributed to the work to be carried out under the *project*, and any other resources under the management discretion of the *contractor* which when allocated to the tasks to be carried out under the *project*, thereby create a cost.

17. *Plan for using and disseminating the knowledge*: means the report on the *contractors'* intentions for the protection, *use* and *dissemination* of the *knowledge* generated under the *project*.

18. ***Pre-existing know-how:*** means the information which is held by *contractors* prior to the conclusion of the *contract*, or acquired in parallel with it, as well as copyrights or rights pertaining to such information following applications for, or the issue of, patents, designs, plant varieties, supplementary protection certificates or similar forms of protection.

20. ***Project***: means all the work referred to in Annex I to this *contract*.

23. ***Rules for Participation***: means the Regulation No. 2321/2002 of the European Parliament and of the Council concerning the rules for the participation of undertakings, research centres and universities in, and for the dissemination of research results for, the implementation of the European Community Sixth Framework Programme (2002-2006) or the Regulation No. 2322/2002 of the Council concerning the rules for participation of undertakings, research centres and universities in the implementation of the Sixth Framework Programme of the European Atomic Energy Community (2002-2006)[5] (Euratom).

29. ***Third party resources:*** means any resources made available to a *contractor*, by a third party, for use in the *project*, and identified in Annex I, based on an agreement established between the *contractor* and the third party prior to its contribution to the *project*. The costs of such resources must be recorded in the accounts of the third party as a cost of the *project*.

30. ***Use***: means the direct or indirect utilisation of *knowledge* in research activities or for developing, creating and marketing a product or process or for creating and providing a service.

PART C – INTELLECTUAL PROPERTY RIGHTS

II.32 - Ownership of *knowledge*

1) *Knowledge* shall be the property of the *contractor* carrying out the work leading to that *knowledge*.

2) Where several *contractors* have jointly carried out work generating the *knowledge* and where their respective share of the work cannot be ascertained, they shall have joint ownership of such *knowledge*. The *contractors* concerned shall agree amongst themselves the allocation and terms of exercising ownership of that *knowledge* in accordance with the provisions of this *contract*.

3) If personnel working for a *contractor* are entitled to claim rights to *knowledge*, the *contractor* shall take steps or reach appropriate agreements to ensure that these rights can be exercised in a manner compatible with its obligations under this *contract.*

4) Where a *contractor* transfers ownership of *knowledge*, it shall take steps or conclude agreements to pass on to the assignee its obligations under this *contract*, in particular regarding the granting of *access rights*, *dissemination* and *use* of the *knowledge.* As long as the *contractor* is required to grant *access rights*, it shall give at least 60 days prior notice to the *Commission* and the other *contractors*, of the envisaged assignment and the name and address of the assignee.

5) The *Commission* or the other *contractors* may object within 30 days of notification to such a transfer of ownership. The *Commission* may object to transfer of ownership to third parties, in particular to those not established in a Member State or an *Associated State*, if such a transfer is not in accordance with the interests of developing the competitiveness of the dynamic, knowledge-based European economy or is inconsistent with ethical principles. The other *contractors* may object to any transfer of ownership, if that transfer would adversely affect their *access rights*.

II.33 - Protection of *knowledge*

1) Where *knowledge* is capable of industrial or commercial application, its owner shall provide for its adequate and effective protection, in conformity with relevant legal provisions, including this *contract* and any *consortium agreement*, and having due regard to the *legitimate interests* of the *contractors* concerned. Details of any such protection sought or obtained shall be included in the *plan for using and disseminating the knowledge*.

2) Where a *contractor* does not intend to protect its *knowledge* in a specific country it shall inform the *Commission*. Where a *contractor* intends to waive the protection of its *knowledge*, the *Commission* shall be informed at least 45 days prior to the corresponding deadline. In such a case and where the *Commission* considers it necessary to protect such *knowledge* in a particular country, it may, with the agreement of the *contractor* concerned, adopt measures to protect the *knowledge*. In this event, and as far as that particular country is concerned, the *Community* shall take on the obligations regarding the granting of *access rights* in the place of the *contractor*. The *contractor* may only refuse if it can demonstrate that its *legitimate interests* will be significantly impaired.

3) A *contractor* may publish or allow the publication of data, on whatever medium, concerning *knowledge* it owns provided that this does not affect the protection of that *knowledge*. The *Commission* and the other *contractors* shall be given 30 days prior written notice of any planned publication. If, before the end of this period, the *Commission* and/or the other *contractors* so request, a copy of this data shall be communicated to them within 30 days after receipt of such request. The *Commission* and the other *contractors* may object to the publication within 30 days after receipt of the data envisaged to be published, if they consider that the protection of their *knowledge* would be adversely affected by this publication. The planned publication shall be suspended until the end of this consultation period. In the absence of any objection within the above-mentioned period, it is deemed that the *Commission* and the other *contractors* agree. The *consortium agreement* may specify the practical details of any such right to object.

II.34 - *Use* and *dissemination*

1) The *contractors* shall *use* or cause to be used the *knowledge* arising from the *project*, which they own, in accordance with their interests. The *contractors* shall set out the terms of *use* in a detailed and verifiable manner, notably in the *plan for using and disseminating the knowledge*, and in accordance with the provisions of this *contract* and the *Rules for Participation*.

2) If *dissemination* of *knowledge* would not adversely affect its protection or its *use*, the *contractors* shall ensure that it is disseminated within a period of two years after the end of the *project*. Should the *contractors* fail to do so, the *Commission* may disseminate the *knowledge*. In so doing, the *Commission* and the *contractors* shall take particular account of the following factors:

a) the need to safeguard intellectual property rights;

b) the benefits of swift *dissemination*, for example in order to avoid duplication of research efforts and to create synergies between *projects*;

c) confidentiality;

d) the *legitimate interests* of the *contractors*.

II.35 - *Access rights*

1) The general principles relating to *access rights* are the following :

a) *Access rights* shall be granted to any of the other *contractors* upon written request. The granting of *access rights* may be made conditional on the conclusion of specific agreements aimed at ensuring that they are used only for the intended purpose, and of appropriate undertakings as to confidentiality. *Contractors* may also conclude agreements with the purpose of granting additional or more favourable *access rights*, including *access rights* to third parties, in particular to enterprises associated with the *contractor(s)*, or specifying the requirements applicable to *access rights*, but not restricting the latter. Any agreement providing for *access rights* to *contractors* and/or third parties must ensure that the potential *access rights* for other *contractors* are maintained. Such agreements shall comply with the applicable competition rules;

b) The *Commission* may object to the grant of *access rights* to third parties, in particular to those not established in a Member State or an *Associated State*, if such

grant is not in accordance with the interests of developing the competitiveness of the dynamic knowledge-based European economy, or is inconsistent with ethical principles. *Contractors* shall ensure that where any potential grant of access rights to *knowledge* is not in accordance with these interests, the *Commission* shall be given 30 days prior written notice of plans to provide such access rights to third parties;

c) *Access rights* to *pre-existing know-how* shall be granted provided that the *contractor* concerned is free to grant them;

d) A *contractor* may explicitly exclude specific *pre-existing know-how* from its obligation to grant *access rights*, by means of a written agreement between the *contractors* established before the *contractor* concerned signs the *contract* or before a new *contractor* joins the *project*. The other *contractors* may only withhold their agreement if they demonstrate that the implementation of the *project* or their *legitimate interests* will be significantly impaired thereby;

e) Except where the *contractor* granting *access rights* so agrees, such rights shall confer no entitlement to grant sub-licences.

2) *Access rights* for execution of the *project* are the following:

a) *Contractors* shall enjoy *access rights* to the *knowledge* and to the *pre-existing knowhow*, if that *knowledge* or *pre-existing know-how* is needed to carry out their own work under that *project*. *Access rights* to *knowledge* shall be granted on a royaltyfree basis. *Access rights* to *pre-existing know-how* shall be granted on a royalty-free basis, unless otherwise agreed before signature of the *contract*;

b) Subject to its *legitimate interests*, the termination of the participation of a *contractor* shall in no way affect its obligation to grant *access rights* to the other *contractors* pursuant to the previous sub-paragraph until the end of the *project.*

3) *Access rights* for *use* of *knowledge* are the following:

a) *Contractors* shall enjoy *access rights* to *knowledge* and to the *pre-existing knowhow*, if that *knowledge* or *pre-existing know-how* is needed to *use* their own *knowledge. Access rights* to *knowledge* shall be granted on a royalty-free basis, unless otherwise agreed before signature of the *contract*. *Access rights* to *preexisting know-how* shall be granted under fair and non-discriminatory conditions to be agreed;

b) Subject to the *contractors' legitimate interests*, *access rights* may be requested under the conditions laid down in the previous paragraph until two years after the end of the *project* or after the termination of the participation of a *contractor*, whichever falls earlier, unless the *contractors* concerned agree on a longer period.

II.36 Incompatible or restrictive commitments

Contractors shall be informed as soon as possible by the *contractor* required to grant *access rights* of any limitations to the granting of *access rights* or of any restriction which might substantially affect the granting of *access rights*, as the case may be.