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AFFAIRS AND  
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*the Australian Government's overseas aid program*

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## **Module Six**

# **Group exercise on patent validity: Relaxin patent**

**Intellectual Property and Biotechnology  
A Training Handbook**

## Contents: Module Six

6.1	OBJECTIVES FOR MODULE SIX.....	2
6.2	BACKGROUND TO THE CASE STUDY .....	3
6.3	RELAXIN PATENT VALIDITY EXERCISE.....	6
6.4	DOCUMENTS FOR THE RELAXIN PATENT VALIDITY EXERCISE .....	29

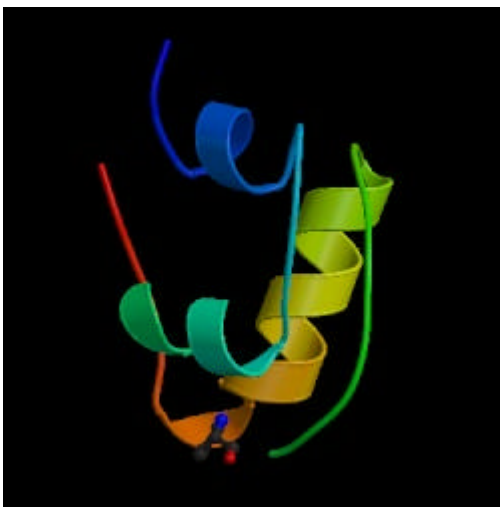
### 6.1 Objectives for Module Six

By the end of this Module you should have further practical experience in how to:

- apply the legal principles relating to the validity of complex biotechnology patents involving DNA sequences
- further explore the issues involved in assessing whether biotechnology inventions are patentable on the basis of:
  - novelty
  - inventive step
  - industrial application
  - usefulness
  - exceptions to patentability such as moral issues and *ordre public*
  - whether the claims are supported in the description

## 6.2 Background to the case study

This case study concerns important issues of patent validity, including consideration of the ethical issues related to the patent right. To set the patent documentation in context, we provide a discussion of some of the background to the invention. Patents, like other intellectual property rights, do not exist in isolation – they are part of a system intended to provide benefits for society. While this exercise concerns the strict legal validity of patents granted on the research outcomes, this exercise should also highlight potential benefits of a patent: in this case, the patent has the potential firstly to produce funds to pay for continuing valuable research, and secondly to provide the investor confidence required to go through the processes necessary to put a new pharmaceutical product on the market.



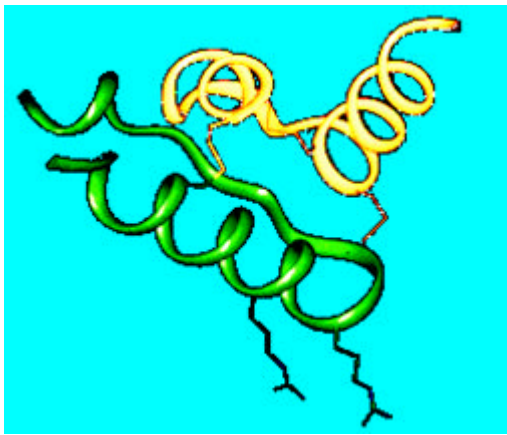
The case study concerns Relaxin, a synthetic peptide hormone. Hormones are normally produced naturally by plants and animals to regulate a wide range of bodily functions and to control the function of organs. Insulin and adrenaline are two examples of hormones, discussed in *Module Two*, which received patent protection in their synthesized form.

The synthesized relaxin was developed in the Howard Florey Institute, a medical research institute in Melbourne, Australia. Australian researchers have often taken a leadership role in their fields, but have generally been criticised for failing to manage their intellectual property to capture the benefits of their research. Relaxin

is one example in Australia of effective intellectual property management, in which the IP has been appropriately protected and the licences have been able to return a reasonable royalty stream to support research work. Other related programs involved even more significant discoveries, but the IP was not adequately protected. So in one case, a nearby public research institute which undertook pioneering research into the GCSF and GMCSF growth factors found that the research led to the situation where a foreign pharmaceutical company was now reaping lucrative financial returns. This case demonstrated the need for effective IP management, to ensure that the products of research flow back to the country where the work has been done, but especially to the laboratories where the discovery was first made so that continuing valuable research can be funded.

At the same time, it can take a long time for basic research to lead into useful products. Relaxin has been a major research focus of the institute since 1975. The fruits of this research are only beginning to be realized. There is often a long delay from the breakthrough research phase to seeing a product on the marketplace: this is especially so for pharmaceuticals, for which the development and regulatory approval process is necessarily long. Considerable pressures can be felt during that period of delay: for instance, management may be under pressure to cut the costs for a project and to review expenditure such as patent fees, when a product is unlikely to return profits for some years. There is a continuing risk of cutting costs for short term gain while damaging longer-term interests.

Relaxin was first described in 1926, but it had been known for much longer that for a child to be born, the ligaments holding the pelvic bones together must change, as must the cervix itself which needs to soften and dilate in order to allow the baby to be born. It was clear that a specific hormone would perform this function. In 1926, a researcher took an extract of a pregnant guinea pig's ovaries. Introducing this into a guinea pig led to great relaxation of the pelvic bones. The chemical extract was called *relaxin* because of this relaxing effect on the ligaments. But the actual hormone was only isolated and its chemical structure determined in 1975, at the Howard Florey Institute (the patent applicant in this case study). This research was based on earlier work which established that the relaxin factor was produced in the ovaries during pregnancy. Based on analysis of discarded pigs' ovaries from an abattoir, the material was isolated, extracted and purified. In tests, this material seemed to have all the biological properties of relaxin.



On further analysis, relaxin was determined to be a peptide (peptides are low-weight polymers of amino acids, in contrast to proteins which are larger and heavier polymers also made up of amino acids). Surprisingly, it was a two chain peptide (rather than the expected single chain structure), the two chains being joined by sulphide bridges – disulphide bonds. Also surprising was the fact that the hormone was analogous in its structure to insulin (even though the individual amino acids which made it up were different). Somehow relaxin and insulin were related to each other.

The research program then determined the structure of relaxin in many other mammals. It transpired that relaxin had evolved in different ways in each species – the only common element was the disulphide bonds. It was an important insight that only a few of the amino acids were important for the biological activity of relaxin. So the structure of relaxin was the same across species, while its specific composition differed by a few amino acids. It was therefore an important finding that only human relaxin would work on humans, and relaxin derived from other mammals would not be effective – unlike insulin (insulin from pigs had been used for many years to treat humans suffering from diabetes). As a result, to use relaxin to treat human diseases, it would be necessary to produce synthetic relaxin, rather than to rely on extracts from other species.

To make synthetic relaxin, it was necessary to determine its genetic sequence and to clone the gene through recombinant DNA techniques when they were just appearing. The researchers already had prior knowledge of relaxin in other species, so they were able to make the necessary probes and primers to extract the necessary findings for human relaxin. It was discovered that the gene coded not for two chains but the one chain. It emerged that there were actually two genes and two types of relaxin in the human (in contrast to the other animals). This research led to patent filings, first in Australia then in other countries.

Some of the biological actions of relaxin in the body are:

1. preventing the uterus from contracting
2. softening (ripening) the cervix at the time of birth to allow the child to pass through
3. effects on the heart
4. affecting mobility of sperm
5. blood pressure

For the first clinical application of synthetic relaxin, the researchers selected its use as a cervical ripening agent for post date (overdue) pregnancies. In the State of Victoria (where the Institute is located), 20% of all births were by caesarean section because of the post date problem, and using synthetic relaxin as a treatment offered a potential alternative to this kind of intervention. The necessary clinical trials turned out to be very expensive, and well beyond the means of the Institute. At this stage, the help of pharmaceutical companies was necessary. With the backing of the patent, the Institute tried to locate financial backers for this program. It proved impossible to get support from within Australia, and the patent was licensed to Genentech (see example in *Module Two*). Genentech funded the necessary clinical trials. The trial phase considered safety, the best method of application and the possibility of side effects. As this was a synthetic version of a natural hormone, side effects appeared unlikely in any case.

The next phase, the efficacy trial, commenced in 1992, when synthetic relaxin was first given to pregnant women. The method chosen was topical application – that is, to apply the synthetic relaxin directly by painting the cervix. There were no adverse side effects, but unfortunately nor was there any positive effect. This was a bad blow for the project at the time. It became clear later on that the problem was with the means of application – it would have been necessary to apply the relaxin intravenously. The effect at the time was that the financial backers asked to terminate the study, as several hundred million dollars had already been spent on the project. However, the team that had been working on the clinical trials and to develop the product decided to set up another company, Connective Therapeutics (now Connectics), to keep the work going. Genentech sublicensed the patent to this spin-off company to keep the project going. This led to change in direction.

Rather than consider the childbirth application (where medical litigation was a major risk), the project then looked at diseases associated with disorders in the connective tissue, for instance scleroderma ('hard skin'), a chronic and ultimately fatal disease caused by overproduction of collagen (a protein which forms fibres that are a major component of bones, tendons and other connective tissue). There was no treatment for scleroderma, which afflicted 300,000 patients in the US (80% of whom are women). Relaxin inhibits the production of collagen, and introducing synthetic relaxin proved to be the first effective treatment of scleroderma, which otherwise proved to be fatal. Relaxin has further potential applications in other disorders caused by fibrosis (the excessive growth of fibrous tissue) in the heart and liver, and also to prevent scar formation. The royalty from the relaxin patent was valuable in supporting continuing research into new clinical possibilities, and improved means of administering relaxin (which cannot be taken orally, because it is destroyed in the digestive tract).

The relaxin patent was approved by the European Patent Office (EPO) in 1992 – so the delay in patent approval was matched by the delays in the clinical program. However, the European patent was opposed by the Green Fraction of the European Parliament. This patent and opposition process forms the basis of this validity exercise. The opposition raised questions of ethics, novelty and non-obviousness, and proved to be a test case for the 'contrary to public order' provisions of European patent law.

## 6.3 Relaxin Patent Validity Exercise

### *How to undertake the case study*

The following memoranda set out how the exercise can be conducted as a group exercise. A particular framework for this exercise is suggested, based on experience in using this exercise in practice. This material can be used in other ways, including for individual personal study. However, for the exercise to be effective, it would be useful to consider the issues at each stage only on the basis of the specific documents suggested for each role (described as Groups A, B, C and D). Memorandum A describes the suggested approach for managing a group exercise

Memorandum

### *After the case study*

While we recommend that it be set aside during the case study, the actual decision of the EPO is provided at the end of this Module, for cross-reference and to provide one perspective on the issues raised by this patent. The extract provided concentrates on the substantive patent law questions considered, and omits material on several other legal issues that were considered at the same time (essentially procedural questions, and questions of standing), although one other issue is still included – a challenge that the EPO dealt with the opposition in a partial manner.

### MATERIALS

Memorandum A.	Explanation of the Validity Exercise (for Exercise Leader and Facilitators)
Memorandum B.	Information for the Introduction unit (for Exercise Leader and Facilitators)
Memorandum C.	Information for the Group Work unit (for Exercise Leader and Facilitators)
Memorandum D.	Information for the Group Report unit (for Exercise Leader and Facilitators)
Memorandum E.	Information for the Review unit (for Exercise Leader and Facilitators)
Memorandum F.	List of Materials issued to participants (for Exercise Leader and Facilitators)
Memorandum G.	Instructions for Group A
Memorandum H.	Instructions for Group B
Memorandum I.	Instructions for Group C
Memorandum J.	Instructions for Group D
Annexes	Reference documents

## MEMORANDUM A.

### EXPLANATION OF THE VALIDITY EXERCISE

#### 1. What is the Validity Exercise?

The Validity Exercise is a role-playing exercise which forms part of a training program on biotechnology patents. The exercise is designed to enhance the learning of participants in relation to the legal and practical aspects of determining the validity of biotechnology patents. The exercise uses an actual application for a biotechnology patent ('the Application') and actual prior art and other documents involved in the prosecution of the Application before the European Patent Office. The exercise requires participants to carry out one of four roles, each of which is a simulation of an actual stage in the prosecution history of the Application.

The suggested approach to the exercise consists of four units, conducted over six sessions. The four units are as follows.

(i) Introduction unit

Exercise Leader explains to all participants the objectives and procedure of the exercise, and elaborates on and clarifies the technological and legal issues raised in the exercise.

(ii) Group Work unit

Each group carries out in parallel a different task which simulates one of the stages in the prosecution of the Patent.

(iii) Group Report unit

Each group reports in sequence to all participants on the outcomes of the task assigned to the group.

(iv) Review unit

Each exercise facilitator in sequence reviews the deliberations of their group in the Group Work unit, and comments on the outcomes of their group as reported in the Group Report unit.

#### 2. Why have the Validity Exercise?

The Validity Exercise provides an opportunity for participants in the training program to apply in a practical context the abstract legal principles concerning the validity of biotechnology patents. The exercise thus provides a review and reinforcement of the legal principles which have been the subject of earlier instruction in the training program.

Because the exercise uses group work, each participant can benefit from the particular expertise, experience and insight brought to the training program by the other participants in the group. Further, the group work enables each participant to develop closer personal relationships with the other participants in the group, and to come to understand their perspectives on the issues raised by the exercise. Finally, the exercise provides an enjoyable and interactive set of sessions, and thus adds to the diversity of the learning formats adopted in the training program.

#### 3. Who are the participants in the Validity Exercise?

The Validity Exercise involves the following participants.

(i) Exercise Leader

The exercise leader is one of the teachers on the training program. The exercise leader may also be one of the exercise facilitators. The exercise leader has responsibility for the overall conduct

of the exercise. In particular, the exercise leader is responsible for allocation of participants and exercise facilitators to particular groups and for the conduct of the introduction unit.

(ii) Group Members

Each participant is assigned to be a member of one of the four groups. The role of the group member is to work collaboratively with fellow group members, to carry out the task assigned to the group. Each group is responsible for determining how it will carry out the assigned task, and for carrying it out.

(iii) Exercise Facilitators

Facilitators may be teachers, practitioners or senior researchers with IP experience. Ideally, there will be four facilitators - that is, one for each of the four groups. Where necessary, however, it is possible to have only two facilitators. In that case, each facilitator assists two groups – that is, one facilitator for each pair of groups (i.e. Groups A/B and Groups C/D).

The role of the facilitator is two-fold. First, in the Group Work unit, the facilitator assists the group in carrying out the assigned task. In particular, the facilitator may need to clarify the precise nature of the assigned task, and help the group with understanding the application of the law to the particular facts of the task. Secondly, in the Review unit, the facilitator provides a review of the deliberations undertaken by the group in the Group Work unit, and comments on the Report given by the group in the Group Report unit. The facilitator is not responsible for carrying out the work of the group.

**4. How are members allocated to groups?**

The exercise leader should allocate participants to one of the four groups in advance of the exercise, so that they can undertake informal preliminary discussions with their fellow group members. So far as practicable, the allocation should ensure that, across the four groups, each group has:

- an equal number of participants
- a consistent proportion of participants from similar backgrounds (e.g. from law, science, administration, policy) – it is particularly valuable if the groups can combine people with backgrounds in scientific research and in intellectual property law and administration
- a consistent proportion of men and women
- where relevant, a consistent proportion of participants from different countries and/or geographical regions

**5. What is the suggested schedule for the exercise?**

The exercise is ideally conducted over six sessions. There should be a break (either in the form of a short refreshment break or a break between days of the training program) after the second, fourth and six sessions. Optionally, there may be a break between the first and second sessions.

The suggested order, content and approximate duration of each session is set out below.

Session	1	2	3	4	5	6
Unit	Introduction	Group Work	Group Report	Review	Group Report	Review
Groups	All	All	A and B	A and B	C and D	C and D
Duration	30 mins	75 mins	45 mins	45 mins	45 mins	45 mins

## MEMORANDUM B.

### INFORMATION ABOUT THE INTRODUCTION UNIT

#### 1. The Purpose of the Introduction Unit

The purpose of the Introduction unit is to ensure that all participants understand:

- the objectives and the process of the exercise
- the role of the group members and of the exercise facilitators
- the facts of the exercise, including a basic understanding of the technology of the Patent
- the task of each group, including the particular legal issues and the basics of the legal principles which apply to the task

The Introduction unit should be conducted by the exercise leader, in the presence and with the assistance of the exercise facilitators. It should allow plenty of scope for all participants to ask questions about the exercise.

#### 2. The Objectives and Process of the Exercise

The exercise leader should explain that the exercise seeks to achieve a number of objectives. In particular, the exercise provides a practical context in which participants are able to apply the legal principles of the validity of biotechnology patents. The exercise thus provides an opportunity for participants to review their knowledge of those legal principles, and reinforce their understanding of how those legal principles apply in practice.

The exercise leader should emphasise that the purpose of the exercise is not to assess or evaluate the participants' learning to date, but rather to provide a different and enjoyable means for continuing the participants' learning. The questions are not to be answered in true/false fashion, but to be used as the basis for a discussion on the nature of the issues involved.

The exercise leader should describe the schedule of the exercise. In doing so, the exercise leader could explain that the tasks constitute a simulation of four stages in the prosecution of an actual patent, and that these tasks fall into two pairs – those of Groups A and B, and those of Groups C and D. Accordingly, the Group Report and the Review of Groups A and B should take place before the Group Report and the Review of Groups C and D.

#### 3. The Role of the group members and the facilitators

The exercise leader should explain that the responsibility for determining how to conduct the task, and for conducting the task, rests with the group members. There is no prescribed or preferred method for undertaking the task, and different groups may approach their tasks in quite different manners. For example, some groups may allocate specific questions or issues to individual group members, whilst other groups may seek to answer all questions or issues collectively – both approaches are equally valid. Likewise, it is equally valid for a group to appoint one member as its spokesperson during the Report unit or instead for a group to have a number of its members speak during the Report unit.

The exercise leader should emphasise that the role of the exercise facilitator is to assist the group in clarifying their understanding of facts and of the legal issues raised in the task. It is not the responsibility of the facilitator to tell the group how to carry out the task, or to carry it out for them.

#### 4. The Invention considered in the exercise

The exercise leader should explain that the exercise focuses on the various stages of prosecution of an application for a patent for an actual invention ('the Invention') before the European Patent Office ('EPO'). The application for the patent ('the Application') is European Patent Application no. 83307553.4 (Document 2 in the Materials issued to participants). The Application was filed in the EPO on 12 December 1983, and claimed priority from an application for the same invention filed in the Australian Patent Office on 13 December 1982.

The Invention was selected for use in the exercise for a number of reasons. First, the Invention is reasonably representative of one of the types of biotechnology inventions for which patents are sought. Secondly, the particular nature of the Invention raises some very interesting and contentious patent issues, both legal and non-legal. Thirdly, the form and content of the Application is reasonably representative of biotechnology patent applications of this type. (It may be noted, in addition, that because the Application was one of the earlier applications made for molecular cloning using recombinant DNA technology, it contains some useful basic information about recombinant DNA technology that is not generally found in later patent applications for this type of biotechnology invention.)

The Invention relates to the discovery of a gene which encodes for the production of a hormone, relaxin, in humans. In fact, as the Application itself states (p. 1), the Invention concerns the discovery of a second gene encoding for a second human relaxin protein (H2-relaxin). As stated in the Application (p. 3), relaxin is a hormone produced in mammals, which has the effect of dilating the pubic symphysis, thus making childbirth easier. It is produced by the ovaries during pregnancy, and released into the blood stream during labour.

The Application states (pp 3-4) that there has already been determined the amino acid sequence for relaxin in pigs, rats and sharks, and the amino acid sequence of and the DNA nucleotide sequence encoding for a first human relaxin protein (H1-relaxin). The similarities and differences between H1-relaxin and H2-relaxin are described in the Application (pp 8-11).

The Application proceeds to describe in some detail the various aspects of the Invention (pp 12-21), which are reflected in the claims at the end of the specification (pp 42-49). The aspects of the Invention are:

- genes for the expression of H2-preprorelaxin, prorelaxin and relaxin, and polymorphic forms, complements, sub-units and variants thereof (pp 12-14)
- DNA transfer vectors comprising the deoxynucleotide sequence corresponding to these genes (pp14-15)
- a prokaryotic or eukaryotic cell transformed by any of these transfer vectors (p. 15)
- processes for making these DNA transfer vectors, for making a fusion protein by incubating a cell culture transformed by an expression transfer vector prepared by that process, and for synthesizing H2 preprorelaxin, prorelaxin and relaxin therefrom (pp 15-18)
- human relaxin analogues and processes for production thereof (pp 18-21).

The Application then sets out the methods and materials by which these aspects of the Invention were made (pp 22-39), and a list of references (pp 40-41).

The Application concludes with the claims (pp42-49). There are 32 claims, each of which relates to a different aspect of the Invention, in accordance with the preceding description (pp12-21). The claims are followed by five figures (1/5-5/5), which are referred to in the preceding description of the Invention.

## 5. The jurisdiction and relevant legislation

Prosecution before the EPO was chosen for the exercise because the relevant law is conveniently contained in the European Patent Convention ('EPC'). A large number of European countries are members of the EPC. Extracts of the relevant provisions from the EPC are in Document 1 in the Materials issued to the participants.

The relevant provisions of the EPC are expressed in reasonably simple and clear terms, and are generally representative of the law of patent validity as it applies throughout the world. Some of the provisions of the EPC (namely those dealing with the exceptions to patentability) do not have direct counterparts in other countries' legislation. Nevertheless, the issues to which those provisions relate are fundamental to all patent laws. Also, similar provisions are found in the TRIPS Agreement (arts 27(2) and (3)) as optional exceptions to patentability.

The legislation extracts contain provisions from Parts II, III, V and VI of the EPC. The basic effect of the key provisions are as follows.

### *Part II – Substantive Patent Law*

#### Article 52 – Patentable inventions:

- art. 52(1) sets out the basic requirements for the grant of a valid patent –*i.e.* an invention, industrial applicability, novelty, and inventive step
- arts 52(2)-(4) deals with inherently unpatentable subject matter –*i.e.* subject matter which is not an invention or which is incapable of industrial application

#### Article 53 – Exceptions to patentability:

- art. 53(a) excludes inventions that are contrary to public policy or morality
- art. 53(b) excludes inventions concerning plant and animal varieties and essentially biological processes for their production

#### Article 54 – Novelty:

6. art. 54(1) sets out the test for novelty –*i.e.* the invention does not form part of the state of the art
7. arts 54(2)-(5) describe the state of the art against which novelty is tested –*i.e.* everything made available to the public before the date of filing of the application, plus other European patent applications with an earlier filing date that are published after the date of filing of the application

#### Article 55 – Non-prejudicial disclosures:

- prescribes disclosures of the invention which are disregarded when testing for novelty –*i.e.* disclosures less than six months before the date of filing which result from an abuse of the applicant or from display at an officially recognised international exhibition

#### Article 56 – Inventive step:

- sets out the test for the presence of an inventive step –*i.e.* the invention is not obvious to a person skilled in the art, having regard to the state of the art

#### Article 57 – Industrial application:

- sets out the test for industrial applicability –*i.e.* it can be made or used in any kind of industry

*Part III – Application for European Patents*

Article 78 – Requirements of the European Patent Application:

- sets out what an application for a patent must contain –*i.e.* a request for grant, a description of the invention, one or more claims, any drawings referred to in the description or the claims, and an abstract

Article 82 – Unity of invention:

- requires that the patent application relate to one invention only

Article 83 – Disclosure of the invention:

8. requires that the application clearly and completely disclose the invention

Article 84 – The claims:

- requires that the claims define the invention, are clear, are concise and are supported by the description

*Part V – Opposition Procedure*

Article 100 – Grounds of opposition:

- sets out the grounds on which an opposition to the grant of a patent may be filed –*i.e.* the subject matter is not patentable within the terms of EPC arts 52-57, the patent does not disclose the invention sufficiently, and the subject matter extends beyond the content of the application

**5. The tasks of each group**

The leader should explain that each group has been given a different task, where each task represents one of the actual stages in the prosecution of the application for a patent for the Invention. The four tasks are as follows.

Group A:

Group A acts as an Examiner in the European Patent Office, in the Biotechnology section. The group is required to examine the Application for compliance with the provisions of the EPC dealing with Patentability and Filing Requirements –*i.e.* under Chapter I of Part II and Chapter I of Part III. In particular, the group is to determine the extent to which the Application satisfies these requirements.

Group B:

Group B acts a European Patent Attorney, specialising in biotechnology patents. The group is required to prosecute the Application before the EPO. In particular, the group is to provide a Response to the first substantive Examination Report of the Examining Division of the EPO.

Group C:

Group C is the European Green Party. The group is required to oppose the grant of the patent for the Invention. In particular, the group is to prepare the Grounds of Opposition, for filing in the EPO prior to the Opposition hearing.

Group D:

Group D acts a European Patent Attorney, specialising in biotechnology patents. The group is required to defend the Opposition to the grant of a patent for the Invention, lodged by the European Green Party. In particular, the group is to prepare the Reply to the Opposition, for filing in the EPO prior to the Opposition hearing.

## MEMORANDUM C.

### INFORMATION FOR THE GROUP WORK UNIT

#### 1. The purpose of the Group Work Unit

The purpose of the Group Work unit is to provide the participants with an opportunity to apply in a practical context the abstract legal principles relating to the validity of biotechnology patents. In particular, the participants are provided with the opportunity to benefit from the expertise and experience of their fellow group members in dealing with a practical task. This constitutes an important part of the learning process, because the practical task involves complex issues of law and of technology, being issues which benefit from a multi-disciplinary perspective.

#### 2. Task of Group A

Group A acts as an Examiner in the European Patent Office ('EPO'), in the Biotechnology section. The group is required to examine European Patent Application no. 83307553.4 ('the Application') for compliance with the provisions of the European Patent Convention ('EPC') dealing with Patentability and Filing Requirements –*i.e.* under Chapter I of Part II and Chapter I of Part III. Relevant extracts of the EPC are in Document 1, and a copy of the Application is Document 2, in the Materials provided to participants.

The group is provided with two pieces of prior art, found as a result of the Search conducted by the EPO Search Division. These are an article in the scientific journal *DNA* (Document 3 in the Materials) and a published application for another European Patent (Document 4 in the Materials). The group is to assume that these two documents are the only relevant documents found as a result of that search.

The task of the group is to determine the extent to which the Application satisfies these requirements. In doing so, the group is required to answer the following specific questions:

1. Do all the claims satisfy article 52(1) –*i.e.* are they for an invention that:
  - (a) is novel, under articles 54 and 55?
  - (b) involves an inventive step, under article 56?
  - (c) is capable of industrial application, under article 57?
2. Are any of the claims excluded by article 52(2)(a) –*i.e.* are they discoveries?
3. Are any of the claims excluded by article 52(4) –*i.e.* are they for methods for treatment of the human body by surgery or therapy?
4. Are any of the claims excluded by article 53(a) –*i.e.* are they contrary to “ordre public” or morality?
5. Do the claims satisfy article 82 –*i.e.* do they relate only to one invention or inventive concept?
6. Do the claims satisfy article 84 –*i.e.* are they clear and concise and supported by the description?

#### Question 1(a):

This requires a comparison between each claim of the Application and what is disclosed in the state of the art. A claim will not be novel if it relates to subject matter which is disclosed in the state of the art. Are either of the two documents part of the state of the art? Is the subject matter of any claim disclosed in the state of the art?

Question 1(b):

This requires a consideration of whether the subject matter of each claim is obvious to a person skilled in the art, having regard to the state of the art which may be considered for inventive step. Are either of the two documents part of the state of the art for inventive step? What type of person is skilled in this art? What would be obvious to that type of person?

Question 1(c):

This requires a consideration of whether the subject matter of each claim is capable of being made or used in any kind of industry. What is an “industry”. Is there an industry in which the subject matter of each claim can be made or used?

Question 2:

This requires a consideration of what is a “discovery”, and also of what is meant by the “as such” qualification imposed by article 52(3). Is the H2 gene naturally occurring? If so, does that make the claims to it a discovery as such? Does disclosing the DNA and amino acid sequences make the claims to subject matter more than a discovery *as such*?

Question 3:

This requires a consideration of what is a method for the treatment of the human body by surgery or therapy. Does this include subject matter that may be used or involved in such a treatment?

Question 4:

This requires a consideration of what is meant by “ordre public” and what is “contrary to law”. How is the relevant public policy/policies to be identified? Are there policies in favour of granting the patent? In relation to what law(s) might the invention be contrary?

Question 5:

This requires a consideration of what is the inventive concept(s) disclosed in the Application, and an analysis of whether the claims relate to only one such concept. How might the Invention disclosed in the Application be conceptualised?

Question 6:

This requires an analysis of whether there is any ambiguity or lack of definition of subject matter in each claim. What is the subject matter of each claim? Has it been adequately defined?

### **3. Task of Group B**

Group B acts a European Patent Attorney, specialising in biotechnology patents. The group is required to prosecute the Application before the EPO.

The group is provided with the first substantive Examination Report of the EPO (Document 5 in the Materials). The Examination Report considers the extent to which the Application complies with provisions of the EPC dealing with Patentability and Filing Requirements –*i.e.* under Chapter I of Part II and Chapter I of Part III. The Examination Report refers to, and the group is supplied with a copy of, a published application for another European Patent (Document 4 in the Materials).

The task of the group is to provide a Response to the first substantive Examination Report. In doing so, the group is required to answer the following specific questions:

1. Are the following objections raised in the Examination Report valid:
  - (a) the claims lack unity under article 82 –i.e. there are three separate inventions, being claims 1-23, claims 24-29 and claims 30-32?
  - (b) the claims (inc. claim 1) which refer to “H2-preprorelaxin” per se lack clarity under article 84 –i.e. they do not identify the specific structural features which distinguish between H1, H2 and known human relaxin?
  - (c) the claims (inc. claim 1) which refer to “or a sub-unit thereof” lack clarity under article 84 and novelty under article 54 –i.e. they are not clearly distinguished from certain of the claims in the earlier European Patent Application publication no. 0,101,309 for H1 relaxin?
2. What amendments, if any, should be made to the Application in light of these objections?

Questions 1(a) and 2:

This requires a consideration of whether or not the three groups of claims relate to the one inventive concept. How should the Invention disclosed in the Application be conceptualised? For instance, what is the technical problem it addresses, and how does it solve that problem? Is there an inventive concept to which more than one of the three groups of claims relate?

Question 1(b) and 2:

This requires an analysis of whether the claims sufficiently describe the subject matter. What is the subject matter of the claims being challenged on this ground? How can and should that subject matter be defined?

Question 1(c) and 2:

This requires an analysis of whether the claims cover subject matter that is disclosed in the H1-relaxin patent application. What is disclosed in the H1-relaxin patent application? Does a claim to a sub-unit of the H2-relaxin gene cover that disclosure? If it does, should these parts of the claims be deleted? What would be the effect of such a deletion on the scope of the claim?

#### 4. Task of Group C

Group C is the European Green Party. The group is required to Oppose the decision of the EPO to grant a patent for the Invention.

The Application was accepted by the EPO, after amendment by the applicant, to become European Patent no. 0,112,149 (‘the Patent’). A copy of the Patent (Document 7 in the Materials) is provided to the group. The group is also provided with a copy of an article in the *New Scientist* magazine (Document 6 in the Materials), which states that the Green Party has opposed the grant of the Patent.

The task of the group is to prepare the Grounds of Opposition, for filing in the EPO prior to the Opposition hearing. In doing so, the group is required to answer the following specific questions:

1. Is it feasible to oppose the grant of the Patent on any of the following grounds –i.e. that the invention:
  - (a) is not capable of industrial application, under article 52(1)?
  - (b) is excluded as a discovery, under article 52(2)(a)?
  - (c) is excluded as contrary to “ordre public” or morality, under article 53(a)?
  - (d) is not novel, under article 54?

- (e) does not involve an inventive step, under article 56?
- 2. If so, what arguments would you make in support of those grounds?

Question 1(a) and 2:

This requires a consideration of whether the subject matter of each claim is capable of being made or used in any kind of industry. What is an “industry”? Is there any industry in which the subject matter of each of the claims of the Patent may be made or used?

Question 1(b) and 2:

This requires a consideration of what is a discovery, and also of what is meant by the “as such” qualification imposed by article 52(3). Is the H2-relaxin gene naturally occurring? If so, does that make the claims to it a discovery as such? Does disclosing the DNA and amino acid sequences make the claims to subject matter more than a discovery as such?

Question 1(c) and 2:

This requires a consideration of what is meant by “ordre public” and what is “contrary to law”. How is the relevant public policy/policies to be identified? Are there policies in favour of granting the patent? In relation to what law(s) might the invention be contrary?

Question 1(d) and 2:

This requires a comparison between each claim of the Application and what is disclosed in the state of the art. A claim will not be novel if it relates to subject matter which is disclosed in the state of the art. What comprises the state of the art? Is the H2-relaxin gene in humans part of the state of the art?

Question 1(e) and 2:

This requires a consideration of whether the subject matter of each claim is obvious to a person skilled in the art, having regard to the state of the art which may be considered for inventive step. What type of person is skilled in this art. What would be obvious to that person?

## 5. Task of Group D

Group D acts a European Patent Attorney, specialising in biotechnology patents. The group is required to defend the Opposition to the grant of a patent for the Invention, lodged by the European Green Party.

The group is provided with a copy of the Patent –*i.e.* the Application as accepted by the EPO, after amendment by the applicant (Document 7 in the Materials). It is also provided with the Grounds of Opposition filed by the Green Party (Document 8 in the Materials).

The task of the group is to prepare the Reply to the Opposition, for filing in the EPO prior to the Opposition hearing. In doing so, the group is required to answer the following specific questions:

1. How should you respond to the technical and legal arguments contained in Parts I and II of the Opposition –*i.e.* the arguments that the invention:
  - (a) is excluded as a discovery, under article 52(2)(a)?
  - (b) is not novel, under article 54?
  - (c) does not involve an inventive step, under article 56?

2. How should you respond to the morality arguments contained in Parts III and IV of the Opposition -i.e. the arguments that the invention is excluded as contrary to “ordre public” or morality, under article 53(a)?

Question 1(a) and 2:

This requires a consideration of what is a “discovery”, and also of what is meant by the “as such” qualification imposed by article 52(3). Is it true to say that claims 1-4 are “described solely in respect of their ability to code” and that “there is no reference whatsoever to their chemical composition”? What is meant by the last paragraph under heading I?

Question 1(b) and 2:

This requires a comparison between each claim of the Application and what is disclosed in the state of the art. What forms part of the state of the art? Is the H2-relaxin gene in the tissue of pregnant women part of the state of the art? Does “isolating” and “purifying” the gene change the situation? Is it true to say that “the elucidation of the chemical structure has no patentability, because it is effected in conventional manner known per se”?

Question 1(c) and 2:

This requires a consideration of whether the subject matter of each claim is obvious to a person skilled in the art, having regard to the state of the art which may be considered for inventive step. What type of person is skilled in this art? What would be obvious to that person? What is the inventive step here? Does the fact that “the structural analyses ... are carried out by machine” mean there can be no inventive step?

Question 2:

Does the fact that tissue was taken from pregnant women offend against public morality. What is the relevance of the taking being for profit? Does the patent give “private ownership” to a gene? If so, does this “disgust” or offend the dignity of man? Does an observance of article 53(a) require the EPO to make enquiries in each member state as to what is contrary to public order and morality? Is there any public policy in favour of the grant of the Patent?

**MEMORANDUM D.**  
**INFORMATION FOR THE GROUP REPORT UNIT**

**1. The purpose of the Group Report Unit**

The purpose of the Group Report unit is two-fold. First, it provides a focus for the deliberations carried out in the Group Work unit. Knowing that a Report is required gives motivation and context for attempting to answer the questions raised by the task. Secondly, a Report by each group provides important information to the members of the other groups. In this way, participants get to learn about the issues and answers involved in tasks other than the one carried out in their group. Having other participants deliberate on and then report about a set of issues is an effective and efficient way of sharing the learning.

**2. The role of the group members**

The role of the group members is to provide a clear and succinct oral report of how the group tackled the task, and of the outcomes of their deliberations. This may be done in a number of equally appropriate ways. For example, a group may appoint one spokesperson to provide the Report. Alternatively, a number of the group members may be involved in providing the Report.

The Report should explain the approach adopted to answering each question, the answer to each question, and the reasons for this answer. For example, in relation to a question concerning novelty, the Report should (briefly) identify the provisions of the legislation which are relevant (i.e. article 54), determine whether the documents provided are part of the state of the art, ascertain what is disclosed by the state of the art, compare this with the subject matter of each claim, and draw a conclusion about whether or not each claim is novel.

**3. The role of the exercise facilitators**

The role of the exercise facilitator during the Group Report unit is limited. If necessary, the facilitator might need to prompt the group to respond to a specific question or issue comprised in the task, or to clarify a statement by the group. The facilitator has the opportunity to comment on, and if necessary correct or expand on, the report of the group during the Review unit which follows.

## MEMORANDUM E.

### INFORMATION FOR THE REVIEW UNIT

Please note: this document provides comment on the substantive legal questions to facilitate the review of the exercise. This information should not be used prior to the group exercises themselves, as it would reduce the value of the groups' own analysis of the issues. These comments are provided at this stage to help ensure that the discussion is focussed and comprehensive.

For further reference, Document 9 in the attached documentation is a copy of the actual decision delivered by the European Patent Office in the Relaxin opposition case. It is suggested that this is consulted and discussed **after** the validity exercise and the review unit.

#### 1. The purposes of the Review Unit

The Review unit provides an opportunity for facilitators to give feedback to the participants on the discussions in the Group Work unit, and on the conclusions they report. It also allows participants to ask questions, and make comments, on any aspect of any of the tasks, either of their own group or some other group. The Review unit can assist in clarifying and revising the legal principles on the validity of biotechnology patents. It is also an opportunity to analyse the different approaches which might be adopted in applying these principles in practice, in particular to consider how they might be applied differently in other countries.

Set out below are some comments on each of the specific questions dealt with by the groups. To the extent to which a group did not address one of these questions, or addressed it in a different manner, the group facilitator can use these comments as the basis for further instruction on that issue.

These comments do not represent a definitive or authoritative answer on any of these issues under European or any other laws, but are provided to stimulate further discussion. The review process might also discuss whether the rules are likely to be different, or be applied differently, in other countries, for example countries in the Asia Pacific region.

#### 2. Comments on the Task of Group A

##### Question 1(a):

- In general terms, the Invention is novel.
- The *DNA* article is part of the state of the art for determining novelty, because it was published on a date (24 August 1982) before the deemed date of filing (which is the priority date, pursuant to article 89) of the Application (13 December 1982, the date of the Australian application).
- The application for the H1-relaxin patent is also part of the state of the art for determining novelty, even though it was published on a date (22 February 1984) **after** the deemed date of filing of the Application. This is because its deemed date of filing (12 August 1982) is before the deemed date of filing of the Application, and so it forms part of the state of the art under article 54(3).
- Neither document discloses H2-relaxin or the gene for it.

- The article from the journal *DNA* is concerned with porcine relaxin. It discloses the DNA sequence for the porcine gene for relaxin and the amino acid sequence of porcine relaxin. These sequences differ in significant ways from the DNA and amino acid sequences for H2-relaxin claimed in the Application.
- The H1-relaxin patent discloses the DNA and amino acid sequences for H1-relaxin. Whilst there is a close degree of similarity between these sequences and the respective sequences claimed in the Application, nevertheless there are important differences. The Application identifies these differences.
- There are some individual claims in relation to which it can be argued there is a lack of novelty.
- Claim 1 refers to 'a sub-unit' or 'an equivalent' of the gene for H2-preprorelaxin. Certain parts of the H1-relaxin gene would be a sub-unit, and might be an equivalent, of the H2-preprorelaxin gene. Accordingly, those sub-units and equivalents are disclosed in the state of the art.
- Thus, claim 1, and any claim dependent on it (eg. claims 3 and 5) or drafted like it (eg. claim 7) is not novel.

Question 1(b):

- In general, the Invention involves an inventive step.
- The *DNA* article is part of the state of the art for determining inventive step, but the H1-relaxin patent application is not. This is because article 56 excludes documents within the meaning of article 54(3) – the H1-relaxin patent application had not been published at the priority date of the present patent application.
- The *DNA* article does not disclose, or suggest, that there is an H2-relaxin gene. More significantly, the *DNA* article does not disclose, or suggest, what is the DNA and/or amino acid sequence of the H2-relaxin.
- Similar to the situation with respect to novelty, it may be argued that claim 1 (and any dependent or similar claim) lacks an inventive step, because the state of the art discloses sub-units and/or equivalents of the gene for H2-preprorelaxin.

Question 1(c):

- In general terms, the Invention claimed in the Application is capable of industrial application.
- The Invention can be made or used in an industry. For example, knowledge of the DNA and amino acid sequences, and in particular how to synthesise them, may be used to produce synthetic compounds for administration to humans.

Question 2:

- In general terms, the Invention is not a discovery as such.
- The Application goes beyond disclosing the existence of H2-relaxin, and in particular discloses the DNA and amino acid sequences of H2-relaxin, thereby providing a means by which H2-relaxin can be synthesised. Synthesised H2-relaxin is not a naturally occurring substance.
- There are some individual claims which it can be argued are for a discovery as such.
- Claim 1 (and any dependent or similar claim) is for a discovery as such, because it does not identify the DNA or amino acid sequences of H2-preprorelaxin.

Question 3:

- None of the claims are for methods for treatment of the human body by surgery or therapy.

- Although the Invention is likely to lead to therapies for treating the human body, the claims themselves are not for any such treatment. The claims are limited to genes, transfer vectors, transformed cells, and production processes for certain of those subject matters.

Question 4:

- The claims do not seem to be contrary to “ordre public” or contrary to law.
- It does not seem possible to identify a public policy which is breached by the Invention.
- Also, it seems possible to identify a public policy in favour of the Invention – *eg* the relief of suffering during childbirth, and the production of new products for treating other diseases.

Question 5:

- It is arguable that the claims relate to more than one invention or inventive concept.
- It may be argued that the claims relating to H2-relaxin and production processes therefor are for an invention different from that claimed in the claims relating to H2-relaxin analogues and the processes for their production.

Question 6:

- Generally, the claims are clear and concise.
- It may be argued that claim 1 (and any dependent or similar claim) is not clear, because it does not specify the DNA and amino acid sequences for H2-relaxin.

### **3. Comments on the Task of Group B**

Questions 1(a) and 2:

- The objection of lack of unity of invention arguably results from too strict an application of the principle.
- It is arguable that there is one general inventive concept disclosed in the Application – the DNA and amino acid sequences of H2-relaxin – and that all the claims relate to this one inventive concept.
- If this argument is not persuasive, the Application should be amended by deleting claims 24-29 and claims 30-32. Two further applications, one for each of these groups of deleted claims, could be made, each claiming a priority date the same as that of the Application.

Question 1(b) and 2:

- The objection of lack of clarity of some claims seems valid.
- Claim 1, and any claim dependent on it (eg. claims 3 and 5) or drafted like it (eg. claim 7), refers to ‘a gene for the expression of human H2-preprorelaxin’, but it does not identify the sequence of the gene or of H2-preprorelaxin. The claim (and any dependent or similar claim) thus could fail to properly define the subject matter for which protection is sought (and arguably also is for a discovery as such, and is not capable of industrial application).
- Claim 1 (and any dependent or similar claim) should be amended, so as refer to DNA encoding for a particular amino acid sequence, and the amino acid sequence should be set out in the claim.

Question 1(c) and 2:

- The objection of lack of novelty of some claims seems valid.
- Claim 1, and any claim dependent on it (eg. claims 3 and 5) or drafted like it (eg. claim 7), refers to ‘a sub-unit’ or ‘an equivalent’ of the gene for H2-preprorelaxin. Certain parts of the

H1-relaxin gene would be a sub-unit, and might be an equivalent, of the H2-preprorelaxin gene. Accordingly, those sub-units and equivalents are disclosed in the state of the art.

- The claim (and any dependent or similar claim) thus lacks novelty.
- The claim (and any dependent or similar claim) should be deleted.

#### **4. Comments on the Task of Group C**

##### Question 1(a) and 2:

- There is arguably some ground, albeit slight in substance, for saying that there is no “industry” in which the subject matter of the claims of the Patent can be made or used.
- This argument addresses the fundamental issue of what is an “industry”. It might be argued that an “industry” is something in which a practical application of the invention can occur, where such application is of economic, as distinct from say intellectual or theoretical, significance.

##### Question 1(b) and 2:

- The argument that the Invention is a discovery is a stronger ground of opposition.
- It can be argued that the claims to DNA fragments are claims to a discovery as such. This argument deals with the fundamental issues of what is a “discovery”, and of what is meant by the “as such” qualification imposed by article 52(3).
- It can be argued that the DNA fragment is naturally occurring, and all the patentee has done is discover the sequence of it. Merely identifying and disclosing the composition of a naturally occurring molecule is not sufficient to warrant the grant of a patent for the molecule.

##### Question 1(c) and 2:

- It is difficult to identify any law to which the grant of the Patent would be contrary.
- There is more scope for arguing that the grant of the Patent is contrary to “ordre public”.
- It might be said that genes are naturally occurring subject matter which should not be capable of being owned by anyone. Reference to the fact that genes are the biological building blocks of human beings might support this assertion.

##### Question 1(d) and 2:

- It could be argued that the subject matter of the DNA fragment claims, and of related claims, are not novel because they concern material that is already in existence. Pre-existing material should not be considered new.
- It is harder to make this argument in relation to the claims dealing with synthesised DNA fragments.
- The process claims seem to have novelty.

##### Question 1(e) and 2:

- There is some ground for arguing that the Invention lacks an inventive step.
- It could be argued that it would be obvious to a person skilled in the art that it would be desirable to identify the sequence of a (second) gene for relaxin in humans, and that given the state of the art about relaxin, it would be obvious to proceed to identify that sequence.
- It might be said that all the patentee has done is apply known and obvious techniques to achieve an obviously desirable piece of information.

## 5. Comments on the Task of Group D

### Question 1(a):

- The claims which refer to the DNA fragments by their ability to encode for a particular amino acid are for more than a discovery as such.
- These claims indirectly described the sequence of the DNA fragments, because a person skilled in the art would know, and the patent specification itself states, which codons code for which amino acids.
- These claims are to more than a discovery as such. They are claims to subject matter which has a particular, and described, chemical composition.

### Question 1(b):

- It can be said that the claimed subject matter lacks novelty only if it has previously been “made available to the public”.
- The fact that the H2-relaxin gene and H2-relaxin were pre-existing, by virtue of being in the human body, does not mean they had been made available to the public. That is to say, there has been no making available to the public, by written or oral disclosure, by use, or in any other way, of H2-relaxin or the gene encoding for it.
- Also, the main claims are not to the H2-relaxin gene, but to DNA fragments encoding for the production of H2-relaxin. These fragments are not the same as the gene for H2-relaxin, because they do not include introns (non-coding sequences which are present in the natural DNA).
- The claims to the DNA fragments, and the rest of the claims, are thus novel.
- The DNA fragments were not “isolated and purified”. Rather, the mRNA was determined, the DNA cloned and recombinant technology used to produce H2-relaxin.

### Question 1(c):

- There were no disclosures in the state of the art which suggested or made obvious the existence of a second human relaxin protein and thus a gene therefor.
- The inventive step was to ascertain that there was a second human relaxin protein.
- The use of automated processes for determining the chemical structure of the DNA fragments does not change the fact that there was an inventive step. The chemical structure could not have been determined without first knowing of the existence and amino acid sequence of the second human relaxin protein.

### Question 2:

- The grant of the Patent does not have the effect of transferring a gene to private ownership. The H2-relaxin gene is not owned by anyone. Rather, the Patent grants limited exclusive rights to certain subject matter (DNA fragments) and processes which were not known, and which did not exist, prior to the making of the Invention.
- The grant of the Patent has not been shown to be contrary to any law.
- The grant of the Patent is beneficial to society in a number of respects. The Patent discloses information that can be used to produce synthetic therapeutic compounds, which provide relief from suffering during childbirth and have other therapeutic benefits.

### **For further study**

After the exercise, training participants may like to read the actual decision delivered by the European Patent Office in this case (attached as Document 9). Do you agree with the way these issues were addressed in this decision?

**MEMORANDUM F.**  
**LIST OF MATERIALS PROVIDED TO PARTICIPANTS**

On the basis of practical experience, it is suggested that the groups initially be given only the documents specified for their role, together with the Memorandum (G, H, I or J) corresponding to their group. This is intended to encourage independent analysis and diversity of views on the issues raised. The remaining documents could perhaps be made available in the review period.

<b>Doc. No.</b>	<b>TITLE OF DOCUMENT</b>	<b>For Groups</b>
1	European Patent Convention 1973 - selected provisions from Part II Chapter I, Part III Chapter I, Part V and Part VI ('EPC')	A, B, C, D
2	European Patent Application no. 83307553.4 ('the Application')	A, B
3	Haley, J. et. al., "Porcine Relaxin: Molecular Cloning and cDNA Structure", <i>DNA</i> <u>1</u> , 155-162 (1982) ('the DNA article')	A
4	European Patent Application publication no. 0,101,309 ('the H1 - relaxin patent application')	A, B
5	European Patent Office Examination Report on Application no. 83307553.4 ('the Examination Report')	B
6	"Greens go to law to block human gene patent", <i>New Scientist</i> , 1 February 1992, page 16 ('the <i>New Scientist</i> article')	C
7	European Patent no. 0,112,149 ('the Patent')	C, D
8	Opposition to European Patent no. 0,112,149 ('the Grounds of Opposition')	D
9	EPO decision on the opposition	After the exercise

**MEMORANDUM G.**  
**INSTRUCTIONS FOR GROUP A**  
**EUROPEAN PATENT OFFICE EXAMINATION REPORT**

**1. Your role**

You are an Examiner in the European Patent Office ('EPO'), in the Biotechnology section.

**2. Your task**

You are to examine European Patent Application no. 83307553.4 ('the Application'), which is Document 2 in the attachments. The Application concerns a gene which encodes for the production in humans of the hormone relaxin. More particularly, you are to examine the Application for compliance with the provisions of the European Patent Convention ('EPC') dealing with Patentability and Filing Requirements –i.e. under Part II Chapter I and Part III Chapter I of the EPC (the relevant extracts of which are in Document 1). You are to determine the extent to which the Application satisfies these requirements.

You are provided with two pieces of prior art, found as a result of the Search conducted by the EPO Search Division. These are an article in the scientific journal *DNA* (Document 3) and a published application for another European Patent (Document 4). You are to assume that these two documents are the only relevant documents found as a result of that search.

**3. Your questions**

- Do all the claims satisfy article 52(1) –i.e. are they for an invention that:
- is novel, under articles 54 and 55?
- involves an inventive step, under article 56?
- is capable of industrial application, under article 57?
- Are any of the claims excluded by article 52(2)(a) –i.e. are they discoveries?
- Are any of the claims excluded by article 52(4) –i.e. are they for methods for treatment of the human body by surgery or therapy?
- Are any of the claims excluded by article 53(a) –i.e. are they contrary to “ordre public” or morality?
- Do the claims satisfy article 82 –i.e. do they relate only to one invention or inventive concept?
- Do the claims satisfy article 84 –i.e. are they clear and concise and supported by the description?

**4. Your materials**

- Document 1: European Patent Convention 1973 - Part II Chapter I, Part III Chapter I, Part V and Part VI (selected provisions)
- Document 2: European Patent Application no. 83307553.4
- Document 3: Haley, J. et. al., “Porcine Relaxin: Molecular Cloning and cDNA Structure”, *DNA* 1, 155-162 (1982)
- Document 4: European Patent Application publication no. 0,101,309

**MEMORANDUM H.**  
**INSTRUCTIONS FOR GROUP B**  
**PATENT ATTORNEY'S RESPONSE TO EXAMINATION REPORT**

**1. Your role**

You are a European Patent Attorney, specialising in biotechnology patents.

**2. Your task**

You are to prosecute European Patent Application no. 83307553.4 ('the Application') before the European Patent Office ('EPO'). The Application is Document 2 in the attachments. The Application concerns a gene which encodes for the production in humans of the hormone relaxin.

More particularly, you are to respond to the first substantive Examination Report of the EPO ('the Examination Report'), which is Document 5. This examination considers the extent to which the Application complies with provisions of the European Patent Convention ('EPC') dealing with Patentability and Filing Requirements –*i.e.* under Part II Chapter I and Part III Chapter I of the EPC (Document 1). The Examination Report refers to a published application for another European Patent (Document 4).

**3. Your questions**

Are the following objections raised in the Examination Report valid:

- the claims lack unity under article 82 –*i.e.* there are three separate inventions, being claims 1-23, claims 24-29 and claims 30-32?
- the claims (inc. claim 1) which refer to "H2-preprorelaxin" per se lack clarity under article 84 –*i.e.* they do not identify the specific structural features which distinguish between H1, H2 and known human relaxin?
- the claims (inc. claim 1) which refer to "or a sub-unit thereof" lack clarity under article 84 and novelty under article 54 –*i.e.* they are not clearly distinguished from certain of the claims in the earlier European Patent Application publication no. 0,101,309 for H1-relaxin?

What amendments, if any, should be made to the Application in light of these objections?

**4. Your materials**

- Document 1: European Patent Convention 1973 - Part II Chapter I, Part III Chapter I, Part V and Part VI (selected provisions)
- Document 2: European Patent Application no. 83307553.4
- Document 4: European Patent Application publication no. 0,101,309
- Document 5: E.P.O. Examination Report on Application no. 83307553.4

**MEMORANDUM I.**  
**INSTRUCTIONS FOR GROUP C**  
**OPPONENT'S GROUNDS OF OPPOSITION TO GRANT**

**1. Your role**

You are a member of the European Green Party.

**2. Your task**

As reported in an article in the *New Scientist* magazine (Document 6 in the attachments), you are to oppose the grant of European Patent no. 0,112,149 ('the Patent') before the European Patent Office ('EPO'). The Patent is Document 7 in the attachments. The Patent concerns a gene which encodes for the production in humans of the hormone relaxin.

More particularly, you are to prepare the Grounds of Opposition, for filing in the EPO. The grounds on which an Opposition may be filed are set out in article 100 of the European Patent Convention ('EPC'), extracts of which are in Document 1.

**3. Your questions**

Is it feasible to oppose the grant of the Patent on any of the following grounds; that the invention:

- is not capable of industrial application, under article 52(1)?
- is excluded as a discovery, under article 52(2)(a)?
- is excluded as contrary to "ordre public" or morality, under article 53(a)?
- is not novel, under article 54?
- does not involve an inventive step, under article 56?
- If so, what arguments would you make in support of those grounds?

**4. Your materials**

- Document 1: European Patent Convention 1973 - Part II Chapter I, Part III Chapter I, Part V and Part VI (selected provisions)
- Document 6: Article in *New Scientist* magazine, 1 February 1992, page 16
- Document 7: European Patent no. 0,112,149

**MEMORANDUM J.**  
**INSTRUCTIONS FOR GROUP D**  
**PATENT ATTORNEY'S REPLY TO OPPOSITION**

**1. Your role**

You are a European Patent Attorney, specialising in biotechnology patents.

**2. Your task**

You are to defend an Opposition filed against European Patent no. 0,112,149 ('the Patent') before the European Patent Office ('EPO'). The Patent is Document 7 in the attachments. The Grounds of Opposition are set out in Document 8. The Patent concerns a gene which encodes for the production in humans of the hormone relaxin.

More particularly, you are to prepare the Reply to the Opposition, for filing in the EPO. The grounds on which an Opposition may be filed are set out in article 100 of the European Patent Convention (extracts of which are in Document 1).

**3. Your questions**

- How should you respond to the technical and legal arguments contained in Parts I and II of the Opposition –*i.e.* the arguments that the invention:
  - is excluded as a discovery, under article 52(2)(a)?
  - is not novel, under article 54?
  - does not involve an inventive step, under article 56?
- How should you respond to the morality arguments contained in Parts III and IV of the Opposition –*i.e.* the arguments that the invention is excluded as contrary to “ordre public” or morality, under article 53(a)?

**4. Your materials**

- Document 1: European Patent Convention 1973 - Part II Chapter I, Part III Chapter I, Part V and Part VI (selected provisions)
- Document 7: European Patent no. 0,112,149
- Document 8: Opposition to European Patent no. 0,112,149

## 6.4 Documents for the Relaxin Patent Validity Exercise

- 1 European Patent Convention 1973 - selected provisions from Part II Chapter I, Part III Chapter I, Part V and Part VI ('EPC')
- 2 European Patent Application no. 83307553.4 ('the Application')
- 3 Haley, J. et. al., "Porcine Relaxin: Molecular Cloning and cDNA Structure", *DNA* 1, 155-162 (1982) ('the DNA article')
- 4 European Patent Application publication no. 0,101,309 ('the H1 -relaxin patent application')
- 5 European Patent Office Examination Report on Application no. 83307553.4 ('the Examination Report')
- 6 "Greens go to law to block human gene patent", *New Scientist*, 1 February 1992, page 16 ('the *New Scientist* article')
- 7 European Patent no. 0,112,149 ('the Patent')
- 8 Opposition to European Patent no. 0,112,149 ('the Grounds of Opposition')
- 9 Decision of the EPO on the Opposition