

Questions and answers concerning patentin and directive

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

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

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1.1 Why is the directive needed?

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

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

In other words: what was there was unclear, unharmonised and unworkable.

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

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

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

1.2 What is a patent?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.5 Does the directive give special advantages to biotechnology inventions?

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

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

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

1.6 Why does genetic material need patent protection?

Key issues, which require clarification, are

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

The human body is made up of billions of cells, all of which contain genes composed of DNA strands of chemical building blocks called nucleotides. Such genes represent the instruction manual of an organism, containing the essential information for development and life of the organism. In humans these genes comprise sequences of about 3,000 million nucleotides amounting to some 100,000 genes. Genes are present in the human body along with very many other chemical substances. The key chemicals of living organisms: amino acids, proteins and nucleic acids are made by living cells thanks to the instructions contained in these genes. Diseases can arise, if these genes contain errors or are processed inappropriately.

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

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

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

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

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

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

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

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

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

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

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

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

1.8 Does the directive permit the patenting of life?

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

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

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

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

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

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

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

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

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

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

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

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

1.9.1 But doesn't gene patenting stifle research?

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

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

However, in relation to commercial research it does not necessarily follow that others are irrevocably blocked as it will often be possible to negotiate a licence under the patent – or challenge its validity. The pharmaceutical industry is opposed to any attempt to impose compulsory licensing as that would undermine the incentives that the patent system provides. A better way is to rely on voluntary licence agreements as we always have done.

Finally, it is always open to third parties to obtain 'dependent patents' - that is to say, patent a new use for an already patented gene. The original finder of the gene could not then commercialise the new use without a licence under the dependent patent. This situation, which tends to stimulate cross-licensing, is inherent in the patent system. It is frequently encountered with pharmaceuticals and is in principle no different in the genomics field.

1.10 Animal breeding

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

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

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

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

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

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

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

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

1.11 Does modern biotechnology really help patients?

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

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

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

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

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

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

1.12 How is biotechnology controlled?

Biotechnology is closely controlled. It does not take place in a legal vacuum.

At European and national levels laws and guidelines provide a framework of strict obligations within which biotechnology users must operate. So researchers must, for instance, provide details of research plans and any changes must be reported to committees responsible to governments. They must also record all results. In addition, medical research in patients or healthy volunteers is covered by specific medical rules and conventions, and subject to scrutiny by ethics committees.

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

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

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

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

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

Predictions about the behaviour of GMOs can be made with the same, if not greater, degree of accuracy as for non-modified biological entities.

Specifically, the existence of patents covering such products enhances the possible control of this, and has no influence on the granting of any permission to place GMOs into the environment.

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

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

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

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

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

1.15 Can animals be patented?

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

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

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

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

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

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

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

1.15.2 Is a patent on a DNA marker possible?

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

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

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

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

1.15.4 Is offspring a subject of the patent?

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

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

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

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

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

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

1.15.6 Information

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

1.15.6.1 The exemption

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

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

1.15.6.2 Application of the derogation

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

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

In fact, although this may vary according to the species, patented animals will be dispersed from farm to farm. For example, in the beef cattle sector, transfers between farms are frequent and types of use are varied (bulls sold for immediate slaughter, for breeding purposes, etc.). Logically, the patentee should then sell breeding stocks with a side contract specifying the requirement to indicate any transfer of semen, embryos or animals. He could then monitor each transfer of patented animals, identify transfers for "commercial reproduction", test each animal and check which ones carry the patented genetic modification, and finally ask for royalties. But such monitoring seems highly difficult: is it realistic to expect farmers to become involved in such patent enforcement?

Is a monitoring of sales and collection of royalties possible given the large volume of sales and numerous changes of ownership? Facing such difficulties, the patentee may find that policing to collect royalties is unnecessary and that marketplace solutions present the most efficient method of allocating the cost of enforcement. He may carry out no monitoring and claim no residual rights to fees but merely sell the animal for a higher price.

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

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

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

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

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

Against this it may be objected:

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

Although often the first and second question are presented together, it is interesting to see that they do not sit well together. The first presupposes that we should leave nature on its own, and the second that nature is owned (by mankind). The latter view clearly implies that you are allowed to use nature for the benefit of mankind.

The patent directive permits the patenting of a range of types of biological material. However, it may be asked whether this is compatible with the view that nature is shared property of mankind as a whole. A particular problem here is the so-called "farmer's privilege".

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

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

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

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

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

1.16.3 Will patents boost an unsustainable development in agriculture?

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

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

1.16.4 Do patents have an adverse effect on animal welfare?

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

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

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

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

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

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

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

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

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

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

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

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

Table 1: Differences USA vs. Europe patent applications

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

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