



### **“The EPO follows the EU’s Directive on biotechnology patents”**

**Munich, 27 October 2005** – The European Patent Office (EPO) has noted the concern that several groups in the European Parliament have expressed about the grant of European patent [EP 1257168](#) B1. However, the Office emphasises that it follows an extremely cautious approach in patenting biotechnological inventions.

In motions communicated to the EPO, members of the European Parliament have stated that, in their view, the grant of this patent, which is entitled “Method of cryopreserving selected sperm cells”, constitutes a violation of the Directive on the legal protection of biotechnological inventions (98/44/EC). The MEPs maintain that the patent also covers non-patentable human germ cells. They have therefore announced their intention to contest the grant of this patent by initiating an opposition procedure before the EPO. Other worries expressed in the motions concern the future development of the EPO’s practice in patenting human embryonic stem cells.

The President of the EPO, Alain Pompidou, has confirmed that such a patent was granted to the US Company XY Inc. of Fort Collins, Colorado, in February 2005, pointing out that the nine-month period during which oppositions to the patent can be filed by third parties will terminate on 2 November 2005: “The European patent grant procedure allows anyone to formally oppose a patent if they are of the opinion that it should not have been granted. This is an inbuilt legal remedy for establishing legal certainty on the patentability of an invention.”

#### **Opposition procedure**

In view of the pending case, Mr Pompidou declined to comment on the individual objections expressed in the motions: “We take the concerns voiced by the MEPs very seriously. However, it will be the task of a dedicated EPO body, the opposition division, to consider the case in the light of the formal grounds brought forward by opponents. To date, such a procedure could not be opened as no oppositions have yet been filed.” He added that every year around 5% of the patents granted by the EPO are contested in opposition proceedings. In two thirds of these cases, the patent is changed or even revoked in its entirety.

The EPO grants patents by applying the [European Patent Convention](#) (EPC). The EPC forms the legal basis for the Office’s institutional structure and its activities and operations. It has been ratified by the 31 [member states of the European Patent Organisation](#), 24 of which are also member states of the European Union. The EPC has enabled the transnational protection of innovations by patents in the European market and is seen by many countries as a model for regional cooperation in the field of intellectual property.

Since September 1999, the EPO has applied the EU Directive in its patenting practice. According to Mr Pompidou: “Following a decision of our supervisory body,

the Administrative Council, this Directive has been incorporated into the EPC Implementing Regulations. We thus strictly adhere to the provisions of the EPC and the Biotechnology Directive.”

### **Strict quality standards and transparency**

Biotechnology is one of the technical fields in which large numbers of patent applications are filed every year. In 2004, the EPO received 6 581 patent applications in biotechnology and granted some 4 000 patents. “We apply very strict standards in examining these applications”, the EPO President said. “The provisions of the EPC and the Directive, together with the case law of the Boards of Appeal, which are the EPO’s judiciary, demand a restrictive approach to patenting biotechnological inventions. We are fully aware that this is a sensitive field of technology and also has important ethical implications. However, one should also bear in mind that obtaining a patent does not imply permission to actually use an invention. This is the responsibility of regulatory bodies, not of the EPO.”

### **Inbuilt legal remedies**

Mr Pompidou acknowledged that, despite all the quality controls in place at the EPO, it is impossible to rule out the possibility that some patents do not meet its high quality standards in all aspects. For the current year the EPO expects to receive 190 000 patent applications. In 2004 the Office granted 60 000 patents, each one of them after a rigorous three-step procedure involving a comprehensive novelty search through more than 55 million documents and a thorough examination for compliance of the claimed invention with patent law. “The task of our 3 400 patent examiners is extremely challenging. They work at the forefront of technology and have to take difficult decisions within a complex legal and ethical framework, knowing that there is always a risk of inaccuracy. However, the European patent system takes that risk fully into account and has inbuilt legal remedies to oppose granted patents”, the EPO President explained.

With the help of the EPO’s free patent information services such as [epoline®](#) and [esp@cenet®](#), it is possible for anyone to inspect files pending before the EPO at all times: “The patent system provides complete transparency on any case pending or granted. Anyone who wishes to do so can monitor progress on any file at all stages of the procedure and even send us observations without getting legally involved in the case, and we will have to take them to account.”

### **Restrictive approach to human embryonic stem cells**

On the question of human embryonic stem cells, President Pompidou pointed out that the EPO has so far taken a very restrictive approach to the patenting of human embryonic stem cells and cell lines obtained from them. Following the “Edinburgh patent” case, the EPO has not granted patents for such inventions. Moreover, it has raised objections to the patentability of inventions pertaining to human embryonic stem cells in a number of applications that have been examined so far. The EPO’s Technical Board of Appeal is called upon to give a first decision on the subject on 18 November. It has the option of referring the issue to the EPO’s highest instance, the Enlarged Board of Appeal, for a definitive legal ruling.

### **Information for journalists:**

1. European patent [EP 1 257 168 B1](#) was granted on 2 February 2005 to XY Inc., Fort Collins, CO (USA), based on a corresponding patent application filed with the

EPO on 22 November 2002. The title is "Method of cryopreserving selected sperm cells".

## 2. Implementation of Directive 98/44/EC

Directive 98/44/EC of the European Parliament and the Council on the legal protection of biotechnological inventions was adopted on 6 July 1998. In its decision of 16 June 1999, the Administrative Council of the European Patent Organisation, which supervises the activities of the EPO and is composed of representatives of all the contracting states to the European Patent Convention (EPC), incorporated the relevant provisions of this Directive into European patent law. Though not legally subject to this formal requirement, the European Patent Organisation decided that European patent law needed to be brought into line with the Directive, primarily in order to comply with the requirement for uniformity in harmonised European patent law.

## 3. Exclusion from patentability of inventions whose exploitation would be contrary to ordre public or morality

The EPC expressly stipulates that the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. However, an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention, even if the structure of that element is identical to a natural element.

Recital 16 of the Directive and the Guidelines for examination in the EPO state that such stages in the formation or development of the human body include germ cells. Moreover, [Rule 23b\(1\) EPC](#) states that the Directive must be used as a supplementary means of interpretation. This is intended in particular to ensure that the recitals preceding the provisions of the Directive are also taken into account and to promote a uniform Europe-wide interpretation of the relevant provisions.

4. [Article 53a EPC](#), in line with Article 6(1) of the Directive, establishes a general principle of exclusion for inventions whose exploitation would be contrary to ordre public or morality. Article 6(2) of the Directive lays down an illustrative list of exclusions from patentability which the EPO has implemented by the introduction of [Rule 23d EPC](#). Recital 38 of the Directive confirms that this list is not exhaustive and that any process whose application offends against human dignity is also excluded from patentability. It thus follows from both the provisions of the Directive and of the EPC that, as regards the human body and its elements, the applicable legal framework rigorously ensures that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded.

## 5. Patentability of human embryonic stem cells and cell lines obtained from them

[Rule 23d\(c\) EPC](#) implements Article 6(2)c) of the Directive. It stipulates that European patents may not be granted in respect of biotechnological inventions which, in particular, concern uses of human embryos for industrial or commercial purposes. The European Group on Ethics considered in its opinion No. 16 that there was no ethical reason for a complete ban on the patenting of inventions relating to stem cells or stem cell lines, although the normal requirements of patentability would have to be met. The EPO's departments of first instance have a much more restrictive practice on the patenting of human embryonic stem cells and cell lines obtained therefrom. According to the practice of the EPO examining and opposition divisions, [Rule 23d\(c\) EPC](#) excludes from patentability all claims to the industrial or

commercial use of human embryos and also all claims to associated products which necessitate the direct and unavoidable use of a human embryo, for example, embryonic cells. Appeals have been filed against several first-instance decisions. The EPO Boards of Appeal will now have to construe the wording of [Rule 23d\(c\) EPC](#) themselves and form their own conclusions on what falls within its scope. In their decisions, the members of the Boards are not bound by any instructions and must comply only with the provisions of the EPC.

## 6. Abuses and risks of a given technology

A patent is an industrial property right for an intangible asset, the invention, which must represent a technological improvement. The right which it accords is to prevent all others - not just imitators but even independent devisers of the same idea - from using the invention for the duration of the patent. A patent does not authorise its holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes. In other words, the grant of a patent does not confer a positive right to use the invention without complying with all the applicable rules of the legal system. Regardless of whether or not a patent is granted, the inventor has to respect all legal provisions that might possibly prohibit the working or marketing of the subject-matter of his invention. Patent law is thus not a suitable tool for preventing any abuses or risks associated with a given technology. It cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards.

## 7. Transparency

The practice of the European Patent Office adheres strictly to the legal principles and high standards laid down by the European Patent Convention. The EPO provides for a maximum of transparency and information on its activities. Patent applications are published 18 months after filing or after the priority date. Once a European patent application has been published, the file relating to it is open to inspection. This means that any member of the public can view the communications between the Office, its first and second-instance departments and the parties involved in the procedure. Such file inspections can be made online and are free of charge. Furthermore, all European patent applications and patents can be accessed on the Internet at [www.espacenet.com](http://www.espacenet.com), while any legal and procedural status information can be obtained from the EPO's *epoline*® server at [www.epoline.org](http://www.epoline.org) free of charge. Procedural information on any patent can be retrieved from the [Online European Patent Register](#).

European patent law also provides for a highly developed system of legal remedies. Any person may present observations concerning the patentability of the invention in respect of which the application has been filed. In addition, any third party can file an opposition to a granted patent, without having to prove a direct interest in the case. The possibility of appeal exists both against the decisions of the examining and opposition divisions. Furthermore, proceedings to revoke the patent, even if its validity has been upheld in opposition proceedings and/or subsequent appeal proceedings, can be instituted in any designated contracting state.

