INTRODUCTION

Background of the report

On April 24 2001 the European Commission appointed the European Group on Ethics in Science and New Technologies (EGE). In his welcome message President Prodi requested the Group to give an Opinion on the ethical aspects of patents resulting from research into stem cells.

In response to this request, the Group announced at its first meeting on May 29 2001 that the next opinion to be issued would deal with the use of human stem cells and the patentability of the inventions deriving from such research. The EU Biotechnology Directive underlines that the EGE is competent in delivering such an opinion. The Directive stipulates in this respect that “the Commission’s European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law” 1.

This report was developed in response to the request of the Group to provide them with the current information and documentation with regard to patents for human stem cell research.

Ever since 1988, when the first proposal for a European Directive on the legal protection of biotechnological inventions was laid down 2, patents on ‘living’ material received much public attention, because of the delicate question to which extent ‘life’ and ‘living material’ is appropriable by way of patents. Since 1998, when human pluripotent stem cells were first isolated, the patent issue gained growing interest in civil society again, because of the legal and ethical implications patents on human stem cells entail. In view of the increasingly explosive nature of this issue, there is an urgent need for intense discussion of the emerging questions.

Scope of the report

The present report starts with a brief overview of stem cell technology in order to assist the reader in understanding the key events in stem cell technology and the subject matter for which patent protection is claimed (Part I).

The report then describes the current patent practice (Part II) and the state of patent legislation with regard to human stem cell technology (Part III). Much of the progress made to date in stem cell technology was dependent on animal models and understandings gained from mouse models and mouse stem cell research. However, this report will mainly focus on the patent practice and patent framework for human stem cell technology.

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Patenting of inventions related to human stem cell research

The report ends by devoting substantial attention to some questions that remain unsettled and offering some routes for reflection (Part IV).

Aim and approach of the report

It has been the aim of the report to provide relevant information with regard to the current patent granting policy - both in Europe and in the US - and the patent law framework in Europe. Relevant and up to date information with regard to patent policy and patent legislation on human stem cell research was gathered in order to enable the EGE to gain insight in this complex and delicate issue and to enable the EGE to elaborate a well-founded opinion.

The author wishes to emphasise that the guiding thought while carrying out this study was to provide the EGE with the necessary prior information and to offer relevant data. It was not the author's intent to put her personal opinion in the forefront.

This results in a report where one can often read that certain developments 'appear' to be inconsistent, or certain interpretations 'seem' to be awkward. This equally results in a study where no position is taken with regard to the patentability of human stem cell research, but where arguments are developed to substantiate a possible decision. Or where various routes of reflections are developed in order to accommodate current patent law to the specific characteristics of human stem cell research, taking into account the public concerns with regard to biotech patenting.

Several approaches were taken to obtain relevant information for this report. Various scientific experts in stem cell research were interviewed. A thorough examination of both European and US patent databases was conducted. An extensive review of former and current European patent legislation and case law was carried out.

The majority of the patents involved emanates from research in academic laboratories, but many patents were also found from private pharmaceutical and biotechnology companies. The report aimed at including both academic and private research and subsequent patenting, and was not limited to either government or private funded research.

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