BIO/2013/1

Annotated agenda

Meeting of the Commission expert group on the development and implications of patent law in the field of biotechnology and genetic engineering

Brussels, 12 December 2013
'Cassis de Dijon' room, rue de Spa 2, 1000 Brussels

9.00 – 9.15 **Arrival of the Members**

9.30 – 9.45 **Welcome address by Mr Pierre DELSAUX, Deputy Director General of the 'Internal Market and Services' Directorate-general ('DG MARKT')**

Mr Pierre DELSAUX will welcome the Members of the Group, explain the rationale underlying its establishment and specify the Commission's overall expectations vis-à-vis the scope of, and methodology for, the work of the Group.

9.45 – 10.15 **Presentation of the Members**

Each Member will present him/herself and describe his/her particular area of competence.

10.15 – 10.45 **Presentation of the mandate and expected contribution of the Group by Kerstin JORNA, Director of Intellectual Property, DG MARKT**

The European Commission is responsible for the monitoring of the application of Directive 98/44 on the legal protection of biotechnological inventions ('The Biotech Directive'). As part of this responsibility and pursuant to Article 16 of the Directive, the Commission shall report regularly to the European Parliament and the Council, notably through so-called 'Article 16c' reports on the development and implications of patent law in the field of biotechnology and genetic engineering.

Two such reports were already issued in 2002 and 2005. Since the publication of these reports however, outstanding scientific advances have occurred, giving rise to new technologies. Concurrently, the EU Court of Justice handed out two landmark decisions relating to crucial provisions of the directive (C-428/08 Monsanto, C-34/10 Brüstle) and the Enlarged Board of Appeal of the European Patent Office also clarified some very important aspects of patent law in this field (G 2/06 Warf, G 2/07 Broccoli and G 1/08 Tomatoes).

Against this backdrop, the Commission has decided to set-up a Commission expert group on the development and implications of patent law in the field of biotechnology and genetic engineering (Decision of 7 November 2012). The mandate of the expert group, which is broader than the scope of the Article 16c report, is to provide the Commission with the necessary legal and technical expertise regarding intellectual property law practice and intellectual property law administration, public and industrial research and development, life sciences including plant and animal breeding, and biotechnology in the context of the application of the Biotech Directive.

Through the establishment of the Group, the ambition of the Commission is to develop the capacity to review and discuss both scientific evolutions and the evolution of EU law in the field of biotechnology and genetic engineering. It is also to identify current trends and future potential challenges. This and the advice of the Group on selected items will contribute to the preparation of the next Article 16c report by the Commission.

10.45 – 11.15 **Coffee break**

11.15 – 12.15 **General discussion**

Biotechnology and genetic engineering play an important role in a broad range of industries, such as agriculture, food production, pharmaceuticals, and environment. The harmonized protection of biotechnological inventions contributes to maintaining and encouraging investment in the field of biotechnology.

Over an open debate, preferably starting in the form of a *tour de table*, the Members will be invited to present their views on what they consider to be the most noticeable developments and trends in the area of biotechnology and genetic engineering, as well as the possible implications, and challenges they represent in terms of patent law in the broadest sense (from a legal, political, economic or technical perspective).

12.15 – 13.00 **Preliminary exchange of views on the working methods of the Group**

The Commission would like to collect the views of the Members on what they consider to be the most appropriate and efficient ways to conduct the work of the group, subject to the applicable rules. Working methods should be discussed, in the light of the relevant provisions of the Decision establishing the Group and of the general rules governing Commission expert groups.

13.00 – 14.30 **Lunch break**

14.30 – 16.00 **Preliminary exchange of views on two priority issues identified by the Commission**

The Commission has to date identified two priority questions for discussion, namely those of the patentability of Human Embryonic Stem Cells and the patentability of plant products deriving from essential biological processes. The Commission will, in turn, briefly introduce the two issues and the Members will be invited to present their preliminary views on these questions.

Patentability of Human Embryonic Stem Cells

According to article 5 of the Biotech Directive, the human body at the various stages of its formation and development cannot constitute patentable inventions. This definition encompasses the human embryo. In Brüstle, the EUCJ has broadly defined the embryo as covering i) any human ovum after fertilisation, but also ii) non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and, iii) any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.

However the case law to date leaves unanswered a number of key questions which are of relevance today. For instance, about i) the patentability of stem cells lines which do not induce the destruction of human embryos, or ii) the patentability of stem cells which come from non-fertilised ovum which are not capable of commencing the process of development of a human being.

Patentability of plant products deriving from essential biological processes

Article 4 of the Biotech Directive provides that plant varieties, as well as 'essential biological processes' for the production of plants are not patentable. However, uncertainty remains as to whether the exclusion of biological essential processes from patentability also affects the admissibility of product claims related to plants.

This question has been referred by technical Boards of Appeal to the Enlarged Board of Appeal of the European Patent Office in the context of non-microbiological process based on sexual crossing of whole genomes and on subsequent selection of plants through the use of a technical step (markers). The decision of the Enlarged Board of Appeal (on the so-called Tomatoes and Broccoli cases) is now expected in the coming months.

16.00 – 16.30 **Concluding remarks by Mr Jonathan FAULL, Director General of DG MARKT**

16.30 – 17.00 **'Wrap-up' session**

The Commission will draw the main conclusions of the meeting and consider the next steps, as well as possible date for the next meetings.