BIO/2014/1 FINAL

SUMMARY MINUTES

1st meeting of the
Expert Group on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering

Brussels, 12 December 2013

1. Opening of the meeting and welcome address by Mr Pierre DELSAUX

Mr Pierre DELSAUX, Deputy Director General of the 'Internal Market and Services' Directorate-general ('DG MARKT') welcomed the Members of the Group. He stressed the European Commission's expectations that the Group and its individual Members would significantly contribute to the Commission's better mapping of the current trends characterizing the biotechnology field, and a more precise understanding of the possible challenges deriving from those trends from the patent law angle. This in view of the elaboration of the forthcoming report on the development and implications of patent law in the field of biotechnology and genetic engineering, pursuant to Article 16 (c) of the Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions ('the Biotech Directive').

He stressed that the scope of the work of the Group is defined by its mandate as provided for in the corresponding Commission Decision, and in particular that the Group is not mandated to discuss ethical issues, which are the competence of the European Group on Ethics in Science and New Technologies. He underlined however that the scope of the mandate is rather broad, in that whilst it is clearly related to the Biotech Directive it should enable the Commission to rely on the Group's expertise to better understand the general trends in the sector, to put the discussion of specific issues in a broader perspective.

2. Presentation of the Members

Each Member, as well as the Commission representatives introduced him/herself and described his/her particular area of expertise.

3. Presentation of the mandate and expected contribution of the Group

The Commission further elaborated on the mission assigned to the Group, the scope of its mandate and the logic of its composition.

The Group is expected 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, with the exception of ethical issues. It should provide the Commission with analysis and position papers on topics related to the

Biotech Directive, thereby assisting the Commission in its reporting requirements in accordance with Article 16 (c) of the Directive.

The Commission explained that the final selection of experts reflects a mix of skills, various points of view and different expertise within the biotechnology field. The group includes 9 experts appointed in their personal capacity and 6 experts representing an interest or an organisation. The composition took into consideration, and reflects, the required balance of expertise. The experts appointed in their personal capacity represent the requisite areas of expertise in academia, the legal profession, and public and industrial research. The interests or organisations selected include stakeholders with a wide representativeness and a strong relevance to the subject-matter of the group. The final selection strikes a fair balance in terms of gender and the widest possible geographical representation.

The Commission further clarified that the mission of the Group is neither to enter into a general discussion on biotechnology or genetic engineering and their stakes, nor to make general recommendations to the Commission on how to develop its policy in this sector. Instead the group is to examine to what extent the new scientific, technological and industrial property law trends in this field either challenge the Biotech Directive, in that they raise issues which cannot be tackled by the principles set out therein, or raise new questions of application or interpretation of those principles. The objective pursued is to determine whether, in view of recent developments, there is a need to clarify certain issues and, if so, how.

4. General discussion

In a first general discussion, the Members of the Group were invited to identify the current trends and challenges in the area of biotechnology and genetic engineering. Members were also invited to share their views on how the sector would look like in 2025, and to identify any new scientific or technical development likely to be of great significance in the future, in particular from the angle of patent law and of the Biotech Directive.

A fruitful debate took place. Experts focused on what they considered to be major developments, new biotechnology applications, the noticeable evolutions of case law, national legislation and expert committee reports in respect of biotechnological patents, current or future legal challenges and areas requiring further investigations. In addition to the subjects as described in point 6 below, the Members identified many items such as – inter alia: the rapid development of bioinformatics; the growing availability of enhanced genomic sequencing techniques; the progress of synthetic biology and of reverse genetics; the development of new breeding techniques; cloning; the so-called 'breeders' exemption'; compulsory licenses and cross-licences under the Biotech Directive; the question of absolute versus 'purpose bound' protection; the public debate about research funding, and about the patentability of what may be considered 'natural processes' in light of recent US case law.

Operational conclusions:

It was concluded that the Commission would prepare a 'mapping' paper for further consideration by the Group at the next meeting, in order to identify the most relevant issues for further, in-depth discussion.

5. Preliminary exchange of views on the working methods of the Group

The Commission briefly introduced what it considered to be the timeline and principles governing the work of the Group. The intention of the Commission is to convene up to four meetings prior to the summer break 2014. The result of the mapping would be circulated to the Members before the next meeting, in order to structure the future discussions and to agree on the working methods. It was emphasized that a chairperson of the Group has to be elected, and that rapporteurs for specific topics could also be elected. The Members were invited to communicate their possible interest for chairmanship to the Commission.

Operational conclusions:

The Group will continue to discuss procedural questions and working methods at the next meeting.

6. Preliminary exchange of views on two priority issues identified by the Commission

A more substantive preliminary discussion took place on two issues identified by the Commission as self-evident subjects for further, detailed discussion within the Group.

Patentability of Human Embryonic Stem Cells

After a short presentation of the issue by the Commission, the Members presented their preliminary views on the patentability of human embryonic stem cells. New techniques inter alia IPS cells, parthenogenesis, SNCT and non-destructive methods in relation to obtaining and using stem cells were mentioned. The Members widely agreed upon the appropriateness of inviting an independent ad hoc expert who could give an account of the latest scientific developments in that field.

Patentability of plant products deriving from essential biological processes

After another short introductory presentation by the Commission, the Members expressed their preliminary views on the patentability of plant products deriving from essential biological processes. The members agreed to a large extent that greater clarity on the scope of the exclusion from patentability of essential biological processes and the potential effect on the patentability of products deriving thereof is needed. Some of the Members also stressed that the interface between patent protection and plant variety protection should be carefully determined. Some also mentioned that the compulsory cross-licencing provided for in Article 12 of the Biotech Directive merits discussion.

Operational conclusions:

The Group will continue to discuss these issues in forthcoming meetings.

7. Concluding remarks by Mr Jonathan FAULL

The Group was addressed by Mr Jonathan FAULL, Director General of DG MARKT, who thanked the Members for their dedication to what he expected to be a very successful process. He underlined the importance of the Group in assisting the Commission in its efforts to tackle patent law issues in a field which is of critical economic and societal importance for the European Union, but is also very complex.

8. ‘Wrap-up’ session

The Commission concluded the day by stating that a 'mapping' paper aimed at identifying the most relevant trends and issues for future discussion, as well as draft summary minutes, would be circulated before the next meeting of the Group.

Annex: List of participants

Name
BOSTYN Sven (Mr)
CSÖRGŐ Szonja (Ms)
FARQUHARSON Andrew (Mr)
ISERENTANT Hannes (Mr)
JACOB Robin (Sir)
KAMPERMAN SANDERS Anselm (Mr)
KNUTH-LEHTOLA Sisko (Ms)
PEREIRA Gautier (Mr)
PUIGDOMÈNECH Pere (Mr)
SATTLER DE SOUSA Clara (Ms)
SCHNEIDER Ingrid (Ms)
TAORMINO Joseph (Mr)
THEN Christopher (Mr)
WÜRTZ LINDUM Peter (Mr)
YEATS Siobhán (Ms)
JORNA Kerstin – EC
ARBAULT François - EC
GAL Jean-Luc – EC
ZAMYKALOVA Lucie – EC
CLEMENT-NISSOU Isabelle – EC
JUHASZ Hilda – EC
KESSLER Charles – EC