SUMMARY MINUTES

7th meeting of the

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

Brussels, 30 October 2014

1. Opening of the meeting

The Chair welcomed the Members of the Group.

2. Adoption of the agenda for the 7th meeting and of the summary minutes of the 6th meeting

The Chair invited the Members to express their comments on the draft agenda. He proposed to add on the agenda a short discussion point concerning the extent to which the Group is satisfied with the answers to its questions that could be gathered from the presentation of Professor Peter Andrews during the 6th meeting on 16 September 2014.

One member expressed dissatisfaction with the nature and scope of the reporting on the substance of Peter Andrew's presentation, as this consisted only of part of the Memorandum of discussion related to the last meeting of the 'stem cell' sub-group. Another member of the Group took the view that the content of Peter Andrews's presentation should be more substantially recorded. As a result of some discussion, the Group agreed that it is primarily for the 'stem cell' sub-group's members to decide whether the questions put forward have been answered to their satisfaction, although the discussion is of interest to the whole Group.

The Commission pointed out first that the circulation of Peter Andrew's PowerPoint presentation in pdf format was made for the sake of reference and did not imply that no further record of the substance of his intervention would be prepared. It was finally agreed that a more detailed but nonetheless synthetic account of the points made by Professor Andrews which are directly relevant to the questions put to him or to the work of the Group more generally will be prepared. The Secretariat (Commission) will elaborate a specific document containing this information. The draft document will then be send to Professor Peter Andrews, in view of his confirmation of the accuracy of its content.

The Chair subsequently invited the Members to comment the draft summary minutes of the 6th meeting. Besides the question of the reporting on Professor Peter Andrews’s presentation, no additional comments were raised.

Operational conclusions:

The draft agenda for the 7th meeting and was agreed upon by the Members.

The draft summary minutes of the 6th meeting were adopted.
The Secretariat will prepare and circulate a separate document recording the key relevant points made by Professor Peter Andrews.

3. Mandate of the Group – Clarifications by the Commission

Based on a supporting document, BIO/2014/19, that had been circulated to the Members (see Annex 2), the Commission clarified the scope of the mandate of the Group, with reference to Article 16(c) of the Biotech Directive and of the Commission's decision establishing the Group. It was further clarified that in accordance of the Decision, the tasks entrusted with the Group are to assist the Commission in preparing a new Article 16(c) report by providing it 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 but excluding the discussion of ethical issues, by means of the provision, as indicated by the Commission services, of analysis and position papers on topics related to the Biotech directive.

The Commission further explained that whilst the approach taken so far has been to let the Group identify itself the issues which it deems relevant to explore in view of its mandate, the Commission attaches great importance to specific conclusions to be reached on specific issues within a reasonable time frame. Should that prove challenging, the Commission could consider specifying in a more target way the questions on which it would seek the Group's opinion within a well identified deadline. The Commission also specified the spirit in which it expected the Group to work: to all extent possible, consensus should be sought on the conclusions of the group. When this is not possible, majority views should be identified. However, minority views could be expressed in the form of dissenting opinions. Finally it was clarified that once thematic discussions carried out in sub-groups are exhausted and result in the Group's (plenary form) final conclusions, new sub-group can be established to deal with other issues identified as a result of the so-called 'mapping' exercise.

4. Deliberations of the sub-groups

The Group temporarily broke out in two parallel sessions of the sub-groups on, respectively, the patentability of human stem cells and the patentability of plant-related issues. Discussions focussed in these sub-groups on some substantive questions identified by the 'stem cell' Deputy Rapporteur Sir Robin Jacob and the extraordinary (absent both the Rapporteur and deputy Rapporteur) 'plant' Rapporteur Mr Sven Bostyn. The Members contributed actively to the discussion. They reached preliminary conclusions on a number of points and identified some issues requiring further substantive discussion.

Operational conclusions:

The Commission will prepare an account summarising the sub-group discussions and transmit it to the relevant Rapporteurs or Deputy Rapporteurs, who will in turn prepare a 'Memorandum of discussion' to be circulated.

5. Plenary session of the Group - discussion of the sub-group outcomes

The outcome of each of the sub-groups was presented by the corresponding Rapporteur at the resumption of the plenary session of the Group. The Chair subsequently opened the floor for
comments. Priority was given to the Members not having participated in the discussions at sub-group level. A number of relevant and constructive comments were made, leading to a fruitful debate allowing to further elaboration of the relevant scope of the future thematic discussions.

Operational conclusions:

The Groups agreed to continue the substantive discussions in the sub-groups dedicated to the patentability of human stem cells and plant-related issues. The first draft of sub-groups' reports covering all issues discussed so far plus the issues remaining to be discussed should be circulated in good time before the next meeting for a first exchange. These first drafts will be the subject of the debate in the sub-groups at the next meeting scheduled for 27 November 2014. The discussions are to be pursued at both sub-group and plenary level.

6. AOB

No point discussed.
Annex 1: List of participants

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<td>BOSTYN Sven (Mr)</td>
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<td>CSÖRGŐ Szonja (Ms)</td>
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<td>FARQUHARSON Andrew (Mr)</td>
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<td>ISERENTANT Hannes (Mr)</td>
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<td>JACOB Robin (Mr)</td>
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<td>KNUTH-LEHTOLA Sisko (Ms)</td>
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<td>PEREIRA Gautier (Mr)</td>
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<td>SCHNEIDER Ingrid (Ms)</td>
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<td>TAORMINO Joseph (Mr)</td>
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<td>VAN DER SPIEGEL Stefaan - EC</td>
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Mandate of the Group

7th meeting of the Commission expert group on the development and implications of patent law in the field of biotechnology and genetic engineering

Brussels, 30 October 2014

'Thierry Stoll' room, rue de Spa 2, 1000 Brussels

By virtue of Article 16(c) of Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions (the 'Biotech Directive'), the Commission shall report annually to the European Parliament and the Council on "the development and implications of patent law in the field of biotechnology and genetic engineering". It follows that the Commission has to report both on the developments that have taken place in this field, and on the consequences or conclusions that may have to be drawn from such developments.

In consideration of the issuance of a new 'Article 16(c) report, the Commission has set up, by means of a Decision of 7 November 2012 ('the Decision'), an expert group on the development and implications of patent law in the field of biotechnology and genetic engineering ('the Group') whose mission is to assist the Commission in preparing the report (Recitals 1 to 4 and Article 2(b)). Whilst the main rationale for the creation of the Group is the assistance to the Commission in complying with its reporting obligation, the scope of the mandate of the group is broader. The tasks of the Group are defined in Article 2 of the decision and provide as follows:

"Article 2

Tasks of the group

The group's tasks shall be:

a) 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

1 This working document is produced in support of a further clarification requested by the Group on the exact scope of its mandate. The relevant legal act formally setting out the Group's mandate is the Commission's Decision of 7 November 2012
biotechnology in the context of the application of [the Biotech Directive], with the exception of ethical issues related to that Directive, which are the mandate of the European Group on Ethics in Science and New Technologies;

b) to assist the Commission in its reporting requirements in accordance with Article 16, paragraph (c) of [the Biotech Directive];

c) to provide the Commission with analysis and position papers on topics related to [the Biotech Directive] as indicated by the Commission services.

In addition and pursuant to Article 3 of the Decision, "[t]he Commission may consult the group on any matter related to the application of Directive 98/44/EC."

It should be also noted that in the annotated agenda of the kick-off meeting of the Group on 4 December 2013, the Commission services indicated that "[t]hrough 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".

It follows from the above that:

i. the primary and core task of the Group is to assist the Commission in the preparation of a new Article 16(c) Report, and that:

ii. in the broader context of the "application of [the Biotech directive]", the Group shall "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" [...] "with the exception of ethical issues related to [the Biotech Directive]".

To that effect, the Group may in particular:

i. be requested, as indicated by the Commissions services, to provide analysis and position papers on topics related to [the Biotech Directive]; (Article 2(c) of the Decision)

ii. be consulted on any matter related to the application of [the Biotech Directive]; (Article 3 of the Decision)

In conclusion, the tasks entrusted with the Group are to assist the Commission – in the preparation of a new Article 16(c) report but also in the broader context of the application of the Biotech Directive – by providing it 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 but excluding the discussion of ethical issues, by means of the provision, as indicated by the Commission services, of analysis and position papers on topics related to the Biotech directive.