RULES OF PROCEDURE
OF THE GROUP OF EXPERTS ON DEVELOPMENT AND IMPLICATIONS OF PATENT LAW
IN THE FIELD OF BIOTECHNOLOGY AND GENETIC ENGINEERING

Brussels, 24 March 2014

THE GROUP ON DEVELOPMENT AND IMPLICATIONS OF PATENT LAW IN THE FIELD OF
BIOTECHNOLOGY AND GENETIC ENGINEERING,

Having regard to the Commission Decision on setting up the group on development and implications
of patent law in the field of biotechnology and genetic engineering¹,

Having regard to the standard rules of procedure of expert groups²,

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Article 1
Convening a meeting

1. Meetings of the group are convened by the Commission after consultation of the Chair and the
group members.

2. Joint meetings of the group with other groups may be convened to discuss matters falling within
their respective areas of responsibility.

3. Meetings of the group shall be held on Commission premises.

Article 2
Agenda

1. The Commission shall draw up the agenda in close cooperation with the Chair and send it to the
members of the group.

2. The agenda shall be adopted by the group at the start of the meeting.

¹ Commission Decision C(2012) 7686 final of 7 November 2012
² SEC(2010) 7649 final
Article 3

Documentation to be sent to group members

1. The Commission shall send the invitation to the meeting, the draft agenda and documents on which the group is consulted to the group members no later than ten working days before the date of the meeting.

2. In urgent or exceptional cases, the time limits for sending the documentation mentioned in 1 and 2 may be reduced to five working days before the date of the meeting.

3. With respect to the summary minutes of the meetings, Article 9 shall apply.

Article 4

Analysis and positions papers of the group

1. As far as possible, the group shall adopt documents or provide its analysis and positions papers by consensus.

2. If a consensus cannot be reached, the decision should be made on the basis of a vote. In the event of a vote, the outcome of the vote shall be decided by a simple majority of the members of the group.

3. In the absence of consensus dissenting opinions may be expressed.

Article 5

Sub-groups

1. At the initiative of the Commission, the group may set up sub-groups to examine specific questions on the basis of terms of reference defined by the group; such sub-groups shall be disbanded as soon as their mandate is fulfilled.

2. The rapporteurs of the sub-groups shall report to the group the progress and the conclusion endorsed by the sub-groups.

Article 6

Admission of third parties

The Commission in consultation with the Chair of the group and after consulting its members may invite on an ad hoc basis experts from outside the group with specific competence in a subject on the agenda to participate in the work of the group or sub-groups. In addition, the Commission may give observer status to individuals and organizations as provided in the horizontal rules on expert groups.
**Article 7**

**Written procedure**

1. If necessary, the group's adoption of a document, or the group's analysis or position paper on a specific question may be delivered via a written procedure (silence procedure). To this end, the secretariat shall send to the group members the document(s) on which adoption by the group is sought. The Commission, after consultation of the Chair, shall set the date of expiry of the silence procedure, i.e. the date and time on which the subject matter of the written procedure shall be deemed adopted if the silence procedure has not been broken. The time limit set for the silence procedure shall not be shorter than five working days.

2. However, if a member of the group breaks the silence procedure and asks for the question to be examined at a meeting of the group, the written procedure shall be terminated without result and the Commission shall put the matter on the agenda of the next meeting of the group for further discussion and/or adoption.

**Article 8**

**Secretariat**

The Commission shall provide secretarial support for the group and any sub-groups created under Article 5(1) above.

**Article 9**

**Summary minutes of the meetings**

1. Summary minutes on the discussion on each point on the agenda and the opinions delivered by the group shall be drafted by the secretariat in consultation with the Chair. The minutes shall not mention the individual position of the members during the group's deliberations.

2. The Commission shall send the draft summary minutes to the group members no later than ten working days after the meeting.

3. The group members shall submit their comments to the secretariat within the given period of time but in any event no later than ten working days after the circulation of the draft summary minutes.

4. The group shall adopt the summary minutes by consensus.
Article 10

Attendance list

At each meeting, the Commission shall draw up, under the responsibility of the Chair, an attendance list specifying, where appropriate, the authorities, organisations or bodies to which the participants belong.

Article 11

Conflicts of interest

1. Should a conflict of interest in relation to an expert arise, the Commission may exclude this expert from the group or a particular meeting thereof or it may decide that the expert in question shall abstain from discussing the items on the agenda concerned and from any vote on these items.

2. At the start of each meeting, any expert whose participation in the group’s work would raise a conflict of interest shall immediately inform the Chair and the Commission.

3. Conflicts of interest shall be reported in writing, e.g. in the summary minutes of the group’s meeting.

4. Paragraphs 1, 2 and 3 shall also apply mutatis mutandis to deliberations taken by the group in written procedure.

Article 12

Correspondence

Correspondence relating to the group shall be addressed to the Commission and shall, as appropriate, be brought to the attention of the Chair and/or the group members by the secretariat.

Correspondence for group members shall be sent to the e-mail address which they provide for that purpose.

Article 13

Publication - Access to documents

1. The Commission shall publish agendas, summary minutes, analysis or position papers of the group, including dissenting opinions as the case may be, either by including it in the Register or via a link from the Register to a dedicated website.
2. Exceptions to systematic publication should be foreseen where disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001\textsuperscript{3}.

\textit{Article 14}

\textbf{Confidentiality of deliberations}

The group’s deliberations shall be in principle confidential, unless the Commission agreed to open the deliberation to the public further to a duly motivated request adopted by the group by a simple majority.

\textit{Article 15}

\textbf{Protection of personal data}

All processing of personal data for the purposes of these rules of procedure shall be in accordance with Regulation (EC) No 45/2001\textsuperscript{4}.

\textit{Article 16}

\textbf{Applicability}

The provisions of these rules of procedure are without prejudice on the relevant provisions of the Decision on setting up a Commission expert group on development and implications of patent law in the field of biotechnology and genetic engineering (C(2002)7686 final).


\textsuperscript{4} Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. (OJ L 8, 12.1.2001, p. 1).