



Brussels, 7.11.2012
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COMMISSION DECISION

of 7.11.2012

**on setting up a Commission expert group on development and implications of patent law
in the field of biotechnology and genetic engineering**

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Whereas:

- (1) Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter referred to as "Directive 98/44/EC") lays down on the Commission the obligation to annually report to the European Parliament and the Council on the development and implications of patent law in the field of biotechnology and genetic engineering.
- (2) Given the complex nature of biotechnology in particular in relation to patent law, the Commission may need to call upon the expertise of specialists in an advisory body.
- (3) It is therefore necessary to set up a group of experts in the area of intellectual property law, in particular patent law and the law on plant variety rights, as well as public and industrial research and development, life sciences including plant and animal breeding, and biotechnology and to define its tasks and its structure.
- (4) The group should assist the Commission in preparing a report on the development and implications of patent law in the field of biotechnology and genetic engineering.
- (5) The group should be composed of experts from intellectual property law practice and intellectual property law administration, public and industrial research and development, life sciences including plant and animal breeding, and biotechnology.
- (6) The group will not touch upon ethical issues related to Directive 98/44/EC, which are the mandate of the European Group on Ethics in Science and New Technologies.
- (7) The composition of the group should be balanced both with regard to gender and geographical origin as far as possible.
- (8) All members should satisfy high standards of active and quality participation during the meetings and in their preparation and follow up if needed.
- (9) Rules on disclosure of information should be laid down.
- (10) Personal data should be processed in accordance with Regulation (EC) No 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 data¹.

HAS DECIDED AS FOLLOWS:

Article 1

Commission expert group

The group of experts on the development and implications of patent law in the field of biotechnology and genetic engineering, hereinafter referred to as 'the group', is hereby set up.

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 biotechnology in the context of the application of Directive 98/44/EC, 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 Directive 98/44/EC;
- (c) to provide the Commission with analysis and position papers on topics related to Directive 98/44/EC as indicated by the Commission services.

Article 3

Consultation

The Commission may consult the group on any matter related to the application of Directive 98/44/EC.

Article 4

Membership – Appointment

- (1) The group shall be composed of a maximum of 15 Members.

¹ Regulation (EC) No 45/2001 of the European Parliament and 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 the free movement of such data (OJ L, 8, 12.1.2001, p. 1).

- (2) Members shall be individuals appointed in a personal capacity, individuals representing a common interest, and/or organisations as referred to in Rule 8 of the horizontal rules for Commission expert groups.
- (3) The composition of the group shall reflect the required balance of expertise in the area of intellectual property law practice and intellectual property law administration, public and industrial research and development, life sciences including plant and animal breeding, and biotechnology.
- (4) All members and their representatives shall satisfy high standards of active and quality participation during the meetings and in their preparation and follow up if needed.
- (5) A call for applications shall be published by the Commission services with a view to selecting the members of the group.
- (6) Members shall be appointed by the Director General of DG Internal Market and Services. Those members shall be chosen from individuals and organisations with competence in the areas referred to in Article 2 and which have responded to the call for applications.
- (7) Organisations shall nominate their representatives. The Director General of DG Internal Market and Services may refuse a representative proposed by an organisation on the basis that the representative does not meet the profile required in the call for applications. Members are appointed for 2 years. Their term of office may be renewed by the Director General of DG Internal Market and Services for a maximum of 2 years. The Director General of DG Internal Market and Services shall decide on the renewal of one or several members on the basis of the quality, regularity and relevance of their expertise as defined in paragraph 3.

Members shall remain in office and active until replaced.

- (8) On the basis of the call for applications, applicants who were deemed suitable candidates for group membership but were not appointed shall be placed on a reserve list, with their consent. The Commission shall use this list for the appointment of replacements for members, if needed. If the Commission considers the reserve list insufficient, it may re-publish the call for applications in order to constitute a new list.
- (9) Members who are no longer capable of contributing effectively to the group's deliberations, who resign or who do not comply with the conditions set out in this Article, or Article 339 of the Treaty, may be replaced for the remainder of their term of office by the Director General of DG Internal Market and Services.
- (10) Individuals appointed in a personal capacity shall act independently and in the public interest. Individuals appointed to represent a common interest shared by stakeholders shall not represent an individual stakeholder.
- (11) Members appointed in a personal capacity shall each year sign an undertaking to act in the public interest and a declaration indicating the absence or existence of any interest which may undermine their objectivity. They shall also declare at each

meeting any specific interest which may be considered as prejudicial to their independence in relation to the items on the agenda.

- (12) The names of individuals appointed in a personal capacity, of individuals representing a common interest, and of organisations, shall be published in the Register of Commission expert groups and other similar entities ('the Register') and on the internet site of the Directorate-General for the Internal Market and Services. The interests represented by individuals shall also be published in the Register.
- (13) Members who do not wish to have their names disclosed may apply for exemption from this rule. A request not to disclose the name of a member of an expert group shall be considered justified whenever publication could endanger his or her security or integrity or unduly prejudice his or her privacy.
- (14) Personal data shall be collected, processed and published in accordance with Regulation (EC) No 45/2001².

Article 5

Operation

- (1) The group shall act at the request of the Commission's DG for Internal Market and Services and shall normally meet on Commission premises.
- (2) The Commission's DG for Internal Market and Services shall provide secretarial services and set the agenda of the meetings in advance and to this effect may take into account suggestions from the members of the group.
- (3) The Commission services may decide that the group meets in full or in subgroup(s) which shall be composed of those members whose expertise and/or interests are of specific relevance to the points of the agenda of the specific meeting. At least one Commission official of the Commission's DG for Internal Market and Services shall attend the meetings of the group and its subgroups. Other Commission officials with an interest in the proceeding may attend meetings of the group and its subgroups.
- (4) The Commission services shall appoint the chairperson of the group and a rapporteur for each subgroup from amongst its members.
- (5) The chairperson or rapporteur will identify existing analyses, reports, case studies or other on-going activities related to the issues put forward by the Commission services. The rapporteur will write an analysis and position paper in advance of meetings of the expert group, which will define more closely, the particular issue to be addressed.
- (6) The analysis and position papers will be discussed during group or subgroup meetings and will be prepared well in advance by the rapporteur(s).
- (7) The Commission's representative may invite experts from outside the group with specific competence in a subject on the agenda to participate in the work of the group

² OJ L 8, 12.1.2001, p. 1.

or subgroup on ad hoc basis. In addition, the Commission's representative may give observer status to individuals, organisations as defined in Rule 8(3) of the horizontal rules on expert group and candidate countries.

- (8) All members of the group and their representatives, as well as invited experts and observers invited for a specific meeting, shall comply with the obligations of professional secrecy laid down by the Treaties and their implementing rules, as well as with the Commission's rules on security regarding the protection of EU classified information, laid down in the Annex to Commission Decision 2001/844/EC, ECSC Euratom³. Should they fail to respect these obligations, the Director General of DG Internal Market and Services may take all appropriate measures.
- (9) The rules of procedure of the group shall be the standard rules of procedure for expert groups, unless the group adopts specific rules.
- (10) The Commission shall publish the relevant documents (such as agendas, minutes and participants' submissions) on the activities carried out by the group either by including it in the Register or via a link from the Register to a dedicated website. 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) N° 1049/2001

Article 6

Meeting expenses

- (1) Participants in the activities of the group shall not be remunerated for the services they render.
- (2) Travel and subsistence expenses incurred by participants in the activities of the group shall be reimbursed by the Commission in accordance with the provisions in force within the Commission.
- (3) Those expenses shall be reimbursed within the limits of the available appropriations allocated under the annual procedure for the allocation of resources.

Article 7

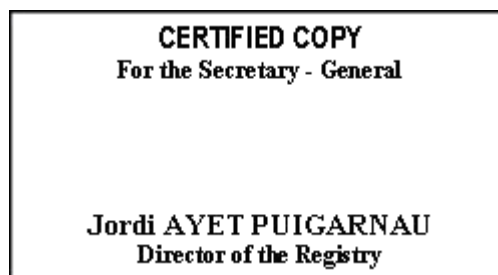
Applicability

³ Commission Decision of 29 November 2001 amending its internal Rules of Procedure (OJ L 317, 3.12.2001, p. 1).

This Decision shall apply until 31 December 2016.

Done at Brussels, 7.11.2012

For the Commission
Michel BARNIER
Member of the Commission



ANNEX

Call for applications for the selection of experts as members of the Commission expert group on development and implications of patent law in the field of biotechnology and genetic engineering

By decision of 7 November 2012 ('the Decision'), the Commission has set up a group of experts on development and implications of patent law in the field of biotechnology and genetic engineering. The task of the group of experts is to assist and advise the Commission in its reporting requirements under Article 16, paragraph (c) of Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (hereinafter referred to as 'Directive 98/44/EC').

The group shall bring together renowned experts from intellectual property law practice and intellectual property law administration, public and industrial research and development, life sciences including plant and animal breeding, and biotechnology.

The Commission is therefore calling for applications with a view to selecting members.

The group of experts shall consist of a maximum of 15 members appointed in accordance with Article 4 paragraph (2) of the Decision.

The Commission will take the following criteria into account when assessing the applications:

- sound understanding of the EU acquis regarding the legal protection of biotechnological inventions and the European Patent Convention;
- proven competence and long term experience in one or more of the following fields; intellectual property law practice, intellectual property law administration, public and industrial research and development, life sciences including plant and animal breeding, or biotechnology;
- demonstrated ability to work in English;
- members of the group of experts must be nationals of a Member State of the European Union or European Economic Area Country;
- the need to strike a fair balance within the group in terms of representativeness of interests and expertise and in terms of gender and geographical origin⁴.

The duly signed applications must be sent by **12 December 2012**. The date of sending will be established as follows:

- Where applications are sent by e-mail to the following address: **Markt-D2@ec.europa.eu** with the subject '**Applications for stakeholder expert group on biotechnology**'. The date of the e-mail will be considered the date of sending.
- Where applications are sent by post to the following address: European Commission, Directorate-General Internal Market and Services, SPA2 5/87, Unit D2 Secretariat,

⁴ Commission Decision 2000/407/EC of June 2000 relating to gender balance within the committees and expert groups established by it (OJ L 154 of 27.6.2000, p. 34).

Room 5/87, Rue de Spa 2 B – 1049, Bruxelles (Belgique), the postmark date will be considered the date of sending.

- Where applications are hand-delivered to the following address: European Commission, Directorate-General Internal Market and Services, Unit D2 Secretariat, Room 5/87, Rue de Spa 2, B – 1000, Bruxelles (Belgique), the date on the receipt given upon delivery will be considered the date of sending.

Each application must be completed in one of the official languages of the European Union and must clearly indicate whether the application is made for individuals in a personal capacity, individuals appointed to represent a common interest shared by stakeholders or for an organisation. However, applications in English would facilitate the evaluation procedure. If another language is used, it would be desirable to include a summary of the CV in English.

All applicants must submit a curriculum vitae indicating their educational background, professional experience and language knowledge (maximum 2 pages) in support of their application.

The following information should also be included (this list is not exhaustive):

- The organisation/company/authority for which the applicant has been working and the length of time he/she has worked there.
- Other organisations/companies/ authorities, for which he/she has worked in the past.
- His/her specific competences in relation to intellectual property law or life sciences.
- The specific projects and or tasks he/she has been involved in concerning intellectual property law and life sciences.
- Any works that he/she has published that concern the application of Directive 98/44/EC.
- Any experience he/she has acquired at EU and international level.
- His/her major professional challenges foreseen in the near future.
- Any interests that he/she has, which may prejudice his or her independence.

Applications from organisations/companies also have to include information on:

- The role which intellectual property law and/or life sciences play in their organisation/ company; the type and quality of their relations with patenting;
- The scale and scope of their activities related to intellectual property law and/or life sciences;
- Their mission and their mandate (where applying organisations/companies).

The Commission shall select members of the group for a 2 year term, renewable once. Members shall give the Commission an independent opinion free from outside influence and shall respect the conditions of confidentiality mentioned in Article 5 of the Commission

Decision establishing the group of experts. They shall commit to act independently and in the public interest.

Travel and subsistence expenses incurred by participants in the activities of the group shall be reimbursed by the Commission in accordance with the provisions in force at the Commission within the limits of the available budgetary appropriations. Members will receive no remuneration for their duties.

The list of members of the group of experts shall be published in the Register of expert groups⁵.

Personal data will be collected, processed and published in accordance with the provisions of Regulation (EC) No 45/2001⁶.

For any further information please contact Ms KANTAS, Telephone (32-2) 29 66 392, E-mail: susanna.kantas@ec.europa.eu

Information on the results of the call for applications will be published at least in the Internet site of the DG Internal Market and Services and, if appropriate, in the *Official Journal of the European Union*.

⁵ Members who do not wish to have their names disclosed may apply for exemption from this rule. The request not to disclose the name of a member of an expert group shall be considered justified whenever publication could endanger his or her security or integrity or unduly prejudice his or her privacy.

⁶ Regulation (EC) No 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 of 12.1.2001, p. 1).