

NGO Alliance on Horizon 2020

June 17 2012

Amendments to the

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down the [rules for the participation and dissemination](#) in 'Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)' Brussels, 30.11.2011 COM(2011) 810 final, 2011/0399 (COD)

Amendment 1 Proposal for a Regulation - Rules for participation Recital 2

Text proposed by the Commission	Amendment
Horizon 2020 should be implemented with a view to contributing directly to creating industrial leadership, growth and employment in Europe and should reflect the strategic vision of the Commission Communication of 6 October 2010 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region "Europe 2020 Flagship Initiative Innovation" ⁴ whereby the Commission engages to radically simplify access of participants.	Horizon 2020 should be implemented with a view to contributing directly to creating <i>citizens welfare, social, economic and ecological sustainability</i> , industrial leadership, growth <i>prosperity</i> and employment in Europe and should reflect the strategic vision of the Commission Communication of 6 October 2010 to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Region "Europe 2020 Flagship Initiative Innovation" ⁴ whereby the Commission engages to radically simplify access of participants.

Amendment 2 Proposal for a Regulation - Rules for participation Recital 16

Text proposed by the Commission	Amendment
The participant Guarantee Fund set up under Regulation No 1906/2006/EC of the European Parliament and of the Council of	The participant Guarantee Fund set up under Regulation No 1906/2006/EC of the European Parliament and of the Council of

18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013)¹² and managed by the Commission has proved to be an important safeguard mechanism which mitigates the risks associated to the amounts due and not reimbursed by defaulting participants. Therefore, a new participant Guarantee Fund (the Fund) should be established. In order to ensure a more efficient management and a better coverage of participants' risk, the Fund should cover actions under the programme set up under Decision No 1982/2006/EC, under the programme set up by Council Decision of 18 December 2006 concerning the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007 to 2011)¹³, under the programme set up by Council Decision [...] of X 2011 establishing the Framework Programme of the European Atomic Energy Community (2012-2013) as well as actions under Regulation (EU) No XX/XX [Horizon 2020] and Regulation (Euratom) No XX/XX of the Council on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020- the Framework Programme for Research and Innovation [Euratom H2020]¹⁴. Programmes managed by entities other than Union bodies should not be covered by the Fund.

18 December 2006 laying down the rules for the participation of undertakings, research centres, ~~and~~ universities ***and civil society organisations*** in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013)¹² and managed by the Commission has proved to be an important safeguard mechanism which mitigates the risks associated to the amounts due and not reimbursed by defaulting participants. Therefore, a new participant Guarantee Fund (the Fund) should be established. In order to ensure a more efficient management and a better coverage of participants' risk, the Fund should cover actions under the programme set up under Decision No 1982/2006/EC, under the programme set up by Council Decision of 18 December 2006 concerning the Seventh Framework Programme of the European Atomic Energy Community (Euratom) for nuclear research and training activities (2007 to 2011)¹³, under the programme set up by Council Decision [...] of X 2011 establishing the Framework Programme of the European Atomic Energy Community (2012-2013) as well as actions under Regulation (EU) No XX/XX [Horizon 2020] and Regulation (Euratom) No XX/XX of the Council on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020- the Framework Programme for Research and Innovation [Euratom H2020]¹⁴. Programmes managed by entities other than Union bodies should not be covered by the Fund.

Justification

Civil Society Organisations are today valuable and full actors of research and innovation. Not to tap into this knowledge pool would be counter-productive for the European Research Area. Take over the definition of CSOs from FP7: non-governmental, not-for-profit, not representing commercial interests, pursuing a common purpose for the public interest (definition from the BSG-CSO funding scheme).

Amendment 3

Proposal for a Regulation - Rules for participation

Recital 17

Text proposed by the Commission	Amendment
In order to enhance transparency, the names of experts that have assisted the Commission or relevant funding bodies in application of this Regulation should be published. Where the publication of the name would endanger the security or integrity of the expert or would unduly prejudice his or her privacy, the Commission or funding bodies should be able to refrain from the publication of such names.	In order to enhance transparency, the names of experts that have assisted the Commission or relevant funding bodies in application of this Regulation should be published. Where the publication of the name would endanger the security or integrity of the expert or would unduly prejudice his or her privacy, <i>exceptionally</i> the Commission or funding bodies should be able to refrain from the publication of such names.

Amendment 4

Proposal for a Regulation - Rules for participation

Recital 19

Text proposed by the Commission	Amendment
Rules governing the exploitation and dissemination of results should be laid down to ensure that the participants protect, exploit and disseminate those results as appropriate, in particular the possibility of additional exploitation conditions in the European strategic interest.	Rules governing the exploitation and dissemination of results should be laid down to ensure that the participants protect, exploit and disseminate those results as appropriate, in particular the possibility of additional exploitation, <i>dissemination or licensing</i> conditions in the European strategic interest, <i>or where a predominant public interest exists</i> .

Justification

The goal of this amendment is to maximize the societal benefit of EU-funded research. In the case of major societal challenges such as health, there is a predominant public interest in the swift and broad dissemination of results and in universal accessibility to the products of frontier research. To prevent adverse effects of patent protection, licensing of results to third parties should be subject to “global access licensing” conditions, to be further specified in articles concerning award procedure, grant agreement and exploitation and dissemination of results.

Amendment 5

Proposal for a Regulation - Rules for participation

Title 1 Introductory Provisions

Article 2 - Definitions

Text proposed by the Commission	Amendment
(10) 'legal entity' means undertakings, research centres and universities, encompassing any natural person, or any legal person created under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations;	(10) 'legal entity' means undertakings, research centres, and universities and civil society organisations , encompassing any natural person, or any legal person created under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations;

Justification

It is of high importance to clearly mention here civil society organisations in order to ensure their participation as full actors.

Amendment 6

Proposal for a Regulation - Rules for participation

Title II Rules for Participation

Chapter I General Provisions

Article 6 – Legal entities that may participate in actions

Text proposed by the Commission	Amendment
The relevant work programme may restrict the participation in Horizon 2020 or parts thereof of legal entities established in third countries where conditions for the participation of legal entities from Member States in the third country's research and innovation programmes are considered prejudicial to the Union's interests.	<p>The relevant work programme shall restrict the participation in Horizon 2020 or parts thereof</p> <p><i>(a) Legal entities (including any affiliated entities) whose participation, by the objectives they pursue, their place of establishment, the nature or the location of their activities, would cause the European Union to breach international law or international humanitarian law as established by a resolution of the United Nations Security Council or by a judgment or advisory opinion of the International Court of justice, shall be excluded from participation in Horizon 2020.</i></p> <p>(b) where conditions for the participation of legal entities from Member States in the third country's research and innovation programmes are considered prejudicial to the Union's interests.'</p>

Amendment 7

Proposal for a Regulation - Rules for participation

Title II Rules for the Participation

Chapter II Grants, Section 1 Award procedure

Article 12 – Proposals, new point 4.

Text proposed by the Commission	Amendment
<p>1. Where appropriate, proposals shall include a draft plan for the exploitation and dissemination of the results.</p> <p>2. Any proposal for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States involved.</p> <p>3. A proposal which contravenes ethical principles or any applicable legislation, or which does not fulfil the conditions set out in Decision No XX/XX/EU [specific programme], the work programme or work plan or in the call for proposals may be excluded from the evaluation, selection and award procedures at any time.</p>	<p>1. Where appropriate, proposals shall include a draft plan for the exploitation and dissemination of the results.</p> <p>2. Any proposal for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approvals that will be provided. As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member States involved.</p> <p>3. A proposal which contravenes ethical principles or any applicable legislation, or which does not fulfil the conditions set out in Decision No XX/XX/EU [specific programme], the work programme or work plan or in the call for proposals may be excluded from the evaluation, selection and award procedures at any time.</p> <p><i>4. Any proposal for research with the potential for further development into a novel medical technology (e.g. drugs, vaccines, medical diagnostics) shall include a draft plan specifying a strategy to guarantee the immediate and widest possible access to this technology, where lack of access to the technology would pose a threat to the protection of public health.</i></p>

Justification

Access to drugs, vaccines and other medical technologies is a key element of functioning health systems and ensuring citizen's access to health. As thoroughly documented in several reports by the World Health Organization WHO (1, 2), considering access strategies as early as during the Research & Development process can contribute decisively to a functioning later health supply. Many different tools exist to fulfil this need, e.g. provisions for dealing with intellectual property, access programs or pricing provisions.

WHO Sources : (1) Report of the Commission on Intellectual Property Rights, Innovation and Public Health. World Health Organisation, Geneva 2006 ; (2) Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. Geneva 2012

Amendment 8

Proposal for a Regulation - Rules for participation

Title II Rules for the Participation

Chapter II Grants, Section I Award procedure

Article 16 – Grant agreement, new point 4

Text proposed by the Commission	Amendment
<p>1. The Commission or the relevant funding body shall enter into a grant agreement with the participants.</p> <p>2. The grant agreement shall establish the rights and obligations of the participants, of the Commission or the relevant funding bodies. It shall also establish the rights and obligations of legal entities, which become participants during the implementation of the action.</p> <p>3. The grant agreement may establish rights and obligations of the participants with regard to access rights, exploitation and dissemination, additional to those laid down in this Regulation.</p> <p>4. The grant agreement shall, where appropriate, reflect the general principles laid down in Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers¹⁶.</p>	<p>1. The Commission or the relevant funding body shall enter into a grant agreement with the participants.</p> <p>2. The grant agreement shall establish the rights and obligations of the participants, of the Commission or the relevant funding bodies. It shall also establish the rights and obligations of legal entities, which become participants during the implementation of the action.</p> <p>3. The grant agreement may establish rights and obligations of the participants with regard to access rights, exploitation and dissemination, additional to those laid down in this Regulation.</p> <p>4. <i>When research is conducted in a field relevant to the preservation of public health, the grant agreement shall contain provisions that foster accessibility of the results to EU and non-EU residents through socially responsible licensing strategies.</i></p> <p>5. The grant agreement shall, where appropriate, reflect the general principles laid down in Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers¹⁶.</p>

Justification

The aim of this amendment is to ensure maximum uptake of innovative solutions and to maximise the societal benefit of EU funded research by integrating socially responsible licensing procedures into grant agreements.

Amendment 9
Proposal for a Regulation - Rules for participation
Title II Rules for Participation
Chapter VII Experts
Article 37
Appointment of independent experts, point 2

Text proposed by the Commission	Amendment
<p>2. Independent experts shall be chosen on the basis of skills, experience and knowledge appropriate to carry out the tasks assigned to them. In cases where independent experts have to deal with classified information, the appropriate security clearance shall be required before appointment.</p> <p>Independent experts shall be identified and selected on the basis of calls for applications from individuals and calls addressed to relevant organisations such as national research agencies, research institutions, standardisation organisations or enterprises with a view to establishing a database of candidates.</p> <p>The Commission or the relevant funding body may, if deemed appropriate and in duly justified cases, select any individual with the appropriate skills from outside the database. Appropriate measures shall be taken to seek gender balance and geographical diversity when appointing independent experts.</p> <p>The Commission or the relevant funding body may call upon the advice of advisory bodies for the appointment of independent experts. In the case of ERC frontier research actions, the Commission shall appoint experts on the basis of a proposal from the Scientific Council of the ERC.</p>	<p>2. Independent experts shall be chosen on the basis of skills, experience and knowledge appropriate to carry out the tasks assigned to them. In cases where independent experts have to deal with classified information, the appropriate security clearance shall be required before appointment.</p> <p>Independent experts shall be identified and selected on the basis of calls for applications from individuals and calls addressed to relevant organisations such as national research agencies, research institutions, standardisation organisations or enterprises with a view to establishing a database of candidates.</p> <p>The Commission or the relevant funding body may, if deemed appropriate and in duly justified cases, select any individual with the appropriate skills from outside the database. Appropriate measures shall be taken to seek <i>interests and</i> gender balance and geographical diversity when appointing independent experts, <i>such as making sure that no special interest represents more than on third of non-governmental experts. In particular, appropriate measures should be taken to prevent the capture of expert groups by private and/or commercial interests.</i></p> <p>The Commission or the relevant funding body may call upon the advice of advisory bodies for the appointment of independent experts. In the case of ERC frontier research actions, the Commission shall appoint experts on the basis of a proposal from the Scientific Council of the ERC.</p>

Amendment 10
Proposal for a Regulation - Rules for participation
Title II Rules for Participation
Chapter VII Experts
Article 37
Appointment of independent experts, point 3

Text proposed by the Commission	Amendment
3. The Commission or the relevant funding body shall take all necessary steps to ensure that the expert is not faced with a conflict of interests in relation to the matter on which the expert is required to provide an opinion.	3. The Commission or the relevant funding body shall take all necessary steps to ensure that the expert is not faced with a conflict of interests in relation to the matter on which the expert is required to provide an opinion, <i>starting with the publication of their full declaration of professional activities and financial interests (i.e. patents, shareholdings...). Stakeholders or persons with conflicts of interests must be prohibited from sitting ‘in a personal capacity’.</i>

Amendment 11
Proposal for a Regulation - Rules for participation
Title III Rules Governing dissemination of results
Chapter I Grants, Section I Results
Article 40 – Exploitation and dissemination of results, point 1

Text proposed by the Commission	Amendment
1. Each participant that has received Union funding shall use its best efforts to exploit the results it owns in further research or commercially, or to have them exploited by another legal entity for these purposes, in particular through transfer and licensing of results in accordance with Article 41. Additional exploitation obligations may be laid down in the grant agreement. Any such additional obligations shall be indicated in the work programme or work plan.	1. Each participant that has received Union funding shall use its best efforts to exploit the results it owns in further research or commercially, or to have them exploited by another legal entity for these purposes, in particular through transfer and licensing of results in accordance with Article 41. Additional exploitation obligations may be laid down in the grant agreement. Any such additional obligations shall be indicated in the work programme or work plan. <i>If the programme is directed towards tackling major societal challenges (health, climate, biodiversity), exploitation, transfer and licensing of results shall take place according to the principles of Global Access Licensing, to ensure maximum uptake of innovative solutions in the best public</i>

	<i>interest, and to foster accessibility of research results to those who are affected. Such licensing and dissemination practices may include the use of non-exclusive licensing as a standard procedure, the implementation of “differential pricing” or “non-assert policies”, the specific obligation of the licensee to grant direct supplies to affected populations, and other tools.</i>
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Justification

In the case of major societal challenges, there is an overriding public interest in the immediate and comprehensive application of research results. In such sensitive research areas, an imperative to claim intellectual property rights and to exploit results may severely harm immediate universal access. Exploitation and knowledge transfer should therefore be designed in a way that ensures accessibility and thus maximises the societal benefit of EU-funded research.

Amendment 12

Proposal for a Regulation - Rules for participation

Title III Rules Governing dissemination of results

Chapter I Grants, Section I Results

Article 40 – Exploitation and dissemination of results, point 2

Text proposed by the Commission	Amendment
<p>2. Subject to any restrictions due to the protection of intellectual property, security rules or legitimate commercial interests, each participant shall through appropriate means disseminate the results it owns as soon as possible. The grant agreement may lay down time-limits in this respect.</p> <p>Additional dissemination obligations may be laid down in the grant agreement.</p> <p>With regard to dissemination through research publications, open access shall apply under the terms and conditions laid down in the grant agreement. With regard to dissemination of other results, including research data, the grant agreement may lay down the terms and conditions under which open access to such results shall be provided, in particular in ERC frontier research or in other appropriate areas.</p> <p>Prior notice of any dissemination activity</p>	<p>2. Subject to any restrictions due to the protection of intellectual property, security rules or legitimate commercial interests, each participant shall through appropriate means disseminate the results it owns as soon as possible. The grant agreement may lay down time-limits in this respect. <i>In the field of major societal challenges (health, climate, biodiversity), licensing of results to third parties shall by default take place on non-exclusive terms so as to enable immediate competition and thereby to foster global accessibility.</i></p> <p>Additional dissemination obligations may be laid down in the grant agreement.</p> <p>With regard to dissemination through research publications, open access shall apply under the terms and conditions laid down in the grant agreement. With regard to dissemination of other results, including</p>

<p>shall be given to the other participants. Following notification, a participant may object if it demonstrates that its legitimate interests in relation to its results or background would suffer significant harm by the intended dissemination. In such cases, the dissemination activity may not take place unless appropriate steps are taken to safeguard these legitimate interests. The grant agreement may lay down time-limits in this respect.</p>	<p>research data, the grant agreement may lay down the terms and conditions under which open access to such results shall be provided, in particular in ERC frontier research or in other appropriate areas. Prior notice of any dissemination activity shall be given to the other participants. Following notification, a participant may object if it demonstrates that its legitimate interests in relation to its results or background would suffer significant harm by the intended dissemination. In such cases, the dissemination activity may not take place unless appropriate steps are taken to safeguard these legitimate interests. The grant agreement may lay down time-limits in this respect.</p>
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Justification

Exclusive licensing in many cases hinders competition and limits accessibility of products to the very taxpayers who funded public research projects through their taxes beforehand. As a consequence, the United States National Institutes of Health (NIH) in their licensing policies promote the use of non-exclusive licensing: „NIH seeks to ensure that a licensee obtains the appropriate scope of rights necessary to develop a potential application of the technology. This ensures that as many companies as possible can obtain commercial development rights, resulting in the concurrent development of many potential applications. This is accomplished through: Negotiating non-exclusive or co-exclusive licenses whenever possible. This allows more than one company to develop products using a particular technology, products which may ultimately compete with each other in the marketplace. NIH recognizes that companies typically need an exclusive market position to offset the risk, time, and expense of developing biomedical diagnostic or therapeutic products, however, companies do not necessarily need to achieve that position by exclusively licensing a government technology used to develop that product. Instead, they frequently are able to add their own proprietary technologies to the technology licensed from the government to ultimately achieve some level of uniqueness and exclusivity for the final product.“ (source: http://www.ott.nih.gov/policy/phslic_policy.aspx)

Amendment 13

Proposal for a Regulation - Rules for participation

Title III Rules Governing dissemination of results

Chapter I Grants, Section I Results

Article 40 – Exploitation and dissemination of results, point 3

Text proposed by the Commission	Amendment
<p>3. Each participant shall report to the Commission or funding body on its exploitation and dissemination related activities. For the purposes of monitoring and</p>	<p>3. Each participant shall report to the Commission or funding body on its exploitation and dissemination related activities. For the purposes of monitoring and</p>

dissemination by the Commission or funding body, participants shall provide any information and documents useful in accordance with the conditions laid down in the grant agreement.	dissemination by the Commission or funding body, participants shall provide any information and documents useful in accordance with the conditions laid down in the grant agreement. <i>To ensure transparency, the reports are to be made publicly available.</i>
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Amendment 14

Proposal for a Regulation - Rules for participation

Title III Rules Governing dissemination of results

Chapter I Grants, Section I Results

Article 41 – Transfer and licensing of results

Text proposed by the Commission	Amendment
<p>1. Where a participant transfers ownership of results, it shall pass on its obligations under the grant agreement regarding those results to the transferee, including the obligation to pass them on in any subsequent transfer.</p> <p>Without prejudice to confidentiality obligations arising from laws or regulations in the case of mergers and acquisitions, where other participants still enjoy access rights to the results to be transferred, the participant who intends to transfer the results shall give prior notice to those other participants, together with sufficient information concerning the intended new owner of the results to permit the other participants to analyse the effect of the intended transfer on the possible exercise of their access rights.</p> <p>Following notification, a participant may object to the transfer of ownership if it demonstrates that the intended transfer would adversely affect the exercise of its access rights. In such case, the transfer may not take place until agreement has been reached between the participants concerned. The grant agreement may lay down time-limits. The other participants may by prior written agreement, waive their right to prior notice and to object in the case of transfers of ownership from one participant to a specifically identified third party.</p>	<p>1. Where a participant transfers ownership of results, it shall pass on its obligations under the grant agreement regarding those results to the transferee, including the obligation to pass them on in any subsequent transfer.</p> <p>Without prejudice to confidentiality obligations arising from laws or regulations in the case of mergers and acquisitions, where other participants still enjoy access rights to the results to be transferred, the participant who intends to transfer the results shall give prior notice to those other participants, together with sufficient information concerning the intended new owner of the results to permit the other participants to analyse the effect of the intended transfer on the possible exercise of their access rights.</p> <p>Following notification, a participant may object to the transfer of ownership if it demonstrates that the intended transfer would adversely affect the exercise of its access rights. In such case, the transfer may not take place until agreement has been reached between the participants concerned. The grant agreement may lay down time-limits. The other participants may by prior written agreement, waive their right to prior notice and to object in the case of transfers of ownership from one participant to a specifically identified third party.</p>

<p>2. Provided that any access rights to the results can be exercised and that any additional exploitation obligations are complied with, the participant who owns results may grant licences or otherwise give the right to exploit them to any legal entity, including on an exclusive basis.</p>	<p>2. Provided that any access rights to the results can be exercised and that any additional exploitation obligations are complied with, the participant who owns results may grant licences or otherwise give the right to exploit them to any legal entity, including on an exclusive basis. <i>Where the results belonging to a participant can be used to tackle major societal challenges (health, climate, biodiversity), and the participant transfers rights to another party, this transfer shall occur according to the principles of “global access licensing” (to be specified in Article 40 – point 1), i.e. in a way that ensures maximum uptake of results and reduces the barriers for future innovation.</i></p>
<p>3. With regard to results which are generated by participants that have received Union funding, the Commission or funding body may object to transfers of ownership or to grants of an exclusive licence, to third parties established in a third country not associated to Horizon 2020, if it considers that the grant or transfer is not in accordance with the interests of developing the competitiveness of the Union economy or is inconsistent with ethical principles or security considerations.</p> <p>In such cases, the transfer of ownership or grant of exclusive licence shall not take place unless the Commission or funding body is satisfied that appropriate safeguards will be put in place.</p> <p>Where appropriate, the grant agreement shall provide that the Commission or funding body is to be notified in advance of any such transfer of ownership or grant of an exclusive licence. The grant agreement shall lay down time-limits.</p>	<p>3. With regard to results which are generated by participants that have received Union funding, the Commission or funding body may object to transfers of ownership or to grants of an exclusive licence, to third parties established in a third country not associated to Horizon 2020, if it considers that the grant or transfer is not in accordance with the interests of developing the competitiveness of the Union economy or is inconsistent with ethical principles or security considerations <i>or is likely to obstruct access to the resulting products in a way harmful to the public interest (namely in the case of novel lifesaving medicines and medical technologies).</i></p> <p>In such cases, the transfer of ownership or grant of exclusive licence shall not take place unless the Commission or funding body is satisfied that appropriate safeguards will be put in place.</p> <p>Where appropriate, the grant agreement shall provide that the Commission or funding body is to be notified in advance of any such transfer of ownership or grant of an exclusive licence. The grant agreement shall lay down time-limits.</p>

Justification

The licensing concept known as “Equitable Access Licensing“, “Socially Responsible Licensing“ or “Global Access Licensing“ (terms to be used interchangeably) refers to an implementation of licensing contracts that aims at maximizing the societal benefit of research results. This concept is based on social obligations that are linked to taxpayer-funded research.

Terms of Equitable Access Licensing respond to the goal of meeting the special needs and living conditions of potential populations concerned. Goals are a) to make the products resulting from the research available to those people most in need of the products, and b) to make the products available at an affordable price to patients in low-income countries.

Amendment 15

Proposal for a Regulation - Rules for participation

Title III Rules Governing dissemination of results

Chapter I Grants, Section 3 Specific Cases

Article 47 – Specific Provisions – Point 8 (new)

Text proposed by the Commission	Amendment
	<i>8. In the case of research where a predominant public interest exists (e.g. research that has the potential for further development into a lifesaving drug, vaccine or medical diagnostic) Global Access Licensing (as defined in Article 40 – point 1) shall guarantee the availability of affordable treatment to all EU citizens as well as to patients in low and middle-income countries.</i>

Justification

In the case of major societal challenges, there is an overriding public interest in the immediate and comprehensive application of research results. In such sensitive research areas, an imperative to claim intellectual property rights and to exploit results may severely harm immediate universal access. Exploitation and knowledge transfer should therefore be designed in a way that ensures accessibility and thus maximises the societal benefit of EU-funded research.