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ALLEA Statement on

Patentability and Research Funding
relating to embryonic Stem Cells
(e-SCs)

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I Previous ALLEA Statements concerning the Patentability of Inventions involving Human Embryonic Pluripotent Stem Cells

- In May 2011 and September 2012 ALLEA issued Statements on *Patentability of Inventions Involving Human Embryonic Pluripotent Stem Cells in Europe*. Both Statements were closely linked to the case *Brüstle v. Greenpeace*, one preceding, and one following the Judgment of the Court of European Union (CJEU) of 18 October 2011 (Case 34/10).

- The first Statement was born out of ALLEA's concern that lack of patent protection in this important area of science and technology could negatively affect badly needed investment in developing therapeutics based on human pluripotent embryonic stem cells.

- The second Statement emphasized that the legal basis expressed by the CJEU for refusing to accept the patentability of inventions where the technical teaching which is the subject matter of the patent

application requires the prior destruction of human embryos or their use as base material. According to the explicit holdings of the Court, its decision is strictly limited to the application and interpretation of wording expressed in the *European Biotechnology Directive 98/44/EC*. The judgment is not based on any broader invocation of ethical imperatives that may be held by some people in parts of the European Union.

- ALLEA expressed its firm hope that the competent bodies of the European Union and its Member States will undertake measures necessary to limit the impact of the CJEU Judgment to the application of the *Directive 98/44/EC*. Only thus could these bodies meet serious concerns of the European scientific community that this Judgment could negatively affect research in this important area of medicine.

II Alleged Impact of the Brüstle Judgment on EU Policy relating to e-SC Research Funding

- To its great concern, ALLEA took note of the *Draft Opinion of 22 May 2012*¹ and the *Opinion of 18 September 2012*² of the Committee on Legal Affairs for the Committee on Industry, Research and Energy, on the proposal for a Regulation to be enacted by the European Parliament and of the Council establishing *Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020)*.³ These documents clearly reveal that, according to the

Opinion of the Committee on Legal Affairs, the Judgment of the CJEU in *Brüstle v. Greenpeace* must be taken to bar EU funding of research „which either involves the destruction of human embryos or which uses human embryonic stem cells“.

- Although the final version of the *Opinion* of the Committee on Legal Affairs does not contain explicit references to the Judgment of the CJEU, the justification for the proposal completely to ban from EU funding any research which either involves the destruction of human embryos or which uses human embryonic stem cells, and leave such funding to individual Member States, clearly indicates that the ban is to be understood as a legal consequence of the Judgment of the CJEU.

1 PA\902069EN.doc.

2 AD\913037EN.doc.

3 The Draft Opinion made explicit references to the Judgment of the CJEU in the „Justification“, and the proposed amendment for ne Recital 25 a). According to proposed new Recital 25 b), „the Union should encourage scientists whose research is funded by the Union budget to patent their inventions in the Union. As human embryonic stem cells are not patentable, this type of research should be excluded from Union funding and funded exclusively by national budgets.“

- ALLEA emphasizes that, as explicitly held by the CJEU, that Judgment cannot be used for anything else than for the application and interpretation of the *Directive 98/44*. The Judgment does not contain any ethical verdict as to research involving e-SCs, an issue entirely left to the competence of the Member States.

- ALLEA is of the firm opinion that the proposal of the Committee on Legal Affairs of the European Parliament finds no justification in the Judgment of the Court. Were this to be accepted, it would most seriously affect research of essential importance to citizens of the European Union.

- ALLEA urges the competent bodies of the European Union not to accept the proposed amendments and to continue the well balanced funding of the respective

research at the Union level. It is emphasized that important basic research needs more EU funding rather than less given that the Court of Justice's holding renders the patent incentive for commercial exploitation more remote.

- ALLEA, finally, emphasizes that although the technology of induced pluripotent (iPS) cells is a promising field of investigation and innovation, this method cannot now replace the use of human embryonic stem cells for fundamental studies and pioneering applications for human health. This has been rightly pointed out by the Forum for Genetic Research of the Swiss Academy of Sciences.⁴

⁴ Valuable feedback from numerous ALLEA member academies on an earlier version of this statement is gratefully acknowledged. This Statement has not been endorsed by the Academy of Athens and by the Royal Spanish Academy of Exact, Physical and Natural Sciences.

Prepared by the
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