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ALLEA Statement on

Patentability of Inventions Involving Human "Embryonic" Pluripotent Stem Cells in Europe

Statement prepared by the

ALLEA Permanent Working Group Intellectual Property Rights

A draft version of this statement has been provided to the ALLEA Member Academies for endorsement. Valuable feedback from numerous academies is gratefully acknowledged.

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Executive Summary

In statements released between 2011 and 2013, ALLEA – via its Permanent Working Group Intellectual Property Rights – has addressed the sensitive issue of the patentability of inventions involving human embryonic pluripotent stem cells in Europe.

In this statement, taking account of recent rapid developments within the life sciences, ALLEA re-addresses the issue and renews its plea that the same moral standards which control research and development in the area of human embryonic stem cells, as well as the "production" and commercialization of human embryonic pluripotent stem cells, from whatever organism, in Europe should also control their patentability.

It is, therefore, necessary to narrow the notion of an invention to its genuine understanding, i.e. to separate it from whatever preceded and whatever follows the invention and is controlled by rules that are in compliance with competent regulations in force and prevailing principles of ethics and morals.

Only such an approach can prevent human pluripotent embryonic stem cells from being ultimately equated to an "embryo", whose definition as it stands will develop further depending on the progress of scientific knowledge.

Patentability of Inventions Involving Human "Embryonic" Pluripotent Stem Cells in Europe

I.

In statements released in May 2011, September 2012, and October 2013 ALLEA has addressed the sensitive issue of patentability of inventions involving human embryonic pluripotent stem cells in Europe. In a passage of its statement of September 2012, ALLEA deplored that the Court of Justice of the European Union (CJEU) in its judgment of 18 October 2011 in the case *Oliver Brüstle v. Greenpeace e.V.* (Case C-34/10).[1]

> "[The Court] has missed the opportunity to provide for a balanced solution, which would ensure that the patenting of inventions involving pluripotent stem cells of human embryonic origin, that are generated or imported in compliance with the competent regulatory provisions of the EU and its Member States, but do not involve any use of human embryos, and which can be commercialized as therapeutics or diagnostics in compliance with the EU legislation and legislation of the respective EU Member States would be subjected to the same moral standards as their commercialization."

A judgment of the CJEU (Grand Chamber) of 18 December 2014 in the case *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trademarks* (Case C-364/13)[2], and the most recent reports in scientific publications on research findings that raise

> "the possibility that by using advanced cell culture

1 EU:C:2011:669.
2 EU:C:2014:2451.

> techniques, including coculture of multiple cell types, and engineering the appropriate culture microenvironment, it might be possible to model human embryogenesis in a petri dish,"[3]

provide reason for ALLEA to take up this issue again.

II.

Upon a referral of the High Court of Justice (England & Wales), Chancery Division of April 2013, in the International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trademarks, the CJEU had to hand down its preliminary ruling on the following question:

> "Are unfertilized human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilized ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term 'human embryos' in Article 6(2)(c) of Directive 98/44 …?"

In its judgment of 18 December 2014, the CJEU, first, reaffirmed its holdings in the *Brüstle* case, and then emphasized that according to that judgment the classification of "human embryo" must also apply to a non-fertilized human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis. The Court recalled that it made it clear in the *Brüstle* case that although those organisms have not, strictly speaking, been the object of fertilization, due to the effect of the technique

3 M. Pera, Embryo Genesis in a Dish – We are at an Early Stage of Developing Embryos from Cells in Culture, Science 356, 137-138 (14 April 2017, Issue 6334). Cf. S.E. Harrison, et al., Assembly of Embryonic and Extraembryonic Stem Cells to Mimic Embryogenesis in Vitro, Science 356, eaal 1810 (2017). DOI: 10.1126/science.aal1810.

used to obtain them, they were, as was apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilization of an ovum can do so. Eventually, the Court (Grand Chamber) ruled as follows:

> "Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as meaning that an unfertilized human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo', within the meaning of that provision, *if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine*." [emphasis added]

III.

ALLEA expressly welcomes the clarifications made by the CJEU in the *International Stem Cell Corporation* case, according to which the term "a human embryo" within the meaning of Article 6 (2) (c) of the Directive requires that the organism at issue must *"in itself, have the inherent capacity of developing into a human being"*, and that *"the mere fact that the organism commences a process of development is not sufficient"*. In view of the rapid development of life sciences referred to at the beginning of this statement (cf. footnote 3), however, ALLEA is anxious that making the term "human embryo", as used in Article 6 (2) (c) of the Directive, dependent on whether the source of the human pluripotent stem cells involved in an invention, in the light of the "current scientific knowledge" does, or does not "in itself have the inherent capacity to develop into a human being", could soon lead to inconsistent and contradictory results. For example: according to the "current scientific knowledge", parthenotes lack the "inherent capacity of developing into

a human being", consequently inventions involving human pluripotent stem cells derived from parthenotes, even by their destruction, are patentable. If, however, in the light of the scientific knowledge, which might be available in the near or more distant future, parthenotes will be treated as having "the inherent capacity to developing into a human being", then inventions involving the same type of human pluripotent stem cells will not be patentable anymore. In this context it appears unclear what exactly is to be understood under the term "inherent capacity".

In ALLEA's understanding such an approach risks the danger that, depending on the future developments of medical and biological sciences inventions involving human pluripotent stem cells could be unpatentable, even if generated from the destruction of "organisms", which will neither enjoy regulatory protection of human embryos in the Member States, nor the protection of human dignity in general. Such an autonomous "evolutionary" / "gliding" definition of the notion of "human embryo" exclusively applied to the interpretation of Article 6 (2) (c) of the Directive, thus entirely detached from the rules controlling research and commercialization in the area of interest, could not stand up either to ethical or to legal scrutiny.

ALLEA, therefore, renews its plea that the same moral standards which control research and development in the area of human embryonic stem cells, as well as the "production" and commercialization of human embryonic pluripotent stem cells, from whatever organism, in Europe should also control their patentability. In order to bring ethical considerations controlling patenting in line with those controlling research, production and commercialization of human embryonic pluripotent stem cells, it is necessary to narrow the notion of an invention to its genuine understanding, i.e. separate it from whatever preceded and whatever follows the invention and is controlled by rules that are in compliance with competent regulations in force and prevailing principles of ethics and morals. Only such an approach, as ALLEA understands the matter, can prevent human pluripotent embryonic stem cells from being in the end equated to an "embryo" whose definition as it stands will develop further depending on the progress of scientific knowledge. By doing so, the existent inconsistency

would be removed, the system brought in line with the requirements of Article 27 (2) TRIPS Agreement, which do not permit the exclusion from patentability of inventions based on *ordre public* or morality, if their commercialization is allowed. Also, Article 5 (1) and (2) of the Directive, so far ignored at present, would regain its genuine purpose. Moreover, the proper function of the patent system would be restored. It would foster innovation and reward inventors instead of providing conditions for free riding by competitors.

ALLEA Permanent Working Group Intellectual Property Rights

Intellectual Property Rights (IPRs), be it patents or copyrights, play an important role in all academic activities. The ALLEA Permanent Working Group Intellectual Property Rights, which has been in existence since the 1990s, has prepared and issued reflections, declarations and recommendations on the most challenging topics of IPRs. At present it is developing a horizon-scanning mechanism to identify emerging issues and suggest appropriate solutions.

Previous statements on patenting in stem cell research:

- May 2011: Patenting of Inventions Involving Human Embryonic Pluripotent Stem Cells in Europe
- September 2012: Patentability of Inventions Involving Human Embryonic Pluripotent Stem Cells in Europe of May 2011 and the Judgment of the Court of European Communities (Grand Chamber) of 18 October 2011 in Case C-34/10
- October 2013: Patentability and Research Funding relating to embryonic Stem Cells (e-SCs)

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