ALLEA Statement on 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

ALLEA Standing Committee on Intellectual Property Rights

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I.

In May of 2011 ALLEA issued a Statement on Patenting Inventions Involving Human Embryonic Pluripotent Stem Cells in Europe, in which, *inter alia*

- ALLEA emphasized that this Statement does not address the regulatory solutions concerning embryo research in European countries, nor does it address embryo research as such but focuses exclusively on a regulatory dilemma and the resulting effects on research efforts based in Europe.

- ALLEA observed that many European countries, such as Belgium, Czech Republic, the Netherlands, Spain, Sweden and the United Kingdom allow research involving human embryos under stringent conditions.

- ALLEA drew attention to legal instruments of the European Union such as the Directive 2004/23/EC on "Setting Standards of Quality and Safety for the Donation, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells", and the Regulation (EC) No. 1394/2007 on "Advanced Therapy Medical Products and amending Directive 2001/84/EC and Regulation (EC) No. 26/2004", which are explicitly applicable to human embryonic stem cells, and which allow controlled use of human embryonic stem cells but at the same time leave it, under certain circumstances, to the national legislator to prohibit the use of such cells.

- ALLEA referred to a decision of the Enlarged Board of Appeal of the European Patent Office (EBA) of 25 November 2008 (OJ EPO 2009, 306 – Use of Embryos/WARF), excluding from patentability inventions involving pluripotent embryonic stem cell lines of human origin, i.e. originally generated from a human embryo and involving its destruction, as use of human embryos for commercial or industrial purposes excluded from patenting as contradicting ordre public or morality under Rule 28 (c) of the Implementing Regulations to the European Patent Convention (EPC) (corresponding to Article 6 (2) (c) of the EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions).

- ALLEA highlighted that as a consequence of the EBA decision, inventions involving pluripotent embryonic stem cells of human origin were not eligible for patent protection under the EPC, notwithstanding the fact that the stem cells have been generated in full compliance with the applicable regulatory provisions (as, e.g. in force in Belgium, Netherlands, Sweden and the United Kingdom and likewise in Australia, Israel, New Zealand or the United States of America), and that this exclusion applied also where the exercise of the disclosed and claimed invention does not use human embryos, and such inventions can be commercialized subsequently as drugs under the EU regulatory laws.

- ALLEA expressed concerns that without patents as a necessary incentive for investments in developing therapeutics based on human pluripotent embryonic stem cells, such developments will take place outside Europe, eventually resulting in Europe becoming a market for therapeutics developed, e.g. in the United States, China, etc., since their marketing, in principle, were allowed in most EU Member States.

- ALLEA, furthermore, referred to the Referral of the German Federal Supreme Court (BGH) of 12 November 2009 to the Court of Justice of the European Union (CJEU) in a dispute between Greenpeace e.V. and Professor Oliver Brüstle (Case C-34/10), in which the validity of a German Patent, which relates to "neuronal precursors, method of production and use for therapy of neural defects", issued by the German Patent Office in 1999, claiming, inter alia, "isolated, purified precursor cells from embryonic stem cells with neural or glial characteristics," is challenged.

- ALLEA expressed its confidence that CJEU will find a balanced solution, which would ensure that inventions involving pluripotent stem cells of human embryonic origin, that are generated in compliance with the competent regulatory provisions, but not involving use of human embryos, and whose products, in compliance with the EU legislation and the legislation of the respective EU Member States, can be commercialized as therapeutics or diagnostics, will enjoy the same incentives by the patent system as other inventions, particularly those in the area of pharmaceuticals.

- ALLEA, finally, observed that excluding from patent protection inventions, the final products of which can be commercialized in one or more of the EU Member States, potentially violates obligations of the European Union and its Member States entered into in international legal instruments, such as the TRIPS Agreement, as explicitly emphasized in Article 1 (2) and Recital 36 of the Directive 98/44/EC.

II.

On 18 October 2011 the Grand Chamber of Court of Justice of the European Union (CJEU) handed down the decision in the *Oliver Brüstle v. Greenpeace e.V.* case (Case C-34/10). It held, *inter alia*, that:

- The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6 (2)(c) of Directive 98/44 also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable.

- Article 6 (2)(c) of Directive 98/44 excludes an invention from patentability 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, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

III.

ALLEA Standing Committee on Intellectual Property Rights in connection with this judgment of CJEU

- Emphasizes that CJEU explicitly pointed out that the purpose of the Directive is not to regulate the use of human embryos in the context of scientific research, but is limited to the patentability of biotechnological inventions (paragraph 40). Thus, the legal consequences of this Judgment are strictly limited to the application and interpretation of Directive 98/44/EC and have no legal impact on application or interpretation of any regulatory provisions dealing either with research in human embryos or commercialization of the results of such research.

- Observes that CJEU, although it in the "Legal Context" pointed to Agreements binding the European Union and/or the Member States and in particular also to Article 27 (2) TRIPS Agreement, did in no way touch upon or express any opinion on potential legal consequences of its interpretation of Article 6 (2) (c) Directive 98/44/EC, in the light of binding international standards set out in Article 27 (2) TRIPS Agreement, which the German Federal Supreme Court had expressly referred to.

- Deplores that the CJEU 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.

- Expects 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 in order to meet serious concerns of the European scientific community that this judgment could negatively affect research in this important area of medicine.

- Expresses the hope that the competent bodies of the European Union and its Member States will thoroughly examine the legal situation resulting from this judgment in the light of the obligations the European Union and the Member States entered into under the TRIPS Agreement, and act, as the case may be, according to the findings, eventually elaborated.

Final version: September 2012

Drafted by the ALLEA Standing Committee on Intellectual Property Rights

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