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All European Academies (ALLEA)

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ALLEA (All European Academies) is association of 53 national academies in 40 European countries. Standing Committee for Intellectual Property Rights of All European Academies, The Federation of National Academies of Sciences and Humanities (SC IPR, ALLEA) is responsible for preparation of consensus statements (position non-papers) concerning the critical issues related to the future of intellectual property rights on selected hot topics. The SC IPR focuses the attention on patenting of processes and products related to stem cells and pan-European and community patent system, digitization of data bases and free access library (ownerships and financing).

Intellectual property rights comprise patents, trademarks, design and geographical locations and copyrights. All these topics concern our every day live: from a song in a supermarket to production of multinational pharmaceutical company. EU Commission estimated that in 2006 about 1.4 mln of SMEs and 8.5 mln jobs was related to the IPR. Knowledge-based industry increased by 24% from 1996 to 2006 (other industry by 6%).

SC IPR activities based on consensus of Committee' members and associated academies. The preparation of documents is slow and laborious but the final statements are balanced and high quality. However the position non-papers are not the winding documents and don't have the legislative position. All the final documents are in free access system available on ALLEA Web page (www.allea.org). Independently these documents are delivered to all interested European and international organisations.

In 2010 SC IPR ALLEA, prof. Joseph Straus is a chairman presently, elaborated two documents of critical value for modern biotechnology:

1) ALLEA Statement on the Future Patent System of the European Union (appendix 1).
2) ALLEA Statement on Patenting of Inventions Involving Human Embryonic Pluripotent Stem Cells In Europe (appendix 2).

These two "position non-papers" will significantly influence the future formation of European as well as national legislation.

See as well a very recent open letter of European scientists concerning the patenting of human embryonic stem cells (www.eurostemcell.org/commentanalysis/open-letter-stem-cell-patent-case-could-have-far-reaching-impact).

Tomasz Twardowski, Member of SC IPR ALLEA

ALLEA Statement on the Future Patent System of the European Union

This statement argues that the current European patent system does not satisfy the IPR needs of scientific research and falls short of the bold vision of the European Innovation Union. The statement supports the creation of a unitary European Union patent, as a supplement to existing European and national patents, of a single European patent judicature, and of a centralized European appeal court. In the absence of an unanimous position amongst Member States, however, the statement welcomes the alternative solution requested by 25 EU member states within the framework of enhanced cooperation, which will result in a European patent having unitary effect in all Member States except Italy and Spain.

Moreover, the statement draws attention in particular to the need to find a harmonized approach to regulations regarding employees' inventions and encourages the European Commission to re- launch efforts aimed at ensuring that European law provides for a grace period similar to the one existing in US law.

I.

Patents protect the results of innovation in the technical sciences and secure investments in research and development. The importance of patent protection in the academic sector has increased in accordance with the growing recognition that research institutions are not only producers of pure knowledge, but also important contributors to the general innovation process and, by extension, to the welfare of society.

Whereas inventions – as contributions to the universal body of knowledge – are truly international in character, innovation processes that result from inventions are localized and regional and international cooperation in the area of patent protection are of utmost importance.

In Europe, the European Patent Convention of 1973 was a major step forward, but scoreboard analyses show that high translation and litigation costs continue to place European actors at significant disadvantage compared to US and Asian competitors. Hence, it has long been a prioritized task for European authorities to improve the patent system in Europe.

With the recent policy emphasis on the European Innovation Union, the scientific communities are called upon to support moves towards rendering more rational and more effective the EU patent system under which they operate. The Common Strategic Framework initiative indicates delivery of a proper IPR environment as one key step towards the Vision Europe 2020. Failure of political decision-makers and legislators to take the necessary measures risks further obstructing the development of a properly regulated market for innovative knowledge in Europe. An appropriate framework for IPR and patenting in Europe would include also provisions that ensure that no obstructions to further research or to equitable availability of products are created.

II.

Fifty years after establishing the first working group for the creation of a European Community patent, and 35 years after the conclusion of the Community Patent Convention in 1975 in Luxembourg (which, incidentally, never entered into force), the EU Commission and the Council are again attempting to create a unitary patent system [1].

Two major issues are still waiting to be resolved, firstly, the structure and composition of the patent judicial system and, secondly, the translation arrangements for European Union patents.

The Council presented a draft Agreement creating a European Patent Judiciary in March 2009 [2]. On 6 July 2009 the Council requested the opinion of the Court of the European Union on the compatibility of the proposed dispute settlement system with the Treaty of the Functio-

ning of the European Union. According to the opinion of the Court, which was delivered on 8 March 2011, the draft Agreement is not compatible with the provisions of the EU Treaty and the FEU Treaty [3].

Having turned the proposal down, the prospect of unitary patent judiciary is presently uncertain. Furthermore, the Commission proposed a Regulation on translation arrangements in June 2010 [4].

The proposal failed, however, to gain the required unanimous support from Member states, even after extensive efforts and a number of compromise proposals. Recognizing that unanimity could not be reached, 12 Member States required in November 2010 the Commission to present a proposal within the framework of enhanced cooperation according to Article 20 of the Treaty of the European Union [5]. The request was subsequently followed by another 13 Member States, which means that all Member states except Italy and Spain are now pursuing this option. The Council authorised the request for enhanced cooperation on 10 March 2011 [6], and the Commission issued on 13 April 2011 its revised Proposal for translation arrangements and implementing provisions [7].

According to this proposal, the EU patent specification published by the EPO in one of the three official languages of the EPC, with translation of the claims into the other two official languages, are to be the authentic text and no further translation will be required. Only in case of a dispute relating to an EU patent shall the patentee provide at the request and the choice of an alleged infringer a full translation of the patent into an official language of the Member State in which either the alleged infringement took place or in which the alleged infringer is domiciled [8].

ALLEA's view

1) The **creation of a European patent with unitary effect**, as a supplement to existing European and national patents, is already long overdue. The possibility of creating **a single European patent judicature** should be explored further and EU law compatible solution elaborated as soon as possible.

While acknowledging the valuable efforts of the European Patent Office, there is no doubt that the lack of a single European patent judicature has led to considerable uncertainty and divergent application of patent law at national level. For instance, European patents granted by the European Patent Office repeatedly experience differing interpretation in designated States, i.e. the same European patent is, e.g. often revoked in Germany and in the United Kingdom, but upheld in France and Spain, etc. In the US a centralized appeal instance – The Court of Appeals for the Federal Circuit – was established in 1982 to overcome problems similar to those experienced in Europe today, and has been, according to the general opinion, a success.

Some background facts

Translations: A European patent validated in 13 countries can cost as much as €20.000, of which costs nearly €14.000 arise from translation fees alone, and in which attorneys fees are not yet taken into account. This risks making a European patent far more than 10 times more expensive than a US patent, costing about €1.850.

It may be noted, however, that also under current rules translations are not required during prosecution of applications, which may last for a considerable period of time, without this seeming to cause competitors of the applicant noticeable distress. Since the entering into force of the European Patent Convention in 1977, European patent applications after their publication and up to the patent grant have been available only in either English (some 85%), German (some 10%) or French (some 5%).

Litigation costs: they can vary significantly according to the type of proceedings, complexity of the case, technical field etc. Parallel litigation in four countries would typically vary between €300.000 and €2 Mio. at first instance alone.

Furthermore, the *considerable costs* stemming from current translation requirements and the need for multiple litigation procedures entail significant disadvantages for European innovators compared to their US and Asian counterparts. These costs are to a large extent unproductive and superfluous. Academic institutions and their researchers/inventors are particularly affected by the present high costs and risks; this often contributes to making them refrain from entering the patenting process altogether. The same is true for their partners from industry, if they belong to the category of SMEs.

ALLEA's views

2) ALLEA welcomes the initiatives by the European Commission and the Council aimed at significantly **reducing the costs** of obtaining patent protection

in Europe. This may induce academic institutions and their researchers/inventors to make more appropriate use of the tools available under the existing and evolving IPR frameworks.

3) The **language regime** proposed by the Commission, which aims at significantly reduced costs for translation, is vital for the success of the unitary patent system.
4) The creation of a **European Patent Judiciary** having jurisdiction both in relation to unitary and European patents is essential in order to avoid costly multiple litigation procedures.
5) A **centralized European appeal court** (but not necessarily a centralized first instance court) is of utmost importance for the coherent and dynamic development of European substantive patent law. A centralized court may be expected to clarify the interpretation of provisions that are of central importance also for academic research, such as for instance the experimental use exception, allowing for experiments to be undertaken on patented inventions.

III.

Even though the preferred solution would obviously be a patent system comprising all Member States, taking into account that such a system seems to be unfeasible in the foreseeable future, the current proposal for a solution within the framework of enhanced cooperation, comprising for the time being 25 Member States, deserves support.

ALLEA's view

6) The current proposal for a solution within the framework of **enhanced cooperation**, comprising for the time being **25 Member States**, is clearly a step in the right direction.

The current proposal gives occasion to the following general observations by ALLEA, which reflect the basic needs of the European academic community to be able to productively use the patent system for successful transfer of knowledge into innovative products and processes, and which have been summarized above as ALLEA's views No.2-5.:

ALLEA draws, however, attention to the fact that even the most recent Proposal for a Council Regulation of the European patent does not provide for a harmonized/unitary regulation of employees' inventions.

ALLEA is fully aware of the past failed attempts of the EU Commission to address this issue, but it is of the opinion that this should not prevent a new attempt for harmonizing at least such basic aspects of employees' invention law as definitions of the different categories of service inventions, the rights of employers and employees to such inventions, or, for instance, who and under what conditions is entitled to apply for a patent. It is no exaggeration to state that laws regulating employees' inventions among EU Member States, such as Belgium, Germany, France, Italy, the Netherlands, Sweden and the United Kingdom, differ nearly to the largest possible extent. Especially in view of the steps taken towards a unitary EU patent this deplorable a situation should be remedied as soon as possible.

ALLEA's view

7) ALLEA encourages renewed efforts to arrive at a meaningful, **harmonized regulation of employees' inventions** that will facilitate implementation of the future unitary EU patenting rules.

ALLEA recognizes that the establishment of a unitary patent system would represent a significant step forward also for patenting within the academic sector, but notes that further improvements are also needed in order to make the patent system better suited for the needs of this sector (as well as for the needs of small and medium sized enterprises).

A comparison of current European law with US legislation and case law in the field of patents makes this abundantly clear, in particular when it comes to the legal framework for the exploitation of academic inventions: the well known *Bayh-Dole Act*, which explicitly allows universities and other research institutions to retain intellectual property rights based on publicly funded research, entered into force as early as 1980. This and other legislative initiatives aimed at the protection and dissemination of research results have made US academic institutions important participants in the innovation process. Comparatively, little has been done in Europe to attain the same goal, except from fragmented initiatives at national level.

In order to promote the role of universities and research institutions in the European innovation process, of

particular importance for future development of a knowledge based economy (KBE) within united Europe.

ALLEA's views

8) ALLEA encourages the European Commission to relaunch efforts aimed at ensuring that European law provides for a **grace period** similar to the one existing in US law, but preceding the Union priority date. This will reduce the risk of accidentally depriving scientists and their institutions of the chance to acquire patent protection while at the same time facilitate early publication and dissemination of research results. Moreover, the introduction of a grace period into European law would certainly increase the chances that the present U.S. patent law reform, which, if adopted, will replace the first to invent system with a "first inventor to file" system, be finally passed by the Congress.

The **rights and obligations of researchers, institutions and industry partners** vary between the Member States, and are to some extent insufficiently clarified. It should be investigated whether harmonization is possible and needed with respect to, in particular, the right to apply for patents and the entitlement to remuneration for inventions that are assigned from researchers to institutions or industry partners. ALLEA and its Member Academies, with their partner organizations in science, industry and politics, could offer to further explore this issue.

European law does not provide a **statutory framework** enabling universities and other publicly funded research institutions to effectively exploit and protect their research results. The need for a harmonized framework and the possible structure and content of such a framework, in particular with respect to results that emerge from public-private partnerships, could be further explored by the ALLEA Standing Committee on Intellectual Property Rights in cooperation with the Member Academies and related scientific organisations.

Competent organs of the European Union and those of the Members States should also invest further efforts for improving the ability of non-industrial research institutions and cooperating SMEs to better use the patent system nationally, regionally and internationally to the benefit of their international competitiveness.

Drafted by Standing Committee on Intellectual Property Rights

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Footnotes

1 Council of the European Union, Proposal for a Council Regulation of the European Union Patent of 27 November 2009 (Doc 16113/09 – ADD 1 – CNS 2000/0177).

2 Council of the European Union, Draft Agreement on the European and Community Patents Court and Draft Statute of 23 March 2009 (Doc. 7928/09).

3 Opinion 1/09.

4 Proposal for a Council Regulation (EU) on the translation arrangements for the European Union patent of 30 June 2010 (COM (2010) 350 final, 2010/0198 (CNS)).

5 Request from Denmark, Estonia, Finland, France, Germany, Lithuania, Luxembourg, the Netherlands, Poland, Slovenia, Sweden and the United Kingdom.

6 Council Decision 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection (OJ L 76, 22.3.2011, p. 53).

7 Proposal for a Council Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements of 13 April 2011 (COM(2011) 216/3) and Proposal for a Regulation of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection of 13 April 2011 (COM(2011) 215/3).

8 Proposal for a Council Regulation implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements of 13 April 2011 (COM (2011) 216/3).

ALLEA Statement on Patenting of Inventions Involving Human Embryonic Pluripotent Stem Cells in Europe [1]

ALLEA draws attention to the fact that European researchers in the field of human embryonic stem cells find themselves in a regulatory dilemma, and, potentially, at a competitive disadvantage, due to the inconsistencies in the application of moral approaches between European legislators and the institutions called upon to enforce the regulatory framework. This dilemma results partly from a decision handed down by the Enlarged Board of Appeal of the European Patent Office in 2008 that restricts patenting on a wide range of results from research into pluripotent human embryonic stem cells. In December 2009, the Federal Supreme Court of Germany referred a number of essential issues to be answered by the Court of the European Union, all also related to the decision of the EBA. This statement explains the situation, urges that the position be clarified as soon as possible, and makes recommendations aimed at strengthening support for R&D capacities in this field in Europe.

I. Introduction (1): Opportunities and obstacles in research on pluripotent human stem cells

Since the late 1990s, technologies that are based on stem cell research have often been discussed in a very controversial manner. On the one hand, there were great hopes in the area of regenerative medicine: human embryonic pluripotent stem cells (i.e.: cells which can develop into tissues of all organs, but which do not have the potential to develop into entire human body), have been viewed as a promising source for generating and regenerating cells of such organs as the liver and pancreas, [2] of heart muscle tissue, [3] and, for instance, for the repair of damaged neural brain cells of patients suffering of Parkinson's, multiple sclerosis or Alzheimer's [4]. On the other hand, stem cell research has been facing severe ethical concerns because embryos had to be used (i.e. destroyed) in order to generate human embryonic pluripotent stem cells.

In the meantime, scientists have succeeded in generating so-called pluripotent human stem cells and stem cell lines by reprogramming adult fibroblast cultures, using pluripotency associated genes (iPS) [5]. Even though iPS can be generated without destroying human embryos, iPS, because of the existing safety risks [6], are not used at present in clinical trials for therapeutic purposes [7]. Their use is limited to pre-clinical toxicology and safety tests, as well as for drug discovery purposes [8]. Thus, for the time being, research into human pluripotent embryonic stem cells and innovative use of them remains essential for the development of therapeutics.

II. Introduction (2): European and national legislation on research into human embryonic stem cells

Research into human embryonic stem cells is well developed in Europe. Many European countries, such as Belgium, the Czech Republic, the Netherlands, Spain, Sweden and the United Kingdom allow research involving human embryos under stringent conditions. Others, like Poland, allow such research by refraining from adopting any specific rules. Legal instruments of the European Union such as the Directive 2004/23/EC on the *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 2001/83/EC and Regulation (EC) No.26/2004 are explicitly applicable to human embryonic stem cells: They 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.

The EU-Directive 98/44/EC on the *Legal Protection of Biotechnological Inventions* does not contain any provision, which would directly relate to human embryonic stem cells. However, Article 5.1 excludes from patent

protection the human body, at various stages of its formation and development, and the simple discovery of its elements. Moreover, the Directive excludes from patent protection also inventions, the exploitation of which is contrary to *ordre public* or morality, and indicates that this includes, in particular, the use of human embryos for industrial or commercial purposes (Article 6.1, 6.2c). At the same time the Directive states that an element isolated from the human body or otherwise produced by means of a technical process, can be patented, provided that the regular patentability requirements are met (Article 5.2).

III. Contradictions arising from the decision of the Enlarged Board of Appeal of the European Patent Office (25/11/2008)

The present statement focuses exclusively on an inconsistency in law, which results from a decision handed down by the *Enlarged Board of Appeal* (EBA) of the European Patent Office of November 25, 2008[9]. According to the EBA inventions involving pluripotent embryonic stem cell lines of human origin, i.e. originally generated from a human embryo and involving its destruction, cannot be patented. This prohibition applies even where the respective stem cell lines have been generated in full compliance with the regulatory rules controlling research in human embryos that apply at national levels (as in Sweden and the UK; and in Australia, Israel and the USA). Nor does it matter, according to the EBA, that the exercise of the invention itself does not depend on any subsequent, repeated use of human embryos.

The Board based its decision on Rule 28.c of the Implementing Regulations to the European Patent Convention (EPC), which entirely corresponds to Article 6.2c of the EU Directive 98/44/EC on the *Legal Protection of Biotechnological Inventions*. According to the Directive, the use of human embryos for industrial or commercial purposes is excluded from patent protection, as an explicit category of inventions, the commercial exploitation of which would be contrary to *ordre public* or morality.

The Board reached that conclusion despite the provision of Article 5.2 of the Directive, which allows, in principle, the patenting of "an element isolated from the human body or otherwise produced by means of a technical process,... even if the structure of that element is identical to that of a natural product."

The Board noted that neither the EU legislator nor the EPC legislator have chosen to define the term "embryo". Yet both must have been aware of such definitions in some national laws, in view of the purpose of the respective provision to protect human dignity and prevent the commercialization of embryos. The Board therefore presumed that the meaning of "embryo" should not be in any way restrictive, because it would have the effect of undermining the intention of the legislature. Restrictive interpretation would leave the question of what is an embryo to be determined in the context of each particular application.

The Board also emphasized that Rule 28.c does not mention claims, but refers to "invention" in the context of its exploitation; accordingly, what needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed.Before human embryonic cultures can be used they have to be made. Since the only disclosed teaching of how to perform the invention involves making human embryonic stem cell cultures through the destruction of human embryos, the resulting "invention" would be excluded from patenting. A contrary view would restrict the application of Rule 28.c EPC to what applicants choose explicitly to put in their claims. However the Board argued that avoiding the patenting prohibition would become merely a matter of skilful drafting of such a claim.. Hence, the Board explicitly added that "making the claimed product remains commercial or industrial exploitation of the invention even where there is an intention to use that product for further research."

It reiterated that "this use involving destruction (of human embryos) is thus an integral and essential part of the industrial or commercial exploitation of the claimed invention and thus violates the prohibition of Rule 28.c EPC."

The Enlarged Board of Appeal also explicitly refused as "neither necessary nor indeed appropriate to discuss... whether the standard of ordre public or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain stem cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo...".

Ultimately, the Board held that the provisions of Rule 28.c EPC, i.e. Article 6.2c of the Directive are

clear in that respect and do not leave any room for interpretation.

As a consequence of this decision inventions involving pluripotent embryonic stem cells of human origin are 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 Belgium, Netherlands, Sweden and the UK, and likewise in Australia, Israel, New Zealand or the United States). This exclusion from patent protection applies also where the exercise of the disclosed and claimed invention, i.e. the technical teaching for solving a technical problem, can be commercialised subsequently as drugs under the EU regulatory laws. Examples would be liver or pancreatic lineages, or early cardiogenic precursors that were technically (in the laboratory) generated from pluripotent human embryonic stem cell lines.

It is to be feared 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. Such developments may even be based on research results of European scientists and researchers, who may have applied and may have been granted patents, e.g. in the US, China, etc., and licensed them outside of Europe. Europe may, eventually, become just a market for those therapeutics, since their marketing is, in principle, allowed, but be prevented from enjoying the economic benefits of the research undertaken.

ALLEA is aware of the fact that the legal uncertainty surrounding stem cell research and the exploitation of its results in Europe has already resulted in a significant move of researchers and research projects in this area (particularly in industry) to Asia and the Americas. ALLEA expresses its concerns that a continued lack of clarity on the issue of patenting risks putting research in Europe at a competitive disadvantage.

IV. Referral of the German Federal Supreme Court

ALLEA is aware of the fact that the Court of Justice of the European Union is at present hearing a case [10] based on a referral of the German Federal Supreme Court of November 12, 2009. In that case the validity of a German Patent11 is in dispute, which relates to "neuronal precursors, methods of production and use for therapy of neural defects", issued by the German Patent Office in April 1999, claiming, *inter alia*, "isolated, purified precursor cells from embryonic stem cells with neural or glial characteristics." In its referral the German Federal Supreme Court asked the Court in Luxembourg to provide an interpretation of Articles 5 and 6, especially Articles 6.2c of the EU Directive with regard to the patentability of inventions involving human pluripotent embryonic stem cells, which function, i.e. can be performed without any use or re-use of human embryos.

V. Recommendations

ALLEA expresses the hope that the **Court of Justice of the European Union** will clarify matters in line with its established case law, namely "...that Article 5.2 of the Directive thus seeks to grant specific rights as regards the patentability of elements of the human body. Even though it provides merely for the possibility that a patent be granted, it obliges the Member States, as is apparent from the 17th to 20th recitals in the preamble to the Directive, "**to provide that their national law does not preclude the patentability of elements isolated from the human body, in order to encourage research aimed at obtaining and isolating such elements valuable to medicinal production.**" [12].

ALLEA also hopes that it be clarified that the Directive **concerns only the grant of patents**, and that the scope of the Directive "does not therefore extend to activities before and after the grant, whether they involve research or the use of the patented product" [13] and that, finally, "the grant of a patent does not preclude legal limitations or prohibitions applying to research into patentable products or the exploitation of patented products, as the 14th Recital of thePreamble to the Directive points out. The purpose of the Directive is not to replace the restrictive provisions which guarantee, outside the scope of the Directive, compliance with certain ethical rules which include the right to self-determination by informed consent." [14]

ALLEA is confident that a **balanced solution** can be found: such a solution should 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 commercialised as therapeutics or diagnostics, will enjoy the same incentives by

the patent system as other inventions, particularly those in the area of pharmaceuticals.

ALLEA draws attention to the ethical guidelines offered by the European Group on Ethics in Science and New Technologies to the European Commission in its Opinion No. 16 of 7 May 2002 on *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*.

ALLEA is also aware 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 which Member States entered into in international legal instruments, such as the TRIPS Agreement. In fact, the same Directive that had been used by the EBA as a mainstay of their argument explicitly emphasizes in its Article 1.2 and Recital 36 that it does not interfere with the obligations which the Member States entered into under the TRIPS Agreement.

As a case in point, ALLEA wishes to refer to a number of patent applications pending in the European Patent Office which are related to inventions involving pluripotent human embryonic stem cells. ALLEA *expresses its hope and is confident* that, taking cue from the current referral by the German Supreme Court and the subsequent reactions of the Court in Luxembourg, the competent institutions of the European Union will undertake all the necessary steps that the principles of the judgment of the Court of Justice of the European Union will, eventually, control also patent applications pending in the European Patent Office, and that the current regulatory dilemma be resolved as soon as possible.

Drafted by Standing Committee on Intellectual Property Rights

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Footnotes

[1] **ALLEA emphasizes that this statement does not address the regulatory solutions concerning embryo research in European countries, nor does it address embryo research as such; it focuses exclusively on a regulatory dilemma and the resulting effects on research efforts based in Europe.**

[2] Cf., e.g., Zaret/Grompe, Generation and Regeneration of Cells of the Liver and Pancreas, 2008 Science 1490.

[3] Cf., e.g., Chien/Domian/Parker, Cardiogenesis and the Complex Biology of Regenerative Cardiovascular Medicine, 2008 Science 1494.

[4] Brüstle/Jones/Learish/Karram/Choudhary/Wiestler/Duncan/McKay, Embryonic Stem Cell-Derived Glial Precursors: A Source of Myelinating Transplants, 1999 Science 754.

[5] Cf. only Takahashi/Yamanaka, Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors, 2006 Cell 663.

[6] Cf. Holden/Vogel, A Seizemic Shift for Stem Cell Research, 2008 Science 561; Wobus, The Janus Face of Pluripotent Stem Cells – Connection Between Pluripotency and Tumourigenicity, 2010 Bioassays 993.

[7] Cf. Alper, Geron Gets Green Light for Human Trial of ES Cell-Derived Product, 2009 Nature Biotechnology 213.

[8] Webb, Burgeoning Stem Cell Product Market Lures Major Suppliers,, 2010 Nature Biotechnology 535.

[9] OJ EPO 2009, 306 – Use of Embryos/WARF.

[10] Case No. C-34/10.

[11] DE 19756864 – Inventor and patentee Professor Brüstle.

[12] Judgment of 16 June 2005, Case No. -45603, Commission of the European Communities v. Italian Republic, No. 70.

[13] Judgment of 9 October 2001, Case No. -377/98, Kingdom of the Netherlands, supported by Italian Republic; and see Kingdom of Norway v. European Parliament and Council of the European Union, supported by Commission of the European Communities, No. 79.

[14] Ibidem No. 80.