EIP

When is an embryo an embryo?

Despite recent guidance, the UK High Court has deemed it necessary to refer a question to the Court of Justice of the European Union (CJEU) that seeks to clarify what is meant by a "human embryo", highlighting an uncertainty that exists in relation to the patenting of stem cells. The case ([2013] EWHC 807 (Ch)) was an appeal from International Stem Cell Corporation (ISCC) against the decision of the UKIPO to refuse two of ISCC's patent applications on the grounds that they included unpatentable subject matter under paragraph 3(d), Schedule A2 of the Patents Act 1977. It was ruled that the inventions concerned "uses of human embryos for industrial or commercial purposes", specifically methods for the production of human stem cells and their use in preparing synthetic corneas.

Starting Point

Paragraph 3(d) of Schedule A2 is an implementation of Article 6(2)(c) of EU Directive 98/44/EC (The Biotech Directive). Recent guidance has been given by the CJEU on how Article 6(2)(c) should be interpreted in the case of Brüstle vs. Greenpeace eV (C-34/10). Both parties (ISCC and the Comptroller) agreed that this case hinged on the judgement handed down in Brüstle, namely the question of what exactly the CJEU had meant when they held that any organism "capable of commencing the process of development of a human being" must be regarded as a human embryo.

Technological Background

ISCC's two applications concerned technology which sought to produce pluripotent human stem cells from human ova activated by parthenogenesis. Parthenogenesis refers to the initiation of cell division by activation of ova in the absence of sperm cells, for example using electrical or chemical stimulation. The activated ovum (parthenote) is

capable of developing into a primitive embryonic structure (called a blastocyst) but cannot develop to term as the cells are pluripotent, meaning that they cannot develop the necessary extra-embryonic tissues (such as amniotic fluid) needed for a viable human foetus. Totipotent cells, by contrast, can differentiate into embryonic and extra-embryonic cells and are able to develop into a viable human being.

In Brüstle, the CJEU took a broad interpretation as to what constitutes a human embryo, taking any fertilised human ovum to be an embryo in addition to an unfertilised ovum into which a mature nucleus has been transplanted, or an unfertilised ovum which has been stimulated by parthenogenesis. Such a definition would, on the face of it, justify the UKIPO's position that ISCC's inventions are precluded from patentability.

The Submissions

ISCC argued that the key question was whether or not the organism which is capable of commencing the process of development of a human being is further capable of becoming a viable human. ISCC submitted that the CJEU's Brüstle test applied only to organisms that could develop into full human beings, meaning that their invention should not be excluded from patentability as their embryos cannot develop past the blastocyst stage. ISCC pointed to the ruling of the German Bundesgerichtshof in light of Brüstle, which ruled that removal of cells from non-viable embryos could not be regarded as the use of an embryo, although the case was not related to parthenotes. Perhaps most importantly, they argued that the CJEU had exceeded its jurisdiction in Brüstle as it incorrectly assumed that it was common ground between both parties that parthenotes could be totipotent and hence were capable of commencing the process which leads to the development of a human being. ISCC indicated the referral from the Bundesgerichtshof as evidence that, when the case was initially heard, it was not certain whether parthenotes could develop into complete humans. On this basis, ISCC's primary case was that the issue was acte clair in its favour and that the appeal should be allowed without a further referral to the CJEU.

The Comptroller took a slightly different view and submitted that the Brüstle test might only refer to the start of the process of development of a human being and does not require completion of said process (i.e. birth of a human or creation of a viable foetus). He went on to outline the similarity between the initial development of parthenotes and viable embryos and indicated that, if this was the mentality of the CJEU in Brüstle, the Court was justified in coming to the conclusion that it did. He agreed with ISCC that it was unclear whether the Brüstle test turned on commencing the process of development or commencing a process capable of creating a viable human being.

The Judgement

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After the Deputy Judge (Henry Carr QC) had made clear that the case was not acte clair in ISCC's favour, all parties agreed that a referral to the CJEU clarifying the patentability of inventions relating to parthenotes was necessary. Mr Carr QC put forward that parthenotes and fertilised ova are not identical at any stage of development and questioned whether the CJEU would have come to the same conclusion had it had access to the facts of the current case. The Deputy Judge appeared to echo the sentiments of many in the biotech community when he concluded that excluding processes which are incapable of leading to a human being from patentability goes against one of the main goals of The Biotech Directive, which is to strike a balance between encouraging biotechnological innovation and respecting the dignity and integrity of the person. He went on to indicate that a total exclusion from patent protection for inventions relating to stem cell research would be "to the detriment of European industry and public health". Hence the state of play for stem cell inventions is still far from clear, although many in the European biotech industry will hope that the judgement of the CJEU may bring some degree of certainty for potential patentees.

By Andrew Sharples and Fergus Tyrrell.