Why an embryo model is not an "*embryo*" under UK Law

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An embryo model will only qualify as a human embryo for purposes of the Human Fertilisation and Embryology Act 1990 ("**HFE Act**") and the Patents Act 1977 if according to current scientific understanding it has the same capacity, if implanted into a woman, of developing without further intervention into a foetus and eventually a human being as that of an embryo developed from an *in vitro* fertilised human egg[1]. A stem cell based embryo model ("**SCBEM**") will only qualify as an "*embryo*" under either Act if it can be shown to have this potential[2]. The test is, however, forbidden by the HFE Act.

In approaching this question, I have considered a range of statutory approaches under English law: common law rules of construction, presumptions, as well as intrinsic and extrinsic aids to interpretation. In practice, these principles overlap, but the approach is worthwhile if only to identify any conflicts that may arise.

Towards the end, I explore the embryo test problem.

1. Rules of statutory construction

The "literal rule"

1.1. Under the literal rule, words are given their common or ordinary meaning if they apply generally to people. However, if the word has a technical meaning (for example, in a scientific or clinical context), it should be interpreted with that technical meaning in that particular context. Under the literal rule, the meaning applied to a word is that which it bore at the time of the enactment of the relevant statute. The legal, social and political context in which the amended term "*embryo*" was enacted in 2008 was not such that Parliament would have understood embryos to include developmental models. The common, ordinary, clinical and scientific understandings of the word "*embryo*" did not at that time extend to developmental models comprised of living human cells. However, if such models were nonetheless "*live human embryos*" they would certainly fall within the contemplation of Parliament.

1.2. The 2008 amendments followed the decision of the Appellate Committee of the House of Lords in *Quintavalle v Secretary of State for Health* ([2003] UKHL 13), in which the Court considered the meaning of the term "*embryo*" as it stood under the HFE Act

[1] Note that this includes fertilised eggs that do not develop to term or even to implantation.

[2] A question of scientific nomenclature would arise were a model to be deemed a "*live human embryo*", namely whether it can be said to be a model at all.

at that time. Lord Millett noted that the "*the definition in paragraph (a) is in part circular, since it contains the very term to be defined. It assumes that the reader knows what an embryo is*." The amended definition of 2008, which still defines "*embryo*" by reference to a "*live human embryo*" remains "*part circular*". The change to the Act merely clarified that the process by which a "*live human embryo*" is produced is immaterial. Lord Millett suggested that an embryo is "*a live human organism containing within its cell or cells a full set of 46 chromosomes with the normal potential to develop and, if planted in a woman, to become a foetus and eventually a human being*". In 2008 (and 1990), Parliament considered that *in vitro* fertilised human eggs exemplified this "*normal potential*"[3]. Adopting the literal approach, we find that only human embryo models having the same developmental prospects as an embryo produced by *in vitro* fertilisation would constitute "*live human embryos*" under the HFE Act.

The "mischief rule"

1.3. The mischief rule requires the court to look to the rationale of the legislation in order to interpret a statutory ambiguity. Examining the original definition of the term "*embryo*" under the 1990 Act by recourse to its legislative context, the House of Lords held in *Quintavalle* that the way in which an entity that is "*not distinguishable in any significant respect from those regulated by the Act*" is produced is irrelevant. The amended definition of 2008 confirms this, by correcting any impression that production process matters. It does this by confirming that embryos may be created by the somatic nuclear replacement of an egg, and by any other technique having the same outcome: i.e. "*a live human embryo*". Although the reference to an egg[4] appears to perpetuate the embryological dictum, *omne vivum ex ovo*, it is predicated by the word "*include*": as in "*references to an embryo include*…". Applying the mischief rule, Parliament's intention is clear. Although a "*live human embryo*" is measured by the biological standards of oocyte-derived embryos, eggs are not presumed to be required in their production. The fact that embryo models are not oocyte-derived does not therefore preclude those that meet those standards from falling under the HFE Act. The court would simply look to the entity itself and ask whether or not it is a "*live human embryo*" as that expression is currently understood.

Purposive construction

1.4. An approach to statutory construction of particular relevance is the decision of the House of Lords in *Quintavalle* in 2003 (see above). *Quintavalle* draws an important distinction between two possible aims. The first is to discover what Parliament actually intended. The second aim is to identify what Parliament *would have* intended had it foreseen later developments. Only the first of these aims is permissible. Consequently, the question to be asked is not whether Parliament positively intended to cover stem cell based embryo models, but whether in 2008 Parliament intended the statutory term "*embryo*" to include entities which are not "*live human embryos*" from the perspective of current scientific understanding.

[3] Somatic nuclear replacement might approach that potential, but the benchmark is set by the *in vitro* fertilised human egg.

[4] As it is elsewhere, in connection with a "*permitted embryo*", which necessitates the use of a "*permitted egg*".

1.5. The House of Lords considered prior examples of statutory terms being interpreted so as to capture things that were unknown at the time of their enactment. "*Telegraph*" had been held to accommodate the telephone; "*bodily harm*" to include psychological harm; "*document*" to include a tape recording; "*cruel and unusual punishments*" to extend to reprimands far less dreadful than those of 1689. The approach to interpretating such statutes assumes that the statute is "always speaking". This means that, instead of searching for the term's historical or original meaning, a court is free to apply its present day meaning to the conditions of the present. As Lord Bingham put it, "*If Parliament, however long ago, passed an Act applicable to dogs, it could not properly be interpreted to apply to cats; but it could properly be held to apply to animals which were not regarded as dogs when the Act was passed but are so regarded now*." To take Lord Bingham's example at face value, if genomic analysis conducted long after the enactment of a (fictitious) Dog Act were to show that racoons should be taxonomically classed as members of the dog family, then they would be captured by the Dog Act. The court declared the 1990 Act was just such "an always speaking" Act. "*The result*" as Lord Steyn remarked, "*is that the 1990 Act may be construed in the light of contemporary scientific knowledge*". Consequently, only if a human embryo model were shown, by the standards of contemporary scientific understanding to be indistinguishable from a "*live human embryo*", then it would fall under the "*embryo*" definition of the HFE Act[5].

1.6. In approaching such a question of construction, the House of Lords adopted a procedure devised by Lord Wilberforce in his dissenting opinion in *Royal College of Nursing of the United Kingdom v Department of Health and Social Security*. Lord Wilberforce had in that case emphasised the need, when considering whether a new state of affairs or a fresh set of facts bearing on policy would fall within Parliament's intention, to have regard to the state of affairs existing before Parliament legislated. His three step test is summarised below, with comments relating to embryo models.

1. Does the subject matter fall within the same genus of facts as those to which the expressed policy has been formulated? A court will hold this to be the case if there can be detected a clear purpose in the legislation which can only be fulfilled if the extension is made.

   The expressed policy of the HFE Act is formulated towards embryos. Current embryo models may be distinguished from embryos in very significant ways, and therefore fall outside the genus of facts to which the expressed policy of Parliament was formulated. However, if, according to contemporary scientific understanding, an embryo model were to become indistinguishable from a "live human embryo*", we may proceed to step 2.*

2. Is the operation of the statute to be regarded as liberal and permissive in its operation or restrictive and circumscribed? Unless there is a clear prohibition of the subject matter, the courts should be less willing to extend expressed meanings.

[5] More accurately, it is the result of a test which would be illegal to conduct in humans. See Discussion.

Could Parliament, faced with the challenging task of enacting a legislative solution to ethical concerns about developmental models, have intended to include embryo models within the scope of the 1990 Act, if it had known of them as a scientific possibility?

*It seems unlikely that a court would seek to extend an Act focused on the protection of human embryos so as to capture developmental models that lack, to quote Lord Millett, "*the normal potential to develop and, if planted in a woman, to become a foetus and eventually a human being*". The House of Lords was forceful in stating that it is not for a court to fill in legislative gaps, and that the answer must be found within the terms of the Act itself. Given the absence of any clear prohibition, a court would not extend the protection that the Act accords to "*live human embryos*" to things that are not embryos. However, if according to contemporary scientific understanding, a particular embryo model were to be deemed indistinguishable from a "*live human embryo*",* a court would consider it to fall within Parliament's intention. *If this event, we would proceed to step 3* of Lord Wilberforce's test.

3. Is the subject matter different in kind or dimension from that for which the legislation was passed? If it is, the court should be <u>much</u> less willing to extend the meaning of a statutory term.

Developmental models, even those seeking to recapitulate significant elements of embryonic development, are of a very different kind to human embryos as described by the House of Lords in Quintavalle: "a live human organism containing within its cell or cells a full set of 46 chromosomes with the normal potential to develop and, if planted in a woman, to become a foetus and eventually a human being*". Given this most fundamental of differences, a court in these circumstance would be "*much less willing*" to include non-oocyte-derived cellular models of early development within the meaning of the term "*embryo*" under the HFE Act. However, if, according to contemporary scientific understanding, a particular embryo model were indistinguishable from a "*live human embryo*", a court would conclude that it is an "*embryo*" under the Act.*

The House of Lords held that a court may consider one additional question:

4. Would Parliament, faced with the taxing task of enacting a legislative solution to the difficult religious, moral and scientific issues posed by the subject, rationally have intended to leave (in this case) live human embryo models <u>outside</u> the scope of Act if it had known of them as a scientific possibility?

The answer to this question depends on whether the models are, judged by contemporary scientific understanding, "live human embryos". This last question highlights the central issue of contemporary scientific understanding. For obvious reasons, this is not something which can be legislated for: the wording of any statute in this area will be read in the light of current scientific knowledge.

The "golden rule"

1.7. This is the common sense rule of judicial interpretation whereby an ambiguity is construed to avoid an absurdity. It does not arise in the present case.

2. Current scientific knowledge

2.1. The state of current scientific knowledge, then, is a central principle when it comes to interpreting the HFE Act. Because current scientific knowledge is a matter of fact, not law, regulators may have regard to the decisions made in relation to statutes addressing the same or borderline subject matter, for example in memoranda of understanding and joint position statements.

2.2. The HFE Act provides two examples: the position of gonadal tissue in relation to the Human Tissue Act 2004[6], and identifying personal information in relation to the Data Protection Act 2018.

2.3. Section 33A of the HFE Act prohibits a person from disclosing information about the use of donated sperm "*of any identifiable individual*" who is not the partner of a person receiving treatment services. HFEA guidance on what constitutes identifying information highlights the challenge of two technologies that make it easier to triangulate donor identity: social media and social DNA testing sites. Although these were not available when section 33A was enacted, the HFE Act is "always speaking" when it addresses developments in information technology, just as it is in relation to advances in genetics or embryology. Nor does section 33A make any reference to data protection legislation. However, because current technological understanding has been assessed by a body having authority over the meaning of identifying information, albeit under a separate statute, a court tasked with construing the expression in the HFE Act would inevitably consider the Information Commissioner's Office's most up-to-date guidance on effective anonymisation[7].

2.4. Similarly, when considering the current scientific understanding of the term "*embryo*" under the HFE Act, we might cautiously consider how the same word is construed under different statutes concerning the same genus of facts. In particular, we might look at how senior courts have interpreted the term "*human embryo*" under the Schedule A2 of the Patents Act 1977, which implements provisions of the EU Biotechnology Directive (Directive 98/44). In doing so, we would look to the December 2014 decision of the Court of Justice of the European Union ("**CJEU**") in *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* ("**ISCC**").

[6] See HFEA and HTA joint statement on ovarian and testicular tissue storage: https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hfea-and-hta-joint-statement-ovarian-and

[7] https://ico.org.uk/media/about-the-ico/documents/4018606/chapter-2-anonymisation-draft.pdf This position may be supported by the law relating to judicial review which, when assessing the reasonableness of a decision, considers the position of an equivalent authority tasked with the same decision.

2.5. The *ISCC* decision was made in response to an application by the UK's Intellectual Property Office, which asked the court to clarify whether human parthenotes (non-fertilised human ova whose division and further development have been stimulated by parthenogenesis) should be regarded as "*human embryos*" under Article 6(2) the Biotechnology Directive. Although human parthenotes are "*capable of commencing the process of development of a human being*" the CJEU held that this is not "*just as an embryo created by fertilisation of an ovum can*"[8] because, according to "*current scientific knowledge*", a parthenote is unable to develop to term[9] and thus into a human being[10]. The CJEU held that without this capacity a parthenote cannot be regarded as a "*human embryo*" under the Biotechnology Directive. It stated that the critical factor is "*the inherent capacity of developing into a human being*". Consequently, if it transpired that a human parthenote did in fact have the "*inherent capacity*" develop to term, it would become a "*human embryo*" for purposes of the Directive. The term "*inherent*" does not mean "*inherited*": an entity having no potential of developing into a human being may acquire an "*inherent capacity*" to do so as a result of an intervention. Thus, the Court distinguished the case of a parthenote with no such "*inherent capacity*" to develop to term from one that, owing to "*additional genetic manipulation*", did have such potential. Such an entity, the CJEU declared, would be deemed a "*human embryo*" under the Biotechnology Directive and, therefore, under the Patents Act 1977 and other European legislation implementing the Directive. For brevity, I adopt the word "entelechy" to denote this "*inherent capacity of developing into a human being*"[11].

2.6. The *ISCC* decision highlights a convergence of approach towards the meaning of the same term: "*human embryo*" (Patents Act) and "*embryo*" (HFE Act). There are important differences between the worlds of these statutes. Notably, whereas the HFE Act seeks to protect the "special status" of the human "*embryo*" identified by the Warnock Committee, the approach to "*human embryos*" of the Patents Act is underpinned by a concept of "*human dignity*" derived from European law. *ISCC* removes this distinction.

2.7. Prior to *ISCC*, the CJEU in *Brustle* had, on the supposed basis of upholding "*human dignity*", forbidden patentability to entities like parthenotes that were incapable of developing to term (i.e. lacking entelechy). However, in conspicuously rejecting this earlier ruling on the basis of current scientific knowledge, the Court in *ISCC* confirmed that "*human dignity*" does not adhere to entities that merely commence the process of development without having the prospect of developing into a human being[12]. With "*human dignity*" denied to parthenotes under one English statute many will consider that the ineffable "special status" (not even a statutory term) would not arise under the other, especially as the same result would arise under the HFE Act. More significant

[8] As the CJEU had held, per incuriam, in *Brustle v Greenpeace 2011*.

[9] Because, unlike a fertilised ovum, parthenotes do not contain paternal DNA, which is required for the development of extra-embryonic tissue.

[10] Paragraph 76, Advocate General Cruz Villalon's Opinion in ISCC. Case C-364/13 (17 July 2014).

[11] For the sake of brevity, not to endorse Aristotle's meaning of the term dogmatically!

[12] Technically, the qualifier, "without further intervention" applies. See above.

is the common rationale of *Quintavalle* and *ISCC*. Entelechy, as determined by current scientific knowledge, is essential to an entity being a "*human embryo*" under both the Patents Act and the HFE Act.

2.8. The genus of fact addressed by the terms "*embryo*" under the HFE Act and "*human embryo*" under the Patents Act are identical. Although the judicial descriptions, "*the inherent capacity of developing into a human being*" (*ISCC*) and "*the normal potential to develop and, if planted in a woman, to become a foetus and eventually a human being*" (*Quintavalle*) only differ in relation to the word "*inherent*", this seems to be implied by the HFE Act. For example, because section 1(1)(b) of the HFE Act states that "*references to an embryo include an egg that is in the process of fertilisation*", a hydatidiform mole is an "*embryo*" in the brief moment at which a sperm enters the egg[13], but loses that distinction immediately thereafter, because it is incapable "*of resulting in an embryo*". By contrast, a parthenote is not even a transient "*embryo*", because the egg is never fertilised and it is incapable of developing into a "*live human embryo*" according to current scientific understanding without further intervention. However, if such an intervention were made, the Act (being indifferent to process) would deem it to be an "*embryo*" if, on the basis of current scientific knowledge, it acquired the capacity for development into a foetus. Indeed, we can say that it would become an "*embryo*" from the point of intervention.

2.9. In short, the two statutes converge on two core principles: current scientific understanding and entelechy, with entelechy assessed by reference to the developmental potential of an *in vitro* fertilised human egg. Only when an entity has, according to current scientific understanding, the same entelechy as an entity that is or has developed from[14] such a zygote, should we conclude that it is an "*embryo*" under the HFE Act or the Patents Act.

3. Interpretative aids

I have briefly listed likely materials for construal. These appear to confirm the view outlined in this note.

Intrinsic

3.1. Explanatory notes may be used as an aid to construction[15]. The Explanatory Memorandum to the 2008 Act refers to the December 2006 *White Paper: Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation*, which stated that "*The wording of the existing law has been challenged on the basis that it did not appear to cover embryos created by these novel processes*" (a reference to *Quintavalle*). The Explanatory Memorandum states that, by bringing the term "*embryo"* up to date with technologies for creating embryos that had been developed

[13] Even though, assuming it lacks a diploid nucleus, it would not be a zygote.

[14] Because a SCBEM that would be deemed to be "*a live human embryo*" would not have passed through the same stages of early development.

[15] Wilson v First County Trust (No.2) [2004] 1 AC 816 at [64]) https://publications.parliament.uk/pa/ld200203/ldjudgmt/jd030710/will-2.htm

since the passage of the 1990 Act (removing the presumption of fertilisation) the amendments to section 1 are intended "*to ensure that the Act applies to all live human embryos regardless of the manner of their creation* […]"; but do not expand the meaning of "*embryo*", which will continue to be defined in broad terms as "*a live human embryo*".

3.2. The long title of the 1990 Act is "*An Act to make provision in connection with human embryos and any subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes* […]". In *Quintavalle*, the Court held that the general wording of the long title was plainly not intended to limit the manner by which an embryo might be created. However, the answer to the question, "what is an 'embryo' under the HFE Act" is not to be found in the terms of the Act itself, and "*there is one course which the courts cannot take, under the law of this country; they cannot fill gaps; they cannot by asking the question 'What would Parliament have done in this current case—not being one in contemplation—if the facts had been before it?' attempt themselves to supply the answer, if the answer is not to be found in the terms of the Act itself."*[16]

Extrinsic

3.3. In passing the HFE Act, Parliament was guided by the Report of the Warnock Committee, which had noted that, "*While the term 'embryo' has been variously defined in considering human embryology, we have taken as our starting point the meeting of egg and sperm at fertilisation. We have regarded the embryonic stage to be the six weeks immediately following fertilisation which usually corresponds with the first eight weeks of gestation counted from the first day of the woman's last menstrual period.*[17]" The Committee's view, that an "*embryo*" is something having the potential, subject to reproductive loss, to become implanted in a uterus, there to develop in the direction of live birth. This is consistent with the judgment in Quintavalle, that Parliament, which was guided by the Report, considered entelechy to be an fundamental quality of an "*embryo*".

3.4. Debate on the Bill that would become the 2008 Act was focused upon processes for creating embryos, not upon what they are, although it concluded that these processes were immaterial.

Committees

3.5. The House of Commons Science and Technology Committee Fifth Report (Session 2006-7) focuses on novel processes for creating embryos, not developmental models. The report defines "*embryo*" as "*An animal in the early stage of development before birth. In humans, the embryo stage is the first three months following conception*" This (12 weeks of development) is four weeks longer than contemplated by the Warnock report, and actually crosses over into the period of foetal development, which (e.g.) Scott Gilbert says commences after 9 weeks.

[16] The Court confirming the judgment of Lord Wilberforce in *RCN v DHSS.*

[17] "Scope of the Inquiry", paragraph 1.4

4. Presumptions

Statute will not impose liability without fault

4.1. Judges may not develop the law to create new offences or widen existing offences so as to make punishable conduct of a type hitherto not subject to punishment[18]. Likewise, Article 7(1) ECHR: "*No one shall be held guilty of any criminal offence on account of any act or omission which did not constitute a criminal offence under national or international law at the time when it was committed*." The HFE Act does not restrict the use of any embryo model that is not, according to current scientific understanding, a "*live human embryo*", in which case it becomes subject to the HFE Act. A court cannot create a new offence. Widening the meaning of "*embryo*" to capture things other than "*live human embryos*" would expose researchers to criminal liability for undertaking activities that, in the absence of a clear prohibition, had been conducted in the reasonable belief of its lawfulness.

Statutes imposing criminal liability are construed narrowly, against the Crown.

4.2. If there is a clear meaning within the statute in question, the literal rule prevails. Otherwise, any ambiguities the consequence of which may be to impose criminal liability will be resolved in the subject's favour. Again, this militates against a broad reading of the statutory expression.

Statute may not be construed so as to infringe international law

4.3. The UK is a State Party to the International Covenant on Economic, Social and Cultural Rights, Article 15(3) of which states that "*The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity*." The UK is also a party to the Vienna Convention on the Law of Treaties, Article 26 of which states that "*Every treaty in force is binding upon the parties to it and must be performed by them in good faith*" (*pacta sunt servanda*). That this fundamental right to research freedom is recognised in the laws of the United Kingdom, is supported by Recital 6 to the Protocol on the application of the Charter of Fundamental Rights of the EU to Poland and the UK. This states that, "*the Charter reaffirms the rights, freedoms and principles recognised in the* Union *and makes those rights more visible, but does not create new* rights *or principles*." Article 13 of the Charter, which states that "*The arts and scientific research shall be free of constraint. Academic freedom shall be respected*" is inferred to have existed in the then territory of the EU. The Explanations note that the Article 13 right "*is deduced primarily from the right to freedom of thought and expression. It is to be exercised having regard to Article 1 (dignity of the human person) and may be subject to the limitations authorised by Article 10 of the ECHR*".

5. The embryo test problem and self-regulation

5.1. It would not only be unlikely for a human SCBEM to qualify as an "*embryo*" under the HFE Act or Patents Act, but it would also be unlawful to carry out an empirical

[18] Lord Bingham ("*The Rule of Law*", 2006 lecture citing *R v Withers* [1975] AC 842 and *R v Rimmington* [2006] 1 AC 459.

test [19]. Without such a test, there can be no scientific understanding as to whether or not a model would in fact comprise a "*live human embryo*". The default position would be that it would not.

5.2. This dilemma may be resolved by testing the developmental potential of a non-human primate model (e.g.) that has developed according to protocols proposed to be used for the facilitating the assembly of a human model. Such a test could not be legally sufficient: even the best proxy test of model could not establish that the human version would be a "*live human embryo*", for the simple reason that is not human. "Current scientific understanding" is not the same as "current scientific hypotheses". However, as the best available test, it might provide a sufficient marker for purposes of self-regulation.

5.3. In particular, human SCBEMs made to the same protocols as a non-human primate proxy that had tested positive could subjected to a regime that directly matches that applicable to human embryos used for research purposes under the HFE Act, notably the restriction of research activities by licensing. If it later transpired that the human version of the SCBEM were incapable of developing into a foetus or towards live birth (and thus not an "*embryo*" as understood by the leading cases), the self-regulatory scheme could be relaxed, but it need not be. It would be open to the governing body to apply its own standards.

5.4. The HFEA could agree to deem such a model an "*embryo*" for purposes of the Act when so advised by the independent scientific and ethical research ethics committee established under the SCBEM framework[20]. It would have no real legal authority over such matters, for example in connection with a breach of a "SCBEM licence", but there are precedents for this sort of arrangement, for example in relation to REC approval of human tissue research conducted outside the NHS and the rules for the use of non-clinical hESCs from the UK Stem Cell Bank.

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[19] In the United Kingdom. Why would someone risk the experiment if a positive outcome led to a term of imprisonment?

[20] i.e. That, in view of the Committee, the model may, if it were implanted, develop in a way that would be sufficiently similar to the development of an embryo created by *in vitro* fertilisation of a human egg as to justify its use to be restricted (in a way based on the limitations – e.g. of purpose and cultivation time – applicable to human embryos under the HFE Act).