Patents Act 1977
Examination Report under Section 18(3)

Basis for examination

1. This application has been examined out of turn because it concerns subject matter which is considered to be excluded. It is hoped that the issue of this examination report will be helpful when you decide how you should to proceed with your application GB0621068.6 which concerns related subject matter.

2. In the examination of this case, I have considered the search and examination reports concerning the proceedings at WIPO and at the EPO with respect to the equivalent applications WO2008/013557 A and EP2049043 A.

Plurality of invention s.14(5)(d)

3. Your claims define two separate inventions not forming a single inventive concept. The inventions are:

   i. Claims 1-21 and 26-36 broadly relate to retinal stem cell-derived synthetic corneas and a method of producing such synthetic corneas, a method of screening to identify an agent that affects corneas by using retinal stem cell synthetic corneas and a method of delivering transformed corneal cells derived from retinal stem cells into a human eye.

   ii. Claims 22-25 concern surgical techniques to replacement a cornea with a synthetic cornea.

4. You will need to amend your claims, so that they relate to only one invention or inventive concept. You will also need to make consequential amendments to the description.

Scope of search

5. In accordance with Section 17(6), only the first of these inventions has been searched. The other invention can be searched if you wish. In this case you will have to file a further Form 9A. Please note, however, that the invention defined by claims 22-25 would appear to be conventional to the art such that it lacks novelty and inventive step.
What this report covers

6. I have not been able to formally consider the novelty or obviousness of the unsearched invention as defined by claims 22-25.

Excluded methods of treatment s.4A(1)(a)

7. Claims 22-25, 33-36 concern methods of surgery or treatment performed on the human or animal body and are therefore excluded from patentability.

Patentability under paragraph 3(d) of Schedule A2 to the Patents Act

8. Human parthenotes are considered, for the purposes of the Act to be human embryos. Method claims 13-20 and product by process claims 2, 10-12 and 21 are excluded by paragraph 3(d) of Schedule A2 to the Patents Act because they are considered to concern the industrial or commercial uses of human embryos. The parthenote-derived cells have not been placed at a depository, so to use these cells a parthenogenetic human embryo is required each time. The products of such processes are therefore excluded because they require that the product be derived by the industrial or commercial use of parthenogenetic human embryos.

9. The exclusion under paragraph 3(d) relates to ‘human embryos’. Neither the Patents Act 1977, as amended, nor European Directive 98/44 from which Schedule A2 to the Patents Act was transposed into UK law in 2000 define the meaning of the term ‘human embryos’. Under UK law, the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008 sets out the definition of a human embryo and the law relating to the regulation of human embryo research and usage. The HFE Act states (at Section 1(1)(a) and 1(1)(b)) that an ‘embryo means a live human embryo….and references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo’.

10. Any human egg undergoing the process of parthenogenesis is considered to fall within the ambit of the definition of human embryo given by the HFE Act 2008 and therefore claims relating to the industrial or commercial use of a parthenogenically activated human oocyte are considered to be excluded from patentability because human parthenotes are considered to be human embryos for the purposes of paragraph 3(d) of Schedule A2 to the Patents Act.

11. The present application concerns the industrial and commercial uses of human parthenotes to yield human pluripotent stem cells. Irrespective of whether the human parthenotes of the present invention are capable of developing to term due to exclusively maternal genetic imprinting Section 1 of the HFE Act (2008) does not require that an embryo has to have any developmental potential nor does it require that there has to be the genetic or epigenetic input of more than one parent and therefore human parthenotes, irrespective of
their developmental potential, are considered to be excluded by paragraph 3(d) to Schedule A2.

**Patentability of corneal product claims**

12. The invention, as defined by claims 1 and 3-9, concerning isolated retinal stem cells and corneas produced from such cells may be construed as relating to products derived from either human parthenote embryos (subject to exclusion from patentability) or from established human embryonic stem cell lines (not considered to be excluded). In order to eliminate doubt as to the patentability of the invention as defined by product claims 1 and 3-9 amendments to the description and claims are required to make clear that a monopoly is sought for products and methods where the starting material has not been obtained from a parthenogenetic embryonic stem cell culture (it appears that no such cells have been deposited), but has instead been obtained from established human embryonic stem cell lines.

**Product by process claims: clarity, novelty and inventive step**

13. The invention as defined in claims 1-12, 21 at least is not new because it has already been disclosed in the following document:

WO03/100011 A2 (ADVANCED CELL TECH) See claims 1, 9-11

14. Claim 1 concerns a retinal-stem cell derived synthetic cornea. As set out in your application this synthetic cornea comprises a cell layer analogous to Bowman’s layer and an epithelial cell layer. It is by no means clear how such a synthetic cornea may be distinguished from the prior art synthetic corneas derived from other types of stem cells because the invention is defined in terms of the process by which it was produced. The Intellectual Property Office considers that a claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product per se, regardless of its method of production.

15. Following the same line of argument, claims 26-36 may be taken to concern the obvious uses of the anticipated product defined by claim 1 such that they at least lack an inventive step.

16. Amendment or argument is required such that it is made clear how the synthetic cornea of claim 1 is to be distinguished from the prior art.

**Clarity**

17. Claim 9 lacks clarity because there is no accession number and because it would seem to refer to the ‘ATTC’ rather than ATCC depository.
18. Claims 7 and 8 specify ranges qualified by the term ‘about’: their scope is therefore unclear.

Registered Trade Marks

19. Although they should preferably be avoided, if you wish to keep the reference(s) to the Registered Trade Marks, you should acknowledge that they are Registered Trade Marks, possibly by using the abbreviation “(RTM)”. If you do not insert an acknowledgment, I will do so. You may acknowledge them by inserting an extra page listing them as Registered Trade Marks.

20. The unacknowledged Registered Trade Marks are as follows:

Microsoft p22
Wordperfect p22
DB2 p22
Sybase p22
Oracle p22
SynVitro p32
Alexa p36
Triton p36
Tween p36-37
VitroHES p33-34
Trapeze p36
Mowiol p36
Dynabead p35
Dynal p35
Hybond p41
Affiimetrix p40
Protrans p40
Glutamax p33, 34, 39