IN THE ENLARGED BOARD OF APPEAL
OF THE EUROPEAN PATENT OFFICE

CASE: G2/06 –
WISCONSIN ALUMNI RESEARCH FOUNDATION

AMICUS CURIAE SUBMISSION OF THE UNITED KINGDOM

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1. This submission is made in response to the invitation of the Enlarged Board of Appeal (OJ EPO 2006, 393) and pursuant to Art. 11b of the Rules of Procedure of the Enlarged Board of Appeal.

2. The questions referred to the Enlarged Board of Appeal arise in a particular context, namely:

   (1) The claims of the patent application in issue are to primate (including human) embryonic stem cells having certain characteristics and to methods of maintaining and using such stem cells. They do not include any claims to human embryos or to the use of human embryos.

   But:

   (2) It was not, at the priority date, possible for the skilled person to prepare the claimed human embryonic stem cells without using, and destroying, spare pre-implantation human embryos.

3. It is only this latter circumstance which has caused this reference to the Enlarged Board of Appeal. There should be no question of this reference calling into question the patentability of human embryonic stem cells *per se*, if the skilled person can implement the invention without the use and destruction of human embryos, whether because of a deposit of a cell line with a recognised depository or otherwise. The United Kingdom would, at

the outset, urge the Enlarged Board of Appeal to emphasise this in its answers to the questions referred.

Art. 53(a) and Rule 23d – an overview

Art. 53(a)

4. Art. 53(a) EPC provides that European patents shall not be granted in respect of:

   "inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."

5. Two main points should be made at the outset. The first main point is that in order for Art. 53(a) to prevent the grant of a patent, it must be the exploitation of the invention which would be contrary to "ordre public" or morality[1]. This point was well made by the Technical Board of Appeal in T 315/03 at §4.2 of the reasons.

6. There are two limbs to this point. Art. 53(a) is not concerned with whether there is a moral objection to making or patenting the invention. It is concerned with whether its *exploitation* would be contrary to morality.

7. Further, Art. 53(a) is concerned with whether exploitation of the *invention* is contrary to morality, not with whether other acts, preparatory, ancillary or subsequent thereto may be morally objectionable. An applicant is seeking commercial rights in respect of a particular invention, yet exploitation of that invention would be immoral. The legislature has decided that in such cases, the applicant should not be rewarded by the grant of a patent – he should not be granted commercial rights when it would be immoral for the invention to be exploited. It is therefore necessary to identify the invention in respect of which commercial rights are sought and to judge the morality of the exploitation of that invention.

8. The second main point is that, in order for exploitation of an invention to be contrary to morality within the meaning of Art. 53(a), it must offend against common European standards of morality. It is submitted that the Technical Board of Appeal in T 356/93 was right, at §6 of the reasons[2], to say:

"The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilization. Accordingly, under Art. 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality."

9. There are certain matters which are regarded across the EPC area as being immoral, for example the use of anti-personnel mines. Patents for anti-personnel mines would rightly be rejected under Art. 53(a). But there are other matters on which differing strands of respectable opinion exist within the EPC area. In some cases the divergence of opinion will exist within each Contracting State. In other cases the opinions will differ between Contracting States, so that in one Contracting State something is generally regarded as immoral, whereas in other Contracting States it is generally regarded as being acceptable.

10. Where there are differing strands of respectable opinion as to whether the exploitation of an invention would be immoral, it is submitted that Art. 53(a) does not prevent the grant of a patent. Article 53(a) does not require the EPO to act as a moral arbiter between such strands of opinion. It requires it to recognise a general consensus across the EPC area that exploitation of an invention would be immoral. But it does not authorize it to refuse patents for inventions the exploitation of which would be regarded as moral by a significant strand of respectable opinion. It is submitted that if exploitation of an invention would be regarded as moral in (at least) a major Contracting State, then a patent should not be refused under Art. 53(a).

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[1] The article also, of course, refers to publication, but this is not relevant in the present case.
[2] Approved in T 315/03 at §10.2 of the reasons

11. After all, it must be remembered that Contracting States retain (at least to the extent permitted by Community law in the case of EU Member States) the ability to proscribe acts which they consider to be immoral. A patent may be granted by the EPO, but the patentee may find that in certain EPC Contracting States, he cannot exploit his patent because the state in question has prohibited it (on moral or indeed other grounds). This is not a reason for refusing to grant a patent in the first place. As Art. 53(a) says, something is not to be deemed contrary to morality merely because it is prohibited by law or regulation in some or all of the Contracting States.

12. Further, it is contended that Contracting States retain the right to apply their own standards of morality to a patent for their territory granted through the EPO process, just as they do to patents for their territory granted through a national process. The right of individual states to do this was expressly recognised by Art. 27(2) of the TRIPS Agreement:

"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public *or morality..."..*

The Biotech Directive

13. In this regard it is also important to consider Directive 98/44/EC ("the Biotech Directive"). It was the passing of the Biotech Directive that led to the introduction of Chapter VI of Part II of the Implementing Regulations to the EPC. Rule 23b(1) requires the relevant provisions of the EPC to be applied and interpreted in accordance with the provisions of that chapter in the case of patents concerning biotechnological inventions. It also requires the Biotech Directive to be used as a supplementary means of interpretation.

14. Recital 14 of the Biotech Directive makes the point (made in paragraph 11 above) that the grant of a patent does not entitle the proprietor to use the invention (but merely to prevent others from doing so) and that therefore the grant of a patent does not override national (or supranational) laws which may restrict or prohibit the use of the invention.

15. Recitals 36 and 39 recognize (expressly in accordance with Art.27(2) of the TRIPS

Agreement) the right of individual Member States to exclude from patentability inventions the exploitation of which would be contrary to moral principles recognized in that Member State. The European Court of Justice also recognized this principle in Case C-377/98[3] at paragraphs 37-38, where it said that Article 6.1:

"…allows the administrative authorities and courts of the Member States a wide scope for manoeuvre in applying this exclusion. However, that scope for manoeuvre is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities."

16. The Biotech Directive also stresses that it is when *exploitation* of the *invention* offends against morality that patentability is to be denied – recital 37 and Article 6.1.

17. Further, it is clear that the particular exclusions from patentability on grounds of morality effected by the Biotech Directive (those identified in Article 6.2) were made because there was a consensus within the Community to the effect that those particular matters were contrary to morality – see recitals 40-45.

18. There can be no doubt that, unlike Art. 6.1 which gives Member States a margin of appreciation (or "wide scope for manoeuvre"), the exclusions in Art. 6.2 are specific – see the decision of the European Court of Justice in Case C-456/03[4] at paragraphs 78-79.

19. Art. 6.2(c) says that uses of human embryos for industrial or commercial purposes shall be considered unpatentable. The consensus between Member States extended only as far as preventing the patenting of uses of human embryos for industrial or commercial purposes. It did not extend to preventing the patenting of the products of the use of human embryos,

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[3] http://curia.europa.eu/jurisp/cgi-bin/gettext.pl?where=&lang=en&num=79988990C19980377&doc=T&ouvert=T&seance=ARRET. See also §6 of the European Commission's 7 October 2002 report (pursuant to Art. 16c of the Directive) on development and implications of patent law in the field of biotechnology and genetic engineering – http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0545:FIN:EN:PDF – and §2.2 of its 14 July 2005 report COM(2005) 312 final – http://eur-lex.europa.eu/LexUriServ/site/en/com/2005/com2005_0312en01.pdf

4 http://curia.europa.eu/jurisp/cgi-bin/gettext.pl?where=&lang=en&num=79949383C19030456&doc=T&ouvert=T&seance=ARRET

nor did it extend to preventing the patenting of uses of human embryos for purposes which were neither industrial nor commercial.

20. This limited consensus was reached at a meeting of the Council of Ministers on 27 November 1997[5]. As the Rapporteur to the European Parliament said in the subsequent debate[6], following which the Parliament accepted the Council's position:

"In relation to the use of embryos, the Council has set some limitations: they are not to be used for industrial or commercial purposes. But I would only ask you to remember that this was done with the United Kingdom in mind. We cannot as European legislators decree that something which does not contravene the underlying legal principles of all Member States is a contravention of public order, and we cannot brand something that we do not jointly regard as abhorrent as a contravention of common decency. That is not acceptable!"

Rule 23d(c)

21. It can be inferred that it was because the consensus reached between EU Member States extended to the other, non-EU, Contracting States to the EPC that the exclusions from patentability identified in Article 6.2 of the Biotech Directive were transposed into Chapter VI of Part II of the Implementing Regulations as being matters which were properly excluded from patentability by Art. 53(a). This is consistent with the submission in paragraph 10 above that the purpose of Art. 53(a) is to exclude inventions from patentability only when there is a consensus across the EPC area that exploitation would be contrary to morality.

22. The particular rule of interest in the present case is Rule 23d, which states:

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[5] See the Common Position explaining that only certain uses of human embryos were to be included - Bulletin EU 11-1997 (en): 1.3.47

[6] http://www.europarl.eu.int/debats/debats?FILE=98-05-11&LANGUE=EN&LEVEL=DOC&GCSELECTCHAP=4&GCSELECTPERS=27. See also to similar effect the comments by the Rapporteur to the Parliament's Committee on Legal Affairs and Citizens' Rights on the legal framework provided by the TRIPS Agreement within which the proposed Biotech Directive was being debated - A4-0222/97 – "an invention whose industrial application is permitted can never be excluded from

"*Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:*

.....

(c) uses of human embryos for industrial or commercial purposes;...."

23. This rule does not alter Art. 53(a), nor the basis on which patentability is denied under that provision, namely that *exploitation* of the *invention* is contrary to morality. It merely specifies that if the invention concerns uses of human embryos for industrial or commercial purposes, then exploitation of that invention is contrary to morality and hence unpatentable under Art. 53(a).

24. This is consistent with the scheme of Art. 6 of the Biotech Directive, on which Rule 23d is based and in accordance with which it should be interpreted. Art. 6.1 says that inventions shall be considered unpatentable where their commercial exploitation would be contrary to morality; Art. 6.2 says that, *on that basis*, uses of human embryos for industrial or commercial purposes shall be considered unpatentable. It is submitted that the scheme of Art. 6 is clear – one cannot have a patent for the use of human embryos for industrial or commercial purposes because the consensus is that the exploitation of that invention would be contrary to morality.

25. Finally, it should be noted that both Art. 5.1 of the Biotech Directive and Rule 23e(1) prevent the patenting of the human body at any stage of its formation and development. Thus patents with claims to human embryos themselves are not permissible. Art. 6.2(c) of the Biotech Directive and Rule 23d(c) complement this by preventing the grant of patents for inventions which concern the *use* of human embryos for industrial or commercial purposes.

Views on patentability of human embryonic stem cells

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patentability".

26. The European Group on Ethics in Science and New Technologies (referred to in recital 44 and Art. 7 of the Biotech Directive) has provided a number of opinions to the European Commission on ethical issues surrounding stem cell research and patenting. Its opinions of 23 November 1998[7] and 14 November 2000[8] contain helpful discussions of the differing attitudes to and legislation regulating embryo research in Member States[9].

27. In its 7 May 2002 opinion "Ethical Aspects of Patenting Inventions Involving Human Stem Cells"[10], the European Group on Ethics in Science and New Technologies (with one dissent – see p.19) expressed the view that there was no ethical barrier to the patenting of inventions "allowing the transformation of unmodified stem cells from human embryonic origin into genetically modified stem cell lines or specific differentiated stem cell lines for specific therapeutic or other uses" – see §2.4. They did, however, emphasise the need to avoid over-broad patents – the claim should refer to a specific and sufficiently accurately described stem cell line and its industrial application – see §2.7.

28. A summary of the history of legislation concerning and attitudes to embryo research in the United Kingdom is annexed to these submissions. As can be seen, the United Kingdom has for some years permitted research on human embryos for the purposes of increasing knowledge about disease and/or enabling such knowledge to be applied in developing treatments for serious disease. The ultimate aim of such research is, of course, the commercial production and supply of therapies for serious disease.

29. In the United Kingdom, the provisions of Art. 6 of the Biotech Directive have been implemented by s.1(3) and Sch. A2, §3 of the Patents Act 1977 as amended[11]. The practice of the United Kingdom Patent Office regarding inventions involving human embryonic stem cells is set out in a Practice Note of April 2003[12]. In summary, its practice is to refuse to grant patents for processes of obtaining stem cells from human embryos (use of human embryos for industrial or commercial processes) or human totipotent cells

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[7] http://ec.europa.eu/european_group_ethics/docs/avis12_en.pdf
[8] http://ec.europa.eu/european_group_ethics/docs/avis15_en.pdf
[9] See also the European Commission survey of July 2004 on national attitudes and legislation relating to human embryo research and use – http://ec.europa.eu/research/biosociety/pdf/mb_states_230804.pdf
[10] http://ec.europa.eu/european_group_ethics/docs/avis16_en.pdf
[11] http://www.patent.gov.uk/patentsact1977.pdf
[12] http:/www.patent.gov.uk/patent/p-decisionmaking/law/p-law-notice-stemcells.htm

(human body at early stage of formation and development) but to grant patents for human embryonic pluripotent stem cells. As to the latter, the Practice Note says:

"although there is some opposition in the United Kingdom to research involving embryonic stem cells, a number of reports from influential UK political, medical and scientific bodies in recent years has emphasised the enormous potential of stem cell research, including embryonic stem cell research, to deliver new treatments for a wide range of serious diseases. This indicates that on balance the commercial exploitation of inventions concerning human embryonic pluripotent stem cells would not be contrary to public policy or morality in the United Kingdom."

It is submitted that this analysis of the position in the United Kingdom is correct.

30. With that introduction, these submissions turn to consider the individual questions referred to the Enlarged Board of Appeal.

Question 1:

Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?

31. Art. 53(a) says that European patents *shall not be granted* in respect of certain inventions. Consistent with this, Rule 23d says that, under Art. 53(a), European patents *shall not be granted* in respect of certain specified biotechnological inventions.

32. As from 1 September 1999, therefore, there has been a rule prohibiting the grant of European patents which are in respect of inventions of one of the specified types. It follows that any patent in respect of such an invention may not be granted after 1 September 1999. Thus, from the date of its introduction, rule 23d has provided a hurdle that must be overcome before any patent for a biotechnological invention can be granted.

33. While expressed differently, it appears that this was the fundamental reason for the conclusion of the Technical Board of Appeal in both T 315/03 and T 272/95 that rule 23d applied to applications pending on 1 September 1999.

34. Accordingly, the United Kingdom submits that the answer to Question 1 is that no patent may be granted after 1 September 1999 in respect of an invention of one of the types specified in Rule 23d.

Question 2:

If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

35. Rule 23d(c) prevents the grant of patents in respect of *inventions* which concern uses of human embryos for industrial or commercial purposes.

36. It is therefore necessary to identify the invention in respect of which the grant of a patent is sought. The invention in respect of which the grant of a patent is sought is, in the United Kingdom's submission, clearly that which is set out in the claims.

37. In the present case, the claims are clearly directed to a class of primate (including human) embryonic stem cells and methods for maintaining and using such cells. The invention is not a human embryo (which would be covered by Rule 23e(1)) nor is it a use of a human embryo for industrial or commercial purposes.

38. The fact that the applicant may have prepared the claimed stem cells using human embryos (and have described that in his application) does not mean that he is seeking the grant of a patent in respect of an invention which concerns the use of human embryos. Similarly, the fact that at the priority date it was necessary for the skilled person to use human embryos to obtain the claimed stem cells does not mean that a patent is sought in respect of an invention which concerns the use of human embryos.

39. It is notable that Arts. 5 & 6 of the Biotech Directive and Rules 23d & 23e(1) together

prevent the granting of patents both in respect of processes for cloning human beings or modifying the germ line genetic identity of human beings and in respect of the human body (whether produced as a result of such processes or otherwise). Further, Art. 6.2(d) and Rule 23d(d) prevent the granting of patents both in respect of processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and in respect of animals resulting from such processes. But Art. 6.2(c) and Rule 23d(c) do not prevent the patenting of the *product* of a use of human embryos for industrial or commercial purposes (unless that product is a human body – see Art. 5.1 and Rule 23e(1)). This difference is conspicuous and significant.

40. As a general principle, the fact that a product was in fact obtained (and may at the priority date be obtainable only) by a process which is not patentable does not make that product unpatentable. For example, a product may be obtained using a method of treatment (e.g. haematopoietic stem cells which need isolation by surgery) but the product itself (if it satisfies the other requirements of the EPC) is patentable. So, in the absence of a specific exclusion, the product of an excluded process is patentable.

41. Also, Rule 23d(c) is directed at the use of human embryos *for industrial or commercial purposes*. Recital 14 of the Biotech Directive indicates that by this expression, the legislator had in mind activities which would be covered by patent protection. This is not so in the present case, as such uses are not claimed. The referring board did not consider this point, merely confining itself to noting that preparation of the claimed stem cells at the filing date necessarily involved the destruction of human embryos.

42. Furthermore, as a general principle exclusions to patentability in this field should be construed narrowly – see e.g. T 320/87 at §6 of the reasons and T 19/90 at §4.5 of the reasons. It is true that the Enlarged Board of Appeal said in G1/04, at §6 of the reasons, that this principle does not apply without exception.

43. Nonetheless, the general principle should apply in this case as well, not least because the specific exceptions of Art. 6.2 were settled upon because they represented the consensus amongst the Member States of the EU, beyond which no consensus existed (see paragraphs

17-20 above). It would be wrong, in the United Kingdom's submission, to interpret these exceptions in such a way that an invention was treated as unpatentable when there was in fact no consensus to that effect. The position is similar to that in G1/04, where differing national laws and practices as to definitions of medical practitioners led the Enlarged Board of Appeal to a narrow construction of the exclusion (see §6.1 of the reasons).

44. Accordingly, the United Kingdom submits that the answer to Question 2 is that Rule 23d(c) does not prevent the patenting of claims directed to embryonic stem cell cultures. This is so even if at the filing date the skilled person could prepare such cultures only by a method which involved the destruction of human embryos.

Question 3:

If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?

45. Art. 53(a) prevents the grant of patents in respect of inventions the exploitation of which would be contrary to morality.

46. As in the case of Rule 23d(c), it is first necessary to identify the invention in respect of which grant of a patent is sought. For the same reasons as those given in relation to Question 2, in the present case the invention is clearly a class of primate (including human) embryonic stem cells and process for maintaining and using such cells.

47. Next, one must decide whether the exploitation of that invention would be contrary to morality.

48. It is submitted, first of all, that there is no reason to believe that the use of the human embryonic stem cells of the claims (e.g. by multiplication and use in research or therapy) would be regarded as contrary to conventionally accepted standards in European society as a whole. There are strands of opinion which regard the use of human embryonic stem cells as immoral because of their origin, but it is submitted that this is not, and has never been, the consensus. Rather, there is a significant strand of opinion which regards such uses as entirely moral because of their immense potential scientific and medical benefits. This is

(as submitted above) the position in the United Kingdom.

49. In cases (unlike the present) where claimed human embryonic stem cells can be made without the use or destruction of embryos, it is submitted that there will be no Art. 53(a) objection to patentability.

50. The reference was only necessary in the present case because of the particular facts, i.e. the fact that the skilled person would have to use spare embryos to make the claimed human embryonic stem cells before he could use them. In the United Kingdom's submission, therefore, the only question is whether the exploitation of the invention can be said to be contrary to morality because of the special facts of the case.

51. It is necessary to consider what "exploitation" means in the context of Art. 53(a). The purpose of Art. 53(a) is to prevent the applicant being given commercial rights in respect of the invention – to prevent the applicant from making money out of doing an immoral act. This indicates that it must be the applicant's exploitation of the invention which must be addressed. It is submitted that the position of a third party skilled person is irrelevant when it comes to consider whether the *exploitation* of the invention would be contrary to morality.

52. Neither the applicant nor any licensee would need to use spare embryos to exploit the invention. On the contrary, they would be able to use the cell culture established by the applicant (as described in the application).

53. If the applicant (or a licensee) wished to work the invention using another cell culture within the claims (perhaps a type of stem cell with additional properties over and above those characterising the claimed stem cells) then it appears that he would have to revert to a spare embryo. But in such a case he would be undertaking research to find such a type of stem cell. He would not be using the embryo for industrial or commercial purposes, but carrying out precursor research activities.

54. Overall, if one asks whether it would be immoral for the applicant to exploit his invention (i.e. the claimed embryonic stem cells) the United Kingdom submits that the answer is no.

It cannot be said that it would generally be regarded as immoral to use the claimed stem cells. The only circumstance in which an issue arises is if the applicant (or his licensee) wishes to prepare further stem cell cultures with additional properties to those of the one already prepared. This would require research using another spare embryo – an activity which also cannot be said to be generally regarded as immoral.

55. In summary, it is submitted that the grant of commercial rights would not allow the applicant to make money out of an immoral act.

56. Accordingly, the United Kingdom would submit that the answer to Question 3 is:

(1) Article 53(a) does not prevent the patenting of claims to human embryonic stem cells where the claimed stem cells can be made by the skilled person without the use or destruction of human embryos.

(2) Article 53(a) does not prevent the patenting of claims to human embryonic stem cells where the applicant or his licensee can make the claimed stem cells without the use of human embryos for industrial or commercial purposes.

Question 4:

In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?

57. For the reasons set out in paragraph 51 above, it is submitted that, in considering whether the exploitation of an invention is contrary to morality, the position of a third party skilled person is irrelevant.

58. It follows that it is irrelevant whether methods are available which would allow the skilled person to make the claimed stem cells without the use and destruction of human embryos.

59. Accordingly, the United Kingdom submits that it is not necessary to answer Question 4.

60. The United Kingdom would confine itself to observing that the answer to Question 4 does not appear to be obvious. There are of course attractions to adopting the approach of the Technical Board of Appeal in T 315/03, at §§8.2 and 9.5-9.7 of the reasons, that the questions arising under Art. 53(a) and Rule 23d(c) must be answered by reference to the position at the priority date, though post-published evidence may be taken into account which is directed to the position at that date. This approach allows a fixed date for assessment unaffected by the time taken for the examination process.

61. On the other hand, it may be unfair to an applicant to try to judge the moral acceptability of his invention as of the priority date. If the applicant is first in a new field, then it may be impossible to judge how acceptable it would have been, at the priority date, for him to exploit his invention. By definition, his invention will not have been published at the priority date and it will be impossible to gauge what reaction the exploitation of his invention would have had at that date. Even if the invention does not open up a new field, an invention may raise ethical questions which have not been considered, fully or perhaps at all, at the priority date. For example, it may be that ethical acceptability of a particular process or product depends on the demonstration of actual or potential scientific or medical benefit. It would be unfortunate if an invention were to be refused protection on the grounds of immorality just because, at the priority date, it had not been possible to demonstrate its benefits.

62. It may be that this approach is envisaged by Art. 53(a) and Rule 23d, which prevent the *grant* of patents whose exploitation would be contrary to morality. This is different from Arts. 52(1), 54 and 56 which are expressly concerned with the state of the art at the priority date and from Art. 83, which is concerned with the contents of the application.

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ANNEX[13]

1. Following the report in 1984 of the Warnock Committee (Report of the Committee of Enquiry into Human Fertilisation and Embryology, Cmnd. 9314), Parliament enacted the Human Fertilisation and Embryology Act 1990 ("the 1990 Act").

2. The 1990 Act[14] created a body called the Human Fertilisation and Embryology Authority ("the HFEA") whose purpose was to regulate and grant licences in respect of embryo research according to the 1990 Act. Section 3 of the 1990 Act prohibited the creation, keeping or use of an embryo except in accordance with a licence. Section 11 and Schedule 2 specified the purposes for which licences could be granted. They were:

   - to promote advances in the treatment of infertility;
   - to increase knowledge about the causes of congenital disease;
   - to increase knowledge about causes of miscarriages;
   - to develop more effective techniques of contraception;
   - to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

3. Following a 1998 public consultation exercise and joint report by the HFEA and the Human Genetics Advisory Commission ("Cloning Issues in Reproduction, Science and Medicine"), the Government established an expert group to undertake an assessment of the benefits of new areas of research using human embryos.

4. The expert group reported in June 2000 ("Stem Cell Research: Medical Progress with Responsibility"[15]). The report considered the scientific and ethical issues concerning stem cell research and reached a number of conclusions and made a number of recommendations – see pp. 9-11 and 44-48.

5. As a result, regulations adding to the purposes for which licences under the 1990 Act could

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[13] Referred to in paragraph 28 of these submissions.
[14] Human Fertilisation and Embryology Act 1990 (c. 37)
[15] http://www.dh.gov.uk/assetRoot/04/01/86/87/04018687.pdf

be granted were proposed by the Government. These changes were supported in a statement from the Royal Society in November 2000[16] - see also the April 2000 paper by the Nuffield Council of Bioethics[17].

6. In January 2001 large majorities on free votes in both Houses of Parliament led to the passing of the Human Fertilisation and Embryology (Research Purposes) Regulations 2001[18]. These Regulations extended the purposes for which a licence could be granted under the 1990 Act to include:

- increasing knowledge about the development of embryos;
- increasing knowledge about serious disease;
- enabling any such knowledge to be applied in developing treatments for serious disease.

7. In 2001 the House of Lords appointed a Select Committee to consider and report on the issues connected with human cloning and stem cell research arising from the 2001 Regulations. The Select Committee reported in January 2002, rejecting claims that the 2001 Regulations were either unnecessary or unethical[19]. More recently, stem cell research has been considered by the House of Commons Science and Technology Committee as part of its review of the 1990 Act[20].

8. In early 2005 the HFEA carried out a survey of public opinion on, inter alia, attitudes to embryo research[21]. 41% of the public regard embryo research as ethical, compared to 34% who regard it as unethical (see p.12).

9. In late 2005 the Government conducted a consultation exercise on possible amendments to the 1990 Act but made it clear that it did not intend to open up those fundamental aspects

[16] "Stem cell research and therapeutic cloning: an update" http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11474
[17] Stem Cell Therapy: the ethical issues http://www.nuffieldbioethics.org/fileLibrary/doc/stem_cell_therapy2.doc
[18] Statutory Instrument 2001 No. 188
[19] House of Lords - Stem Cell Research - Report
[20] House of Commons - Science and Technology - Fifth Report – see §§174-182
[21] Public Attitudes to Fertility Treatment, Embryo Research and the Regulation of this work, July 2005 http://www.hfea.gov.uk/cps/rde/xbcr/SID-3F57D79B-80B03137/hfea/2005-01-07_FINAL_European_Consortium_EACC_public_attitudes_to.pdf

of the legislation which are widely accepted in society or which had recently been debated and conclusively resolved in Parliament, including the use of embryos for research[22].

22 For the report following the review see http://www.peoplescienceandpolicy.com/downloads/DH_consultation.pdf - see §1.6 for the terms of reference.