

FUTURE PATENT POLICY IN EUROPE PUBLIC HEARING 12/07/2006

**Presentation on behalf of CARE
for Europe by David Fieldsend,
Manager, Brussels Office**

‘ETHICAL ASPECTS OF THE PATENTING OF BIOTECHNOLOGICAL INVENTIONS’

0.0 BACKGROUND

- 0.1 Ladies and Gentlemen: Good morning. I represent CARE (Christian Action Research & Education) a registered charity and ethical campaigning association supported by 100,000 individual Christians and churches of all denominations, the greatest concentration of these being in the United Kingdom. Our stance on contemporary bioethical issues is summarised in the Declaration on Human Genetics and other New Technologies in Medicine appended to this Statement as Annexe I.
- 0.2 CARE submitted written evidence and was later called to give oral evidence to the European Parliament’s Temporary Committee on Human Genetics and New Technologies in Medicine. We also gave evidence at the Public Hearing organised by the European Parliament at the commencement of the legislative

process on the Directive on Human Tissues and Cells which has now been adopted as Directive 2004/23/EC. Our evidence statement to that Hearing is appended as Annexe II.

- 0.3 We support the ambition of the European Union to become ‘the most advanced knowledge-based economy in the world’ and recognise that market share in the face of globalised economic competition can only be maintained if research and innovation leading to new products and processes for the benefit of all in society are rewarded by legally enforceable financial contributions from those who come eventually to place these products on the market.
- 0.4 The European Union, as the proposed Constitutional Treaty makes clear, is a Union of values. Decisions on what should be patentable and for how long therefore need to be taken within an ethical framework (particularly taking into account the EU Charter of Fundamental Rights, the European Convention on Human Rights and the Council of Europe Convention on Biomedicine and its Protocols) as made clear on page 3 of the Commission’s consultation document.

1.0 ETHICAL ISSUES

- 1.1 A number of ethical issues are raised by the process of patenting inventions and the influence this has on the speed and character of the implementation and market exploitation of these inventions as well as the willingness of others to carry out subsequent research and innovation with a relationship – whether direct or indirect to the patented invention.
- 1.2 For the benefit of stimulating discussion at the Hearing I have set out these issues by way of normative statements of principle. The justification and reasoning for these is set out in later sections of my written text available on the web site but which there will not be time to rehearse in this oral presentation:-

DISCOVERY

- 1. Patents should only be available for genuine inventions and not for mere discoveries of something pre-existing in nature. No patents on life!**

The first purpose of any patenting system must be to protect the public interest in stimulating innovation and securing scientific progress. The private rights granted to companies and individuals must be proportionate to the achievement of that end. The granting of patents where there is no novelty only serves to hinder future real innovation based on the ‘discovery’.

Where innovation is rewarded by patent rights the approval needs to be carefully crafted so as to only relate to the specific application applied for. Otherwise future alternative applications (which may considerably advance scientific progress) with the same ‘ingredients’ may be inhibited.

2. **Although the prohibition on patenting nature should in principle extend to all life-forms – whether plant, animal or human – it is in the idea of patenting the human body that the strongest ethical objection is raised on the grounds of an assault on the most fundamental of human rights.**

DIGNITY

3. **As stipulated in the EU Charter of Fundamental Rights, the human body and the parts thereof should not be as such the subject of commercial exploitation – and therefore patenting.**

The dignity, integrity and non-ownership of the human body is the most fundamental human rights principle. Great care needs to be taken that this is not compromised by patent grants.

4. **Where patents are granted in relation to subsequent manipulations and processing of human tissues, cells and genes after they have been extracted from the body, they should be carefully limited to the manipulations and processes concerned and not grant the patent holders proprietary rights over the original cells, tissues and genes *per se* .**

Since the mapping of the human genome was completed, the identification of individual gene sequences is a relatively straightforward mathematical exercise. That minimal effort should not be rewarded by granting patents for genes *per se*, as these can be the building blocks for a myriad of subsequent therapies. At present this is being compromised by widely varying interpretations of Art 5.2 of Directive 98/44.

DIAGNOSIS

5. **In the world of biomedicine a clear distinction needs to be drawn between patents for cures (where products compete for targeted sufferers) and patents for diagnosis (which often rely on the accurate identification of a single item in a mass population).**

Although the EPC (Art 52(4)) outlaws the patenting of diagnostic methods, too widely drawn patents on eg. gene sequences are now compromising the development and application of diagnostic method.

DIABOLICAL

Some processes are felt to be so unethical at either the national or international level that legitimising them through the grant of patent is

felt to offend against morality or *ordre publique*. Some of these are specified in Art 6 of Directive 98/44 and the Oviedo Convention.

6. To protect morality and *ordre publique* at least no patents should be granted for:-

- **material taken from human embryos, or for means for the creation of human embryos specifically for the purposes of research including by so-called ‘therapeutic cloning’ by somatic cell nuclear transfer or other means.**
- **Processes of gene therapy with the aim of modifying the inheritable germline genetic identity of human beings.**
- **Processes for modifying the genetic identity of animals likely to cause them suffering without any compensating medical benefit.**

2.0 THE EXISTING AND PROPOSED LEGISLATIVE SITUATION IN EUROPE

- 2.1 There are currently 25 national patent jurisdictions within the European Union and a European patent process under the European Patent Convention which is an independent international process governed by Treaty for which both EU and non-EU Member States are signatories.
- 2.2 The Commission now proposes to supplement and/or replace parts of the current legislative framework with an EU Community patent process which would allow a single application to lead to a patent simultaneously valid in all EU Member States. This would be either in addition to or instead of the current national authorisation processes. A European Patent Litigation Agreement is also currently under discussion which would provide a single European process for the enforcement of patent rights, regardless of the procedure under which these patent rights may have come to be granted.
- 2.3 CARE for Europe does not currently take a view as to which of the three possible patent authorisation processes (national, EPC or EU Community) or any combination of any two of them is to be preferred. However, what we do strongly advocate is a single set of rules as to what is and is not patentable to apply preferably across Europe as a whole, but at least to all EU Member State and EPC signatories. In our view the best basis for this is EC Directive 98/44 which is currently supposed to apply to both EU Member State and EPC decisions. However, we are unhappy with the inconsistent way this is currently being interpreted in both national legislation and EPC case law and would therefore like to advocate (as called for in a number of European Parliament resolutions) a review of the working of the Directive with a view to its possible amendment to clarify the situation.

3.0 EXPLANATION FOR ETHICAL PRINCIPLES

3.1 THE IMPORTANCE OF LIMITING PATENTS TO REAL INVENTIONS ONLY AND WHEREVER POSSIBLE ISSUING PATENTS ON A PURPOSE-BOUND BASIS

- 3.1.1 Traditional patent law has respected the need to have the combination of novelty (or non-obviousness), an innovative step and an industrial application of that step before a patent can be granted. Practice in the USA in recent decades has departed from this principle with very unfortunate consequences for both the progress of science and public health. *Inter alia*, this includes the fact that some 20% of the 23,688 human genes are already covered by a US patent¹.
- 3.1.2 The enshrining of this provision in the European Patent Convention² is very much to be welcomed and it is of the utmost importance that any future EU Community Patent process incorporates the same provisions.

3.2 THE NECESSITY TO PROTECT THE DIGNITY, INTEGRITY & NON-OWNERSHIP OF THE HUMAN BODY

- 3.2.1 The right of the human individual to autonomy and integrity of the person is axiomatic to the contemporary human rights consensus.
- 3.2.2 The difficulty in interpreting this right as it applies to biotechnology is in making a correct differentiation between the human body and its many parts and processes *in their natural state* and medical and therapeutic techniques which involve interventions on human tissue and cell material *outside of the body* such that the resulting material used to treat patients is clearly qualitatively different from the original source material. The allowance in Art 5.2 of Directive 98/44 for an element isolated from the human body to be patentable '*even if the structure of that element is identical to that of the natural element*' is not helpful in this regard.
- 3.2.3 Both Germany and France have now enacted legislation transposing the provisions of Directive 98/44 which treat human genes differently from other chemical substances on ethical grounds and limited patent availability to 'purpose-bound' protection of particular applications rather than the gene sequences *per se*. In its 2005 Report under Art 16c of the Directive³ the Commission refrained from taking a position on the differences in national transpositions of the Directive on this point as between purpose-bound patent

¹ *Does legal ownership of genes, stem cells and other biological material go beyond the pale?* San Diego Union Tribune 20th April 2006

² Article 52, Convention on the Grant of European Patents (European Patent Convention), 12th Edition. Published by the European Patent Office April 2006.

³ COM(2005) 312 final, section 2.1

protection and classical open-ended protection for a gene sequence. This fence-sitting is much to be regretted.

3.3 THE RESTRICTION OF BIOMEDICAL PATENTS TO CURES RATHER THAN DIAGNOSIS

- 3.3.1 Article 52(4) of the European Patent Convention stipulates that '*Diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible to of industrial application*'. However, subsequent interpretations of this through case law at the Technical Board of Appeal have attributed widely different scopes to this exception.
- 3.3.2 At issue is whether a procedure is only a diagnostic method for the purposes of this Article if it is carried out by a doctor in the presence of, and involving physical contact with, the patient and leading to an immediate diagnosis at one extreme or whether methods of screening which do not involve physical contact (eg. x-rays) or rely on subsequent lab tests to confirm diagnosis (eg. blood test) or are carried out by a non-medical technician are also included⁴. An opinion of the Enlarged Board of Appeal in December 2005⁵ has now gone a long way towards clarifying the interpretation of Article 52(4) in the direction of a generally wider scope of exclusion. But some grey areas nevertheless remain.
- 3.3.3 But these problems pale into insignificance when compared to the problems for the development and implementation of diagnostic methods caused by patents for gene sequences which are too loosely drawn. Two outstanding examples of this relate to the identification of genetic defects which give a predisposition to the development of breast and ovarian cancer in women – the so-called BRCA1 and BRCA2 sequences and the genes and proteins of the AIDS (HIV) pathogen.
- 3.3.4 In the case of BRCA1 & 2 a US company, Myriad Genetics of Salt Lake City, Utah initially claimed proprietary rights to all versions of both genetic mutations and to tests to identify their presence worldwide and filed for and received various EPO patents to this effect between 2001 and 2003. Hospitals would not be able to carry out such tests in their own laboratories but would have to send off all samples to the US for testing, thus considerably slowing down the process of diagnosis⁶.
- 3.3.5 In the event objections lodged against these patent grants were successful in revoking most, but not all, of them with Myriad retaining exclusive rights to testing for a particular variant of BRCA2 only found in Ashkenazi-Jewish women⁶.

⁴ Ricker, M. *The Exclusion of diagnostic methods from patentability by the EPC: a case for review?* *Nature Biotechnology* 22(9):1167-1168 September 2004

⁵ G 0001/04 (OJ EPO December 2005)

⁶ Van Ommen, G. *Geneticists oppose singling out Jewish women in European breast cancer patent* European Society of Human Genetics, 15 June 2005

- 3.3.6 In the case of the genes and proteins of the AIDS(HIV) pathogen a European patent was first issued in 1993 (Patent EP 181 150) and after lengthy litigation re-issued in a modified form in 2003 to the Chiron company, but who had in the meantime agreed to share the patent rights with a number of European countries, in exchange for substantial payments. Amongst the reasons of objection brought forward by litigants was a threatened 3000% increase in the cost of analyzing blood samples for the German Red Cross⁷.
- 3.3.7 All of this could have been avoided if a clear prohibition on the patenting of gene sequences *per se*, as opposed to specific industrial applications making use of them, was understood to be enshrined in European law and observed by all.

3.4 THE NEED TO RESPECT ETHICAL SENSITIVITIES AND ‘ORDRE PUBLICUE’

- 3.4.1 All societies have an irreducible minimum of activities which are considered to be ‘beyond the pale’ by a broad consensus. These are likely to be specifically outlawed by custom and practice and provisions in either criminal or constitutional law.
- 3.4.2 In the case of European society the various national prohibitions are backed up by European ethical instruments, the most widely known being the EU Charter of Fundamental Rights and the Council of Europe Convention on Human Rights and the various associated documents including, most relevantly in this case, the Convention on Human Rights and Biomedicine (commonly known as ‘the Oviedo Convention’) and its various associated Protocols.
- 3.4.3 Based on these documents and national jurisprudence Directive 98/44 lists at Article 6(2) the following as being unpatentable:
- (a) *processes for cloning human beings*
 - (b) *processes for modifying the germ line genetic identity of human beings*
 - (c) *uses of human embryos for industrial or commercial purposes*
- 3.4.4 Some patents at least initially granted by the EPO (most notably the infamous ‘Edinburgh Patent’ (Patent EP 0 695 351)⁸) seemed to clearly contradict this provision. This patent issued in 1999 provided for the ‘*isolation, selection and propagation*’ of stem cells without distinguishing between those of a human and animal origin. Following opposition it was subsequently amended to exclude any application to human cells.
- 3.4.5 The most controversy has probably surrounded indent (c) on uses of human embryos. As the extraction of embryonic stem cells is definitely a ‘use of the embryo’, moreover one that inevitably entails the destruction of the embryo concerned, an argument can be advanced that the resulting embryonic stem cell lines should not be patentable. However, at the present time the Commission

⁷ *The True Cost of Gene Patents: The Economic and social consequences of patenting genes and living organisms* A Greenpeace Documentation. March 2004

⁸ COM(2002) 545 final, section 5.2.1.2

line, backed up by the European Group on Ethics (EGE) appears to be that only totipotent cells (because they retain full human potential) should be excluded from patentability and merely pluripotent stem cells (regardless of source) should be patentable, but only for specific industrial applications⁹.

3.4.6 Although not yet put to the test in the absence of any available therapies based on human embryonic stem cells, this aspect of ethical provision could usefully be clarified, not least because for a number of European states the use of material which requires the destruction of human embryos is a recognised offence against *ordre publique* and morality.

SUPPORTING INFORMATION

References

Convention on the Grant of European Patents (European Patent Convention), 12th Edition. Published by the European Patent Office April 2006

Convention on Human Rights and Biomedicine, Council of Europe, 4 April 1997

LaFee, S. *Does legal ownership of genes, stem cells and other biological material go beyond the pale?* San Diego Union Tribune 20th April 2006

Ricker, M. *The Exclusion of diagnostic methods from patentability by the EPC: a case for review?* Nature Biotechnology 22(9):1167-1168 September 2004

Van Ommen, G. *Geneticists oppose singling out Jewish women in European breast cancer patent* European Society of Human Genetics, 15 June 2005

Then, C. *The True Cost of Gene Patents: The Economic and social consequences of patenting genes and living organisms* Greenpeace Documentation, March 2004

European Community Documents

Directive 2004/23/EC
COM(2005) 312 final
COM(2002) 545 final

© CARE (Christian Action Research and Education) for Europe AISBL 2006
57 rue Archimède, B-1000 Brussels, Belgium.
Tel: +32 2 732 1147. Fax: +32 2 732 1228. E-mail: info@careforeurope.org

⁹ COM(2005) 312 final

ANNEXE I

DECLARATION ON HUMAN GENETICS AND OTHER NEW TECHNOLOGIES IN MEDICINE

We, the undersigned, acknowledge that scientific and technological progress has the potential to positively transform the health and wealth of our society. This cannot happen if this progress does not protect and promote human dignity; the right to life; the fundamental uniqueness and equality of every human being from the moment of conception to natural death; the special responsibilities of parents and families; and the promotion of individual and common good.

Despite the common contemporary perception of ethical pluralism that refuses to accept the existence of commonly shared European ethical principles, we hold that the tragic events of September 11, has demonstrated that there is universal agreement on the evil nature of some human acts (terrorism). Furthermore, that it is universally valid and 'reasonable' to pursue the moral 'good' of global peace. Thus, regardless of cultural or religious context, it is possible to construct a system of ethical principles that we can all share. Indeed, we affirm the fact that respect for human dignity is at the heart of every International and European legal Instrument upholding fundamental rights and is the foundation of every European constitution.

Respect for Human Dignity in the field of Biomedical research requires universal acceptance of the principle that Science must serve Humanity rather than Humanity serving Science. There is a particular need to protect vulnerable, handicapped, or unborn members of the Human Family. Human life, in whatever form, whatever its appearance or capacity, has inherent and indisputable dignity. Basic biological principles irrefutably show that from the moment of conception or creation the embryo inside or outside the womb is a unique human being with a unique genetic code. Even the creation of twins during the first days of life does not deny the individual character of these new human beings. The period of gestation of the Embryo requires no fundamental alterations or changes to the genetic pattern established at fertilisation. This fact alone seriously undermines the assertion that the embryo is merely a "potential human being" or the attempted distinction between "human beings" and "human persons".

On research on human embryos and stem cells

The creation of human embryos for research purposes, the production of hybrids or chimeras and any commercial exploitation of human embryos must be forbidden.

To allow research that involves the destruction of human embryos, and therefore research on human embryonic stem cells, would undermine the foundations of democratic societies, not least because it represents a form of instrumentalisation of some human beings for the sake of other human beings. This kind of research is therefore against human dignity and fundamental human rights and must be outlawed by civilised societies. Experimentation on the human embryo must only be permitted in individual cases where the aim is to protect the life and health of a specific embryo. Biomedical solutions in the field of human stem cell research must only be permitted with techniques using adult stem cells and the re-programming adult cells, more efficient than techniques using embryonic stem cells.

On human genetic testing and interventions

Any intentional pursuit of research activity intended to modify the genetic heritage of human beings which could make such changes hereditary must be forbidden.

Pre- and post-natal genetic testing should only be permitted if it is demonstrated there is a reasonable proportionality between the risks involved for the embryo by the sampling technique and any the potential therapeutic benefits. Professional genetic counselling must always be provided. Patients and their families are entitled to professional, humane, and life-protecting guidance that supports them in their decision-making. Eugenic pressure on parents not to accept a child with a handicap should be outlawed.

On human cloning

When human dignity is at stake in a civilised society, the ends can never justify the means.

Human cloning, regardless of its purpose and method, is ethically unacceptable and should be legally prohibited. Every clone created necessarily involves a violation of fundamental human rights and the human dignity that society must protect. We wholeheartedly commend the existing European and International agreements banning human cloning that have recognised the dangers of eugenics that we now face and urge European citizens of good will to stand together with us for the sake of future generations.

ANNEXE II



PROPOSED EU HUMAN TISSUES DIRECTIVE PUBLIC HEARING 29/01/03

Evidence Statement on behalf of CARE for Europe by David Fieldsend, Office Manager, Brussels

BACKGROUND

Ladies and Gentlemen: Good afternoon. I represent CARE (Christian Action Research & Education) a registered charity and ethical campaigning association supported by 100,000 individual Christians and churches of all denominations, the greatest concentration of these being in the United Kingdom. Our stance on contemporary bioethical issues is summarised in the Declaration on Human Genetics and other New Technologies in Medicine appended to this Statement.

We support the ambition of the European Union to introduce regulation in this sensitive area and are appreciative of the many benefits that flow from the availability

of donated human tissues and cells. We are satisfied that the proposed quality controls to protect the health and safety of the recipients of donated material are likely to be both ethical and effective. However, we have a number of concerns in relation to the proposed regime governing the interests of donors.

ETHICAL ISSUES

These issues are dealt with in Chapter III entitled ‘Donor Selection and Evaluation’ which will therefore be the focus of attention in this Statement.

To put the underlying ethical dilemma related to this process at its starkest we are dealing here with the ‘cannibalisation’ of one human individual to provide ‘spare parts’ which will improve the life chances, or even be essential to the survival of another human individual or individuals.

The EGE report felt that the only ethical justification there could be for this process was that of a ‘*voluntary act of solidarity*’ (para 7 of Explanatory Memorandum). We agree with that concept and consider that it is only fulfilled when the following **six** criteria are respected with regard to the position of the donor:-

- 1. The donation is basically an act of altruism and not primarily motivated by financial gain. AND The ‘voluntary’ nature of the donation is not undermined by the offer of a disproportionate financial inducement such that those in financially vulnerable circumstances will feel strong economic pressure to donate.**

This also affects the position of the recipient. Where ‘donation’ is elicited by excess economic pressure there will be a temptation for ‘donors’ not to make a full and frank disclosure of their medical history in order to gain the financial inducement. Adverse public health consequences inevitably follow.

- 2. This ‘altruism’ on the part of the donor is not compromised by the possibility of donated material later becoming a basis for commercial gain by others.(1)**

Unfortunately the high sounding language of Recitals 12 and 13 is not borne out in the proposed legislation at Articles 12 and 13. The mere ‘take fully into account the principles of’ in relation to the Convention on Human Rights and Biomedicine is too weak (2) and the ‘shall encourage’ wording in Article 12 is not an effective requirement at all (3). Only a binding legislative requirement can prevent high standards in this area being undermined by the ‘lowest common denominator’ Member State provision becoming effectively adopted through litigation at the European Court of Justice where single market considerations will take priority over unenforceable statements of principle.

- 3. The donor’s altruism is informed by full disclosure to them of the risks and benefits of the necessary procedures for procuring the material to be donated and transferring it to the recipient/s.**

The information requirements at Annex III are the bare minimum and do not really form a satisfactory basis for Europe-wide safeguards. Something like the code for

'Advance Directives' contained in the recently considered United Kingdom Mental Incapacity Bill would be more effective.

- 4. The 'voluntary' nature of the donation is not undermined by the potential donor being in an emotionally, psychologically or otherwise vulnerable state. eg. elderly, handicapped, couples seeking fertility treatment etc.**

An age bar of 60 years should be considered to prevent pressure on elderly individuals to consent to an Advance Directive or tissue donation.

- 5. The 'voluntary' nature of donation is not undermined by authorising the use of material from pre-birth human individuals who are not capable of granting consent in any meaningful sense.**

Article 3/c states that the term '*donor*' for the purposes of this Directive includes '*non-natus*' sources of human cells or tissue. Such sources could not possibly comply with the principle of voluntary solidarity.

- 6. The 'altruistic' nature of the donation is safeguarded by the identity of both donor and recipient being mutually anonymous – with the exception of gamete donation for the reasons outlined below.**

We believe that it is right that an exception to the general rule of donor anonymity should be made in the case of the donation of gametes (sperm and ova) for artificial reproduction. In a number of Member States adopted children now have the right to discover the identity of their biological parents once they reach maturity. It is considered to be such an indispensable part of the knowledge of 'who they are' that it should not be denied to them. Studies have backed up the need for this by documenting adverse psychological consequences from the denial of this right. We do not consider that there is any sound argument for not extending this right to children conceived by artificial reproduction methods. Concerns that have been expressed about the possible adverse effect on the level of donations of the removal of donor anonymity have not been born out in practice in those jurisdictions where the right of artificially conceived children to know the identity of their biological parents has been granted. (4)

Where the donor is deceased or incapacitated we would expect these same criteria to be safeguarded in relation to responsible next of kin on the basis of their intimate knowledge of the donor's intentions and outlook before they became incapacitated. However, we do not accept that there can be responsible next of kin in relation to embryos/foetuses who have not had the chance to communicate their wishes/intentions. We would also support an extension of these donor protection requirements to tissues taken for research purposes.

CONCLUSIONS

The Directive in its present form is not even handed as between the interests of donors and the interests of recipients of human tissues. Binding legislation is proposed to protect the interests of recipients by way of quality control of the testing, processing

and storage of donated materials. However, the promotion of ethical standards for the donation process to implement the high sounding principles contained in the Recitals – specifically that donation should be purely voluntary, based on well informed consent and linked to the reassurance for the donor that donated materials will not subsequently be used as a vehicle for commercial gain – is left entirely to the discretion of Member States’ who are merely ‘encouraged’ to bear these principles in mind when forming their own legislation.

We strongly advocate a correction of this imbalance by making the interests of both parties the subject of binding community legislation. Not forgetting that these interests are, in any case, related as quality control will be compromised if and inappropriate level of financial inducements is offered to secure ‘donations’.

SUPPORTING INFORMATION

References

- (1) See ‘Moore v Regents of the University of California (in *Legislating for the New Predictive Genetics*, Galton and O’Donovan, Human Reproduction and Genetic Ethics, vol.6, no.2, 2000) where it was ruled that *‘failure to inform a patient that a cell line from his spleen had been developed into a pharmaceutical product and patented, was a breach of fiduciary duty affecting the patient’s consent, or alternatively that there had been no consent.’*
- (2) The phrase *‘taking into account the principles of’* is a meaningless expression in legal terms. In **Ishak v Thowfeek** ([1968] 1 WLR 1718, PC) before the United Kingdom Privy Council it was held that one could take a principle into account and then promptly ignore it – but it had still been technically taken into account for legal purposes.
- (3) If the Directive fails to introduce binding Community legislation on this matter it is likely, on the basis of precedent, to be ultimately decided by the European Court of Justice in the context of intra-Community trade. (see Advocate General Van Gerven in Case C-159/90 SPUC v Grogan [1991] ECR 53 at paragraph 31.)

The EGE report refers to *‘the need to regulate the conditions under which human tissues circulate within the European market’*. There is a single market. That market will not indefinitely tolerate the distortion generated by differential national procurement regimes. This particularly becomes the case if there is (as seems likely without community regulation) a widening divergence of treatment of ‘commercial’ considerations. Will donors in Member States sticking to a strict interpretation of voluntarism (or the Member State authorities acting on their behalf) be able to be confident that their donation will not become a means of commercial gain further down the line in a different Member State with a more liberal interpretation? Wouldn’t any export prohibition on this basis be seen as a barrier to trade? When importation of material from third countries is concerned there is supposed to be

monitoring in place to ensure that procurement methods in that third country are up to European standards – but whose European standards? Likely those of the lowest common denominator, ie, the Member State with the most liberal interpretation of these provisions.

(4) In Sweden the numbers of gamete donors dropped back following the introduction of legislation removing donor anonymity BUT they then began to pick up again and that trend has gradually reversed. *‘Evidence from Sweden and New Zealand indicates that not only can reports of a decline be exaggerated, but it is also possible for service providers to maintain viable DI services using only identifiable donors’* (*Sharing Genetic Origins Information in Third Party Assisted Conception: A Case for Victorian Family Values?* Blyth, Children and Society, vol. 14, no. 1, 2000). Similar legislation has also been passed in Austria and Victoria (Australia). In the latter case the legislation also allows the donor to obtain non-identifying information about the offspring.



© CARE (Christian Action Research and Education) for Europe AISBL 2002
57 rue Archimède, B-1000 Brussels, Belgium.
Tel: +32 2 732 1147. Fax: +32 2 732 1228. E-mail: info@careforeurope.org