

PART IV. ROUTES FOR REFLECTION

Part III carefully examined the patent law framework for inventions relating to human stem cell research and offered an overview of the many and varied questions the patentability of human stem cells entails. Part III also offered some touchstones, which can offer some guidance in this delicate matter.

If the European Group on Ethics reaches the conclusion that patent law should exclude human stem cells from patent protection, alternative IPR systems to guarantee exclusivity for the inventions resulting from human stem cell research can be examined (Chapter 1).

Should the European Group on Ethics decide that inventions relating to human stem cells are patentable in principle, various scenarios can be envisaged to accommodate current patent law to some delicate issues arising from patenting material from human origin and to meet various objections and public concerns relating to the patenting of human stem cells (Chapter 2).

CHAPTER 1. LOOKING FOR ALTERNATIVE IPR SYSTEMS

It appears that the EU legislator promotes exclusivity on biotechnological inventions by way of patents. Another way to retain exclusivity on the results of biotechnological research is to maintain the development as a trade secret. A trade secret may consist of a formula for a chemical compound, a process of manufacturing, a pattern for a machine or other device. The trade secret is any knowledge which is not generally known to those in the same business and which provides a competitive advantage to the owner of the trade secret over his competitors²⁷⁷.

From an inventor's point of view, the protection by way of trade secrets indisputably has several assets. First, trade secret protection is not limited as to subject matter: no limitations whatsoever exists on the type of development that can constitute a trade secret. Secondly, no substantive requirements are to be met: a trade secret does not have to rise to a level of novelty or inventiveness. Thirdly, there are no formal requirements to be fulfilled to obtain a trade secret: the rights arising under a trade secret come into existence upon its conception. Finally, there is no time limit on trade secret protection: trade secret protection can theoretically last indefinitely²⁷⁸. Trade secret protection has one main disadvantage. If the trade secret becomes known to the public, by independent development by a third party or by unauthorised disclosure, the exclusivity a trade secret provides no longer exists²⁷⁹.

From a public interest point of view the protection by way of trade secrets appears not to be favourable. A patent confers on its proprietor the exclusive right to stop others from using/making his invention without his permission within a particular territory

²⁷⁷ VAN OVERWALLE, G., *The Legal Protection of Biotechnological Inventions in Europe and in the United States*, Leuven, Universitaire Pers, 1996.

²⁷⁸ A classic example of a trade secret is the Cola-Cola formulation, which has been maintained a trade secret and which has provided the Coca-Cola Company with exclusivity for almost 100 years.

²⁷⁹ VAN OVERWALLE, G., *The Legal Protection of Biotechnological Inventions in Europe and in the United States*, Leuven, Universitaire Pers, 1996.

and for a given period (usually 20 years). The essence of all patent systems is that the owner of the invention receives the exclusive right to control commercial exploitation of the invention for a limited number of years, in return for disclosing details of the invention in a written published document²⁸⁰.

This explains why various people, although reluctant to the patent system to obtain exclusivity for new biotechnological developments, might nevertheless prefer the patent system to the trade secret system.

CHAPTER 2. CONFIRMING THE PATENTABILITY OF HUMAN STEM CELLS, BUT NOT UNCONDITIONALLY

Starting from the assumption that human stem cells are patentable, there might be some manoeuvring room left, however, to accommodate patent law to some delicate issues arising from patenting material from human origin and to meet various objections and public concerns relating to the patenting of human material.

This can be achieved in a number of ways. Firstly, by introducing additional *requirements* for the grant of a patent, for example through the incorporation of an informed consent requirement. Secondly, by restricting the *scope* of a patent, through the promotion of restricted claiming. Thirdly, by tempering the *effects* of granted patent, through the introduction of responsible governance of patent rights.

A. Adding new patent requirements. The informed consent issue

1. Incorporation in patent law

a. Key issue

Article 5 of the 1996 Convention on Human Rights and Biomedicine²⁸¹ stipulates that “an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time”. Article 22 adds that “When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures”.

In attempt to accommodate current patent law to principle laid down in articles 5 and 22 of the Convention on Human Rights and Biomedicine, the EU Biotechnology Directive introduced recital 26, which stipulates that “Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law”.

²⁸⁰ Ibidem.

²⁸¹ Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine* (Convention on Human Rights and Biomedicine), Oviedo, 4 April 1997. (See <http://conventions.coe.int/treaty/en/treaties/html/164.htm>).

In legal doctrine opinions diverge as to the question of whether or not recitals are legally binding. A first school of thought claims that recitals are *not* legally binding on national authorities, unless they are reproduced as articles²⁸². Following this school of thought, one might argue that since the informed consent recital is not duplicated as an article, there is no legitimate reason for national authorities to give effect to this condition. A second school of thought takes the view that recitals *are* legally binding on national authorities, unless there are valid overriding considerations recognised by EC law for not implementing them²⁸³. In view of the differing opinions in legal doctrine, we turn to the pre- and post- Directive history of this recital to gain some additional insight.

b. Guiding elements

On September 25 1996 the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) stated in Opinion n° 8 that “when inventions are based on elements of human origin, [they] involve the issue of fundamental rights of the human person”²⁸⁴. The GAEIB specified that the collection or sampling of elements from a human being relies on the consent, co-operation and generosity of the person collaborating in the research. The GAEIB underlined that this “raises ethical questions concerning the information provided to the donor, his/her consent concerning the future use of the elements - whether it is used for research or commercial purposes - and the compensation he/she may claim”²⁸⁵. “The ethical principle of informed and free consent of the person from whom retrievals are performed, must be respected. This principle includes that the information of this person is complete and specific, in particular on the potential patent application on the invention, which could be made from the use of this element. An invention based on the use of elements of human origin, having been retrieved without respecting the principle of consent will not fulfil the ethical requirements”²⁸⁶. Thus, according to the GAEIB (1) complete and specific information on the potential patent application has to be provided to the donor and (2) the donor should have had the opportunity to give his consent with the envisaged purposes. The GAEIB, however, did not decide whether the informed consent requirement should be accommodated in patent law or whether this principle should be cured in other laws.

In the line of the GAEIB opinion, the European Parliament proposed a new article 8 bis containing requirements concerning an invention which consists of biological material of plant or animal origin or human origin (amendment 76) in the course of 1997²⁸⁷. The Commission did not accept that amendment in its amended proposal. With regard to the requisites relating to inventions based on elements from human origin – more in particular the introduction of an informed consent

²⁸² European Court of Justice, Case C-162/97, November 19 1998 (*Gunnar Nilsson, Per Olav Hagelgren, Solweig Arrborn, Agriculture*), paragraph 54 of the judgement. Also see the references cited in BEYLEVELD, D., ‘Why Recital 26 of the E.C. Directive on the Legal Protection of Biotechnological Inventions Should be Implemented in National Law’, *Intellectual Property Quarterly (I.P.Q.)*, 2000, (2), 6-9.

²⁸³ This is the position taken by D. BEYLEVELD in the aforementioned article.

²⁸⁴ GAEIB, Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, September 25 1996 (Opinion n° 8), point 1.6.

²⁸⁵ Opinion n° 8, point 1.7.

²⁸⁶ Opinion n° 8, point 2.4.

²⁸⁷ *Official Journal EC – C* - 22 September 1997, 286/(87), 99-100.

requirement - the Commission said that such a requirement did not comply with the requirements on the protection of personal data^{288 289}.

The Council shared the Commission's misgivings about this amendment and further pointed out that the patents offices would not be able to verify that foreign legislation that the agreement of the person concerned had been given and that therefore the requirements contained in the amendment could not be conditions for patentability²⁹⁰.

However, the Council incorporated some important features of the amendment in recital 26 of its Common Position. Recital 26 states the principles whereby the person from whose body material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law, although the lack of such agreement could not affect the patentability of the invention in question²⁹¹.

The objections which were put forward by the Commission and the Council are twofold: the first objection relates to the non-compliance with legislation on personal data protection, the second objection refers to the impracticability of the requirement.

In the action for annulment of the Directive launched on October 19 1998 before the Court of Justice, the Netherlands submitted that the absence of a provision requiring verification of the consent of the donor or recipient of products obtained by biotechnological means undermines the right to self-determination²⁹². This objection concerns the right to human integrity, in so far as it encompasses, in the context of medicine and biology, the free and informed consent of the donor and recipient.

The Court stated in its judgement of October 9 2001 that reliance on this fundamental right is clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products. The Court underlined that the grant of a patent does not preclude legal limitations or prohibitions applying to research into patentable products or the exploitation of patented products, as the recital 14 of the preamble to the Directive points out. The purpose of the Directive is not to replace the restrictive provisions, which guarantee, outside the scope of the Directive, compliance with certain ethical rules, which include the right to self-determination by informed consent. The Court decided that this plea, therefore, had to be rejected²⁹³.

If we understand this ruling correctly, the Court does not put a veto on an informed consent requirement concerning patent purposes. The Court only opposes the incorporation of such a requirement *in* patent law, the Court has taken the view that the introduction of an informed consent principle in patent law is inappropriate. It

²⁸⁸ Directive No 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, *Official Journal EC - L* - 23 February 1995, 281.

²⁸⁹ *Official Journal EC - C* - 11 October 1997, 311/12.

²⁹⁰ Common Position (EC) n° 19/98 adopted by the Council on 26 February 1998 with a view to adopting Directive 98/.../EC of the European Parliament and of the Council on the legal protection of biotechnological inventions (98/110/02), *Official Journal EC - C* - 8 April 1998, 110/(17), 29, point 25.

²⁹¹ *Official Journal EC - C* - 8 April 1998, 110/(17), 29, point 26.

²⁹² Fifth plea in law, second part of the action brought on 19 October 1998 by Kingdom of the Netherlands against European Parliament and Council of the European Union (Case C-377/98) (98/C 378/23), *Official Journal EC - C* - 5 December 1998, 378/13. Also see Judgement of the Court of Justice, 9 October 2001, Case C-377/98, Kingdom of the Netherlands, supported by Italian Republic and by Kingdom of Norway v. European Parliament and Council of the European Union, supported by Commission of the European Communities (See <http://www.curia.eu.int>).

²⁹³ See Court of Justice, 9 October 2001, points 79 to 81.

appears, however, that the Court did not turn down the possible introduction and subsequent enforcement of an informed consent requirement concerning patent purposes in a law *outside* patent law. In this respect, one can think of national or Community legislation *before* patent grant, e.g. legislation on research or patient rights. One can also think of legislation *after* patent grant, e.g. legislation concerning health or consumer protection. It thus appears that the Court's decision does not run counter to GAEIB Opinion n°8, since the Court does not seem to oppose an informed consent principle as such, but is only set against the incorporation of such a principle in patent law, whereas the GAEIB, favouring the introduction of an informed consent principle, did not specify in which legislative framework this ethical principle had to be implemented.

The judgement of the Court of Justice does not give a clear-cut answer with regard to the current legal disagreement on the binding effect of recitals. However, one can imagine the ruling starts from the unsaid underlying assumption that recital 26 is binding.

The EGE has underlined that one of the fundamental ethical principles in the debate on human stem cell research is the principle of individual autonomy and has emphasised that this principle entails the giving of informed consent and the respect for privacy and confidentiality of personal data²⁹⁴. In view of the latest ruling of the Court of Justice, it appears that one should no longer reflect on the need for an explicit introduction of a prior and free informed consent into patent law. Unless the EGE takes the view that there are some compelling and weighty reasons, which can justify a dissenting approach in the case of human stem cells, the EGE should probably reconcile oneself to the judgement. Further investigation should be carried out on other possible ways, outside patent law, to accommodate an informed consent requirement concerning patent purposes. In doing so, a look might also be casted on the practical consequences of the incorporation of such a requirement would entail, among other things the consistency with the principle of anonymous donation²⁹⁵.

2. Implementation through a voluntary code of conduct

a. Key concept

Ethical concerns regarding the patenting of inventions based on biological material of human origin or using such material, can be taken care of *within* patent law or can be cured in other laws by introducing a supplementary provision, prescribing that the person from whose body the material is taken must have had an opportunity of expressing free and informed consent to possible patenting. Such a provision can be issued by a government and carries an obligation to comply. Non-compliance may result in a regulatory penalty. It might be argued in this respect, that the informed consent requirement is issued by the EU²⁹⁶ and/or by a national government²⁹⁷ and

²⁹⁴ EGE, 2000, p. 14, paragraph 2.2 and p. 17, paragraph 2.10.

²⁹⁵ Cf. EGE, Opinion n° 11, Ethical Issues of Human Tissue Banking, 21 July 1998 (Also see http://europa.eu.int/comm/european_group_ethics/docs/avis11_en.pdf).

²⁹⁶ See, however, the discussion concerning the binding effect of recitals (Supra).

²⁹⁷ E.g. Belgium who intends to incorporate an informed consent requirement as a new article in its current patent act of 1984. See VAN OVERWALLE, G. 'The Legal Protection of Biological

that non compliance, in casu the non-existence of an informed consent, results in the nullity of the patent involved.

Ethical concerns relating to the patenting of inventions based on biological material of human origin or using such material might, however, can also be addressed *outside* law, by way of 'standards'. A voluntary code of conduct is a standard that sets forth principles to guide a company's performance. Although a 'standard' sets forth rules or guidelines, compliance is not mandatory. One of the aims of a code often is to protect the public image of a company, large corporations often aim at convincing consumers they act morally. Hence, the penalty for nonconformity with a standard comes from the marketplace or the public and the threat of bad publicity²⁹⁸.

These days, the issue of informed consent has become a matter of great public concern. Yet, if the (national) government's hands are tied or political consensus is hard to achieve, private sector standards are an option. If it appears undesirable to implement the informed consent requirement through legal action, the establishment of informed consent concerning patent matters through voluntary codes of conduct might be considered.

b. Elements of the code

Various types of codes of conduct have been listed. One type is a company code, where an individual company or enterprise desires to make the public aware of its good deeds or intentions and to protect the self- or public image of a company. Another type is the trade association code, which is adopted by a group of firms or an association of firms. A third type is the multistakeholder code, which brings together firms, industry, NGO's and/or trade unions. A last type is the intergovernmental code²⁹⁹.

A voluntary code of conduct shares a core set of elements: a set of non-legislatively required elements; agreed to by one or more individuals or organisations; designed to influence, shape, control or benchmark behaviour; to be applied in a consistent manner and/or reach a consistence outcome by all participants³⁰⁰.

A voluntary code dealing with human genetics and patenting, can include the following elements. Firstly, a code can contain guidelines with regard to informed consent, access to medical records and privacy and protection of medical data. With regard to informed consent and patents, the code can explain that the research carried out on biological material from human origin may possibly lead to new applications, for which patents will be filed. The code can further make clear that whenever a patent application is taken into consideration for an invention based on the use of

Material in Belgium', *International Review of Industrial Property and Copyright Law*, 2000, (259), 282.

²⁹⁸ ECHOLS, M., 'Solutions in Terms of Self-Regulation or Self-Imposed Moral Codes of Business Corporations', Paper submitted at the Invitational Conference 'The WTO and Concerns Regarding Animals and Nature', Tilburg, Netherlands, 17 December 2001.

²⁹⁹ U.N. Research Institute for Social Development (Rhys Jenkins), *Corporate Codes of Conduct: Self Regulation in a Global Economy*, (UNRISD, Geneva, 2001).

³⁰⁰ MOFFET, J., BREGHA, F. and STOKOE, P., 'The Implications of Voluntary Codes of Conduct for Competition or Competitiveness', Paper submitted to the *CAVA Workshop on the Design and Implementation of Voluntary Approaches – Free Rider, Competitiveness and Transaction Cost Issues* (1999).

biological material from human origin, the specific patient/testee/donor of the tissue will be asked for his/her consent for the patent.

Secondly, the code can also include schemes with regard to the appropriation of industrial or commercial benefits arising from the patents based on material of human origin. Inspired by article 21 of the Convention on Human Rights and Biomedicine, stipulating that "the human body and its parts shall not, as such, give rise to financial gain", the code might state that no remuneration to the person from whom the samples are retrieved, or to his/her eligible party, can be allocated³⁰¹. In this respect the code could further stipulate that the financial profits deriving from patenting and/or subsequent licensing, will partly be deposited in a fund, commonly shared by the patients, the researchers and the company leaders. The code can underline that the donor of the biological material (patient/testee) does not have any direct claim whatsoever on these profits³⁰².

Thirdly, the code can include the establishment of an advisory board. With regard to the composition of the board, the code can prescribe that the board consists of patients (or representatives of patient organisations), researchers, legal experts and company leaders. With regard to the role of the board, the code can stipulate that one of the roles is to give advice on the possible ways of re-investment of the financial gains and funds arising from the commercial exploitation of the patent and to reflect on adequate schemes for the establishment of an "appropriate return".

Fourthly, the code may involve ethical rules and the possibility of disciplinary action for failure to comply with these rules³⁰³. Fifthly, a code can comprise a system for certifying that free and informed consent procedures with regard to patenting have been observed, in other words the code can include details on a verification process to check whether appropriate informed consent measures have been followed. Finally, the code can possibly include a label alerting consumers to the compliance with the practises laid down in the code of conduct. The label can become commensurate with a standard and denote a moral position rather than (or in addition to) a quality standard³⁰⁴.

A code can aim at an all-inclusive approach and focus on all elements described. Conversely, a code can have a more modest line and enclose only some of the elements suggested. It is up to the company/stakeholders to decide.

c. Adoption of the code

A code as outlined above, can, wholly or partially, be adopted in various ways. One option is to invite individual companies to adopt the code. Alternatively, a group of

³⁰¹ Article 21 of the Convention on Human Rights and Biomedicine stipulates that "the human body and its parts shall not, as such, give rise to financial gain". Inspired by this principle of non-commercialisation of the human body, the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) took the view in its Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, that "no remuneration to the person from whom the samples are retrieved, or to his/her eligible party, can be allocated". GAEIB, Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, September 25 1996 (Opinion n° 8), point 2.3.

³⁰² The idea of the deposit in a fund was raised by SMIT, C., KENT, A. & POORTMAN, IJ., *Biomedical Research and Patenting: Ethical, Social and Legal Aspects*, European Platform for Patient's Organisation, Science and Industry, 1996, 13. It has been further elaborated in the field of biological material from plant and animal origin by DRAHOS, P.,

³⁰³ Cf. ECHOLS, M.

³⁰⁴ Cf. ECHOLS, M.

companies or an association of firms might be encouraged to adopt the code. Ultimately, attempts can be made to bring together all stakeholders - industry, academia, patient organisations, NGO's - and to pursue the adoption of the model code. Recent cases illustrate that there is an upward trend in the creation of NGO initiated standards or partnerships that impose voluntary codes or actions on industry³⁰⁵. Similarly, one could think of agreements between a company or industry and patient organisations relating to issues, which concern both parties, including, amongst others, informed consent procedures and patenting.

Experts believe that the possibility of using voluntary measures or codes of conduct to address moral concerns relating to animal welfare and nature is a viable option, based on the experience with the use of 'self-regulation' regarding labour, environmental and human rights concerns³⁰⁶. The exact details of a possible code of conduct in the field of human cell research still has to be further examined and possible ways of implementation have to be further investigated. However, the whole concept of introducing ethical principles in patent law - more in particular embedding the informed consent principle in patent practice - by way of voluntary single- or multi-company standards or multi-stakeholder codes of conduct appears to be a very valuable idea, deserving encouragement and further reflection.

B. Limiting patent scope. The breadth of claim issue

Over the last years, the scope of biotech patent claims has increasingly been put into question. More in particular, the scope of gene patent claims has been criticised. It is often contended that broad product protection for gene sequences might lead to an over-reward for the patentee and to hindrance of research.

To get out of this deadlock, it has been suggested that in the delicate field of human biotechnology, product claims on the basic compounds – genes, cells – should no longer be granted at all, but only process claims should be delivered. In the same line of reasoning, it has been proposed to limit product protection to a sufficiently specific and identified use of the product, in other words to provide only a purpose limited protection instead of absolute product protection for gene sequences. Suggestions have been made to limit product protection to the concrete function and intended use as disclosed in the patent application.

1. Gene patents

In the field of genomics, it has been suggested that patents should no longer be granted for DNA, but only for new medicinal products, new vaccines and genetic tests that are developed on the basis of DNA. For example, drugs to combat cardiovascular diseases, cancer, infectious diseases, diabetes or fertility problems, new vaccines against HIV or flu and genetic tests for disorders such as Huntington's disease or cystic fibrosis. In other words, only patents on the end products would be granted, while patents on the base product used to make these products would be refused. Expressed in technical terms, this means that there would be no more patents on DNA as a research tool (*product claims*), but there would be patents on the use of DNA to diagnose, prevent or treat a specific disease (*use claims*) and on the resulting end

³⁰⁵ See ECHOLS, M.

³⁰⁶ Cf. ECHOLS, M.

product. Patents on products that monopolise 'life' or the genetic raw materials of life would thus be avoided and patents would only be granted on the resulting products³⁰⁷.

In the line of this reasoning, Germany announced it would implement the directive, but at the same time initiate an amendment process on the European level to support the needed improvements and clarifications, in particular to examine the scope of product patents in the biotech field³⁰⁸.

2. Stem cell patents

The extensive patent search carried out in the framework of this study, demonstrated that various patent claims are product claims, encompassing human stem cells. A first question, which arises, is whether it is justified and desirable to apply the suggested restrictions with regard to human genes to claims on human stem cells. Do human genes and human stem cells share the same essential characteristics or do they differ materially from one another? Can stem cells be qualified as research tools? According to the NIH stem cells are research tools which open many doors of opportunity for biomedical research³⁰⁹. If human genes and human stem cells have to be assessed in a different way, in what way? From a technical point of view or from a philosophical perspective?

Another, equally important set of questions relates to the nature of product patents. Is there any difference from an ethical perspective between product patents and process patents? Do both type of claims represent different underlying views with regard to the human body, with regard to the possible appropriation of the human body?

Instead of excluding certain specific subject matter, as listed in the set of examples in art. 6 (2)), why not opt for an overall exclusion of product claims with regard to the human body, and the admissibility of process and use claims? Why not exclude claims on human *stem cells* (product claims) and only admit patent protection for *methods* describing techniques for producing pluripotent human cells exhibiting an embryonic cell phenotype (process claims), or for well defined *applications* (use claims)?

³⁰⁷ JACOBS, P. & VAN OVERWALLE, G., 'Gene Patents: An Alternative Approach', *European Intellectual Property Review*, 2001, 505-506. Contrary to what I said in the Introduction, I have expressed my personal point of view here, because I believe it is a valuable line of reasoning which is shared by others, e.g. BOBROW, M. & THOMAS, S., 'Patents in a Genetic Age. The Present Patent System Risks Becoming a Barrier to Medical Progress', 409, *Nature*, 15 February 2001, 763-764. Also see the following footnote.

³⁰⁸ The rumour is spread that the German Justice Department is considering introducing a new law in Germany, which would prohibit *all* product per se protection in Germany and that the German Government might try to have a similar amendment made to the EPC. It has also been reported that EPO staff members have made personal statements in the media, questioning the absolute product protection as provided in the EPC. Also notice the European Parliament Resolution of 4 October 2001 on the Patenting of BRCA1 and BRCA2 ('Breast Cancer') Genes (B5-0633, 0641, 0651 and 0663/2001) calling on the Council, the Commission and the Member States "to adopt the measures required to ensure that the human genetic code is freely available for research throughout the world and that medical applications of certain human genes are not impeded by means of monopolies based on patents" (Document B5-0633, 0641, 0651 and 0663/2001, Point 4) (Also see http://www3.europarl.eu.int/omk/omnsapir.so/pv2?PRG=DOCPV&APP=PV2&LANGUE=EN&S DOCTA=22&TXTLST=1&POS=1&Type_Doc=RESOL&TPV=PROV&DATE=041001&PrgPrev=PRG@TITRE|APP@PV2|TYPEF@TITRE|YEAR@01|Find@%42%52%43%41%31|FILE@BIBLIO01|PLAGE@1&TYPEF=TITRE&NUMB=1&DATEF=011004).

³⁰⁹ See NIH, 2001, ES-4.

Applying the same restrictions to human genes and human cells would be in line with TRIPs which emphasises that patents shall be available and patent rights enjoyable without discrimination as to the field of technology (article 27 (1)TRIPs). It is even said that the requirement of non-discrimination with regard to technical areas might even lead to the conclusion that the limitations have to be generally applicable in all fields of technology.

If the limitation of patent claims is to gain acceptance, there are a number of problems that will crop up. First, the Directive will probably have to be altered to provide a legal basis for the suggested limitations. Putting the Directive back on the political agenda will not be easy. Second, the EPC might have to be changed as well. It is not clear whether the EPC offers a legal basis to limit patent claims to that extent. In case the current legal basis suffices, the EPO will have to undergo a radical change of outlook and will have to turn its policy and legal precedents upside down. Third, many companies and research institutions will have to change their patent policy of broad patenting.

C. Governing the exercise of patent rights. The science and technology transfer issue

Patent law purports to strike a balance between two conflicting interests: the individual interest of the inventor/investor, which seeks financial recognition, and the promotion of public interest, which benefits from economic prosperity. The ongoing public debate, illustrates that many citizens take the view that the balance inherent to patent law has currently been distorted, especially as far as gene patents and drug patents are concerned, and that too much weight is being given accorded to the individual interest of the inventor/investor³¹⁰.

Presupposing that the EGE takes the view that human stem cell research can enjoy patent protection, the EGE might nevertheless consider to further reflect on possible ways to organise and direct *post* grant patent use in ways which strive to promote a better balance between private en public interest.

The issue of responsible post patent use is not restricted to the human stem cell research. However, the EGE might take the view that the human stem cell debate provokes an opinion on the post patent aspect as well.

1. The U.S. model

a. Key concept

In considering more responsible patent use, one might turn to the policy of the NIH Office of Technology Transfer, for further guidance. Maria FREIRE, Director of the Office of Technology Transfer of the National Institutes of Health, recently appeared

³¹⁰ VAN OVERWALLE, G., 'Klinische proeven en volksgezondheid. Naar een herijking van het algemeen belang in het octrooirecht' ['Clinical Trials and Public Health. Towards a Reassessment of Public Interest in Patent Law'], *Tijdschrift voor privaatrecht*, 2000, (899), 967.

before the U.S. Senate to address how intellectual property considerations affect basic science and the future development of products for public benefit ³¹¹.

In the U.S., transfer of federally funded technology from the not-for-profit sector to the for-profit sector is provided for by Congress in the 1980's, notably by the Bayh-Dole Act, the Stevenson-Wydler Technology Innovation Act of 1980, and amendments, including the Federal Technology Transfer Act of 1986 (FTTA).

Generally speaking, these laws pursue a double goal. On the one hand, they establish certain rights: they allow government owned and government funded research laboratories to retain title to their inventions, in other words they permit the grantee to retain title to intellectual property developed with federal funds and to license its rights to for-profit entities. The exercise of these rights, however, follows a different regime, depending on the user. *Third parties* interested in practising a government funded invention in which they have no ownership may enter into an *exclusive* licensing agreement with the patent owner. Congress gave federal grantees the ability to patent and exclusively license government-funded inventions. The *government* has a *non-exclusive*, royalty-free right to use the patented technology by or on behalf of the government. This would allow the government laboratories and contractors the right to use the patented technology for further research.

On the other hand, these laws impose certain obligations: promoting utilisation, encouraging commercialisation and ensuring public availability of these technologies.

b. Underlying presumptions

It is clear from this overview, that the current NIH policy is based on two presumptions. The first assumption is that *patent protection* is highly desirable. In the current, sometimes heated debate on the position of newly gained knowledge resulting from university funded research, and the delicate question of whether or not this newly gained knowledge is appropriable by way of patents, the position of the NIH is clearly that inventions, resulting from publicly funded research should be protected by way of patents.

The second assumption is that *fair access* to patented inventions, open sharing of research tools is vital to maximise the benefit to the public. The NIH takes the view that it is not merely the existence of a patent that raises concern for the (biomedical) research community, but that the concern mostly arises when the patent holder chooses to exercise its rights through licensing or other contractual agreements in a manner inconsistent with the advancement of basic research ³¹². In this way the NIH tries to keep a balance between private and public interest, between protection and access.

This policy was illustrated when President Bush announced on August 9 2001 that federal funds may only be awarded for research using human embryonic stem cell lines that meet certain criteria ³¹³.

³¹¹ FREIRE, M., Statement of National Institutes of Health, Before Senate Appropriations Subcommittee on Labour, Health and Human Services, Education and Related Agencies, August 1 2001 (See www.nih.gov/news/stemcell/080101freire.htm).

³¹² FREIRE, M., Statement of National Institutes of Health.

³¹³ Bush literally said: "As a result of private research, more than 60 genetically diverse stem cell lines already exist and I have concluded that we should allow federal funds to be used for research on these existing stem cell lines where the life and death decision has already been made. This allows

At this occasion, various scientists have asked about the effect that patents that have been filed and/or issued over the past few years will have on human embryonic stem cell research. The NIH emphasised that the issuance of patents on new developments need not adversely affect continuing research, provided that the patent owners devise a licensing and sharing strategy to allow basic research to proceed. Experience has shown that conditions imposed by patent owners can be crafted both to ensure research uses and to provide appropriate incentives for commercial development^{314 315}.

c. Limited scope

The series of laws, enacted by Congress in the 1980's and founding the current NIH policy, appear to be rather limited in scope, from two points of view. The first limitation relates to the *beneficiaries* of the statutory research exemption: this exemption only applies in case of federally funded research. The starting point of the U.S. transfer of technology framework is the underlying idea that the grantees and contractors have a broad discretion in the patenting and licensing of new technologies. With regard to federally funded research, the government has only limited authorities over these activities: the government has a statutory, non-exclusive, royalty free licence to enable government research institutions to use patented technology for further research. With regard to research entirely funded by the private sector, the government has no statutory license and is not involved in patenting or licensing decisions and it is strictly a private matter whether, and under what terms, new intellectual property is made available to others for commercial or research purposes. Comparing the U.S. situation with the European framework at this point, there are two striking differences. First, a non-exclusive use of patented technology for research purposes, is common practice in Europe. Anticipating the establishment of a Community patent, many member states copied the research exemption from article 27 (b) of the Agreement relating to Community patents, done at Luxembourg on 5 December 1989³¹⁶, in their national patent legislation³¹⁷, which aimed at making

us to explore the promise and potential of stem cell research without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life", WHITE HOUSE, Fact Sheet, Embryonic Stem Cell Research, 9 August 2001 (see www.whitehouse.gov/news/releases/2001/08/20010809-1.html).

³¹⁴ See <http://www.nih.gov/news/stemcell/082701list.htm>.

³¹⁵ An often cited model example is the US patent 6.200.806 on human pluripotent embryonic stem cells was issued to the Wisconsin Alumni Research Foundation (WARF) of Madison, Wisconsin (This patent has been examined supra). Pursuant to its rights under its patents, WARF negotiated a commercial license, for a limited number of cell types, to Geron Corporation of Menlo Park, California. WARF, as well as many other cell providers, have publicly stated that they are very interested in making their cells available for use in federally funded research. Although the specific terms and conditions of availability must be determined between providers of the cells and the recipients, the NIH is pleased by the willingness of the researchers who have derived cells to make them available for use by federally funded researchers. The NIH urges all providers to make their cells available in accordance with its policy on access to research tools. See <http://www.nih.gov/news/stemcell/082701list.htm>. The NIH policy is laid down in a document entitled *Sharing of Biomedical Research Resources, Principles and Guidelines for Recipients of NIH Research Grants and Contracts* available at: http://ott.od.nih.gov/NewPages/RTguide_final.html.

³¹⁶ *Official Journal EC – L* - 30 December 1989, n° 401, p. 0001 – 0027. Article 27 (b) stipulates: "The rights conferred by a Community patent shall not extend to: (a) ... (b) acts done for experimental purposes relating to the subject matter of the patented invention".

patented technology widely available to researchers and to open opportunities to advance science. Second, this statutory research exemption is not limited to federally funded research, but equally applies to private funded research as well.

The second limitation relates to the *purpose*. The statutory exemption seems to be restricted to further research, and it is not clear whether the exemption also applies when the research is carried out with a commercial goal. On this point, the situation in Europe is rather ambiguous as well. The experience over the last years has clearly shown that the boarder line between basic research and applied science has sometimes become very thin and that federally funded research is often carried out with a combined, scientific and commercial, goal.

This all leads to conclude that the U.S. example is not as pioneering as it appeared at first sight.

2. European routes

Various initiatives indicate that there is a growing interest in the establishment of a science and technology transfer system at the European level. Although Europe has a well-established research exemption, various lacunas still remain. First, although the wording might be largely the same, the exact scope of the research exemption differs from member state to member state, since it is differently interpret by the national courts. Second, transfer of technology agreements as well as material transfer agreements, are mainly within the competency of the member states, and their content differs from member state to member state. Third, the efforts at the European level - regulations that are being developed in view of the 6th FP - are limited to EU funded research. Fourth, the proposals that are currently being developed also raise the question, to which extent the underlying principles take into account a well-balanced private interest – public interest approach.

Therefore, it might be significant if the EGE explicitly declares that further investigation has to be conducted on the establishment of a harmonised, well-balanced, patent use framework, governing EU as well as nationally funded research, applicable to government funded as well as private funded research, especially in the field of human cell research. The EGE could further recommend that the necessary legislative steps be taken to promote a transfer of technology policy in the European Community and in the member states to ensure that the balance between exclusivity and access is carefully monitored to maximise public health benefit. It can only be hoped that continued dialogue between public and private actors, between national and European authorities, between scientists and companies will result in an understanding that will contribute to this debate and to harmonised, global and well balanced transfer mechanism between academia and industry and vice versa.

CHAPTER 3. SUMMARY

Part IV offered some routes for reflection, assuming a decision on the patentability of inventions relating to human stem cell research has been taken.

³¹⁷ Article 27 (b) has been implemented, for example, as article 28 (1) (b) of the Belgian Patent Act of 1984, article 53 (3) of the Dutch Patent Act of 1995 and article 11 (2) of the German Patent Act of 1981 (the so-called *Versuchsprivileg*).

In case the European Group on Ethics should have reached the conclusion that patent law should exclude human stem cells from patent protection, it was felt necessary to examine whether there are no alternative IPR systems to guarantee exclusivity for the inventions resulting from human stem cell research can be examined.

It appears that the EU legislator promotes exclusivity on biotechnological inventions by way of patents. Another way to retain exclusivity on the results of biotechnological research is to maintain the development as a trade secret. From a public interest point of view the protection by way of trade secrets appears not to be favourable, the main reason being that details of the invention in a written published document is not imposed.

Should the European Group on Ethics have decided that inventions relating to human stem cells are patentable in principle, various scenarios were offered to accommodate current patent law to some delicate issues arising from patenting material from human origin and to meet various objections and public concerns relating to the patenting of human stem cells.

A first scenario directly related to patent granting *requirements*. It was suggested that the implementation of an informed consent requirement for patent purposes *outside* patent law is examined and that the insertion of the informed consent principle by way of a voluntary code of conduct is considered.

A second route related to the *scope* of patents. It was suggested that the breadth of claims is reconsidered and that the issuance of product claims in the field of human stem cell research is reassessed.

A third issue concerned the *effects* of granted patents. Various schemes are analysed to establish a more responsible use of patent rights.