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"HUMAN RIGHTS IN THE PATENT PROCEDURE"
-
THE ISSUE OF PRIOR INFORMED CONSENT OF HUMAN DONORS TO THE PATENTING OF INVENTIONS BASED UPON THEIR GENETIC MATERIAL

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Abstract

Concern about the roles of ethics and human rights in patenting biotechnology has been particularly serious over the past decade.
In Europe, Directive 98/44/EC has established several ethics-based exclusions from patentability in the field of biotechnology and has adopted numerous non-binding principles in this regard. One of these is the principle of prior informed consent (PIC) of donors to patenting of human genetic material.
The United States on the other hand, in line with their common law tradition, has not chosen to enact specific legislation; emphasising the limited nature and effect of the patent system and deciding on the matter in case-law.
The question this paper addresses is how human rights can play a role in very limited, specific questions of patent law such as PIC; which human rights could concretely apply in relation to PIC; how they are to be balanced with one another; and how this is to be assessed in view of the utilitarian nature of the patent system.

Key Words

Patent; biotechnology; donors; human genetic material; prior informed consent; PIC-Directive 98/44/EC; TRIPS

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The present report addresses issues in relation to the prior informed consent of human donors to the patenting of inventions based upon their donated genetic material. It is the outcome of a workshop held by NCCR IP-9 on 28 March 2007 in Berne; focusing especially on the human rights aspects of this discussion. I would particularly like to thank all the participants at the workshop and especially the other speakers: Denis Monard, François Meienberg, Jerzy Koopman, Markus Schefer and Anthony Taubman (in order of presentation).

1 Introduction

The regulation of biotechnology is fairly complicated and fragmented. It needs to deal with a number of factors making the establishment of legal rules seemingly more complex than for other subjects of law. The highly technical nature of the technology, the pace of its evolvement, the pressuring and diverging public opinions, the ethical concerns, the risks and the difficulties in assessing them, the fostering of research in the field, among others, all need to be taken into account when construing rules covering biotechnology.

Biotechnology raises questions of liability, intellectual property, medical law, competition law, social security, human rights, and many others. All of them are intertwined and should constitute a well-balanced set of laws. This paper focuses on a very limited 'legal-procedural' cog in the wheel of biotechnology regulation: the issue of prior informed consent of human donors to the patenting of inventions based upon their donated genetic material. In particular, it investigates the potential linkages between the said issue and human rights.

Ethical concerns about (patenting) biotechnological inventions have been at the centre of many debates, papers by non-governmental organisations (NGOs), academic reflections and even international agreements, yet the influence of human rights on patent law seems limited. Human-rights arguments cannot be made directly before a patent officer in the absence of the legal means to do so or when they are being blocked by narrow interpretations (cf. the ordre public and morality-concept in Europe). When it comes to tailoring patent rules, furthermore, human rights are often said, in particular in relation to biotechnology, to cut both ways. The NCCR workshop reported on here, discussed whether there is a human-rights-rooted need for a prior-informed-consent (PIC)-provision in patent law and how this can or should be organised.

When analysing the application of the patent system to biotechnology, one must be aware of the limited nature of patents: a patent does not confer the right to exploit, to commercialise or even to *use* a given invention, but only grants the right

to the patent holder to exclude others from doing so. A patent is a time-limited negative monopoly right. It is established through the rationale of fostering advancement in innovative technologies by the dual effect of providing an economic incentive to invest in research on the one side (by the promise of a monopoly right for new and inventive inventions), and the forced disclosure of the invention in return thereof and hence the avoidance of trade secrets on the other. For biotechnology as much as for any other technology, the major effect of patent law is hence the protection and attraction of investments.

The patentability of biotechnology had already been debated before Crick and Watson discovered the existence of *deoxyribonucleic acid* or DNA in the 1950s.[1] In fact, Louis Pasteur's purified yeast was granted a patent at the end of the 19th century and the United States were already systematically opening their patent system to living matter in the 1930s when they enacted the famous Plant Patent Act.[2] The appearance of 'modern' biotechnology or genetic engineering, however, significantly enhanced the technicality of inventions in this field, the potential of the technology and hence also the need for investments. The discussion on systematically opening the patent system to biological material, including to human biological material, hence became increasingly pressing and ended with preliminary decisions to do so in the 1980s[3] and 1990s[4] in most industrialised countries.

1 J. WATSON and F. CRICK, *The Molecular Structure of Nucleic Acids*, Nature, Vol. 171, 1953, p. 737.

2 United States Code, Title 35 (Patents), Chapter 15 (Plant Patents), § 161-164 (Hereafter 35 USC 161-164), available at: http://www.wipo.int/clea/docs_new/pdf/en/us/us007en.pdf (last visited November 2006).

3 See: United States Supreme Court, *Diamond v. Chakrabarty*, 16 June 1980, 447 US 303; United States Patent and Trademark Office, *PTO Notice on Plant Life-Patentable Subject Matter*, 8 October 1985 in I.P. COOPER, Biotechnology and the Law, 2005 Revision, Thomson West Publishing, Appendix H3; and United States Patent and Trademark Office, *Notice: Animals-Patentability*, 1077 Official Gazette of the United States Patent & Trademark Office 8, 21 April 1987.

4 Cf. Directive 98/44 of the European Parliament and of the Council, on the legal protection of biotechnological inventions, July 6, 1998, Official Journal of the European Communities, 30 July 1998, L 213/13. (Hereafter 'Directive 98/44/EC').

In Europe today, 'biological material'[5] is generally patentable in the same way as any other type of invention. Regardless of whether the material previously occurred in nature,[6] it will be patentable provided that it has been isolated from its natural environment or produced by means of a technical process and that the other requirements of patentability are fulfilled (novelty, inventiveness, industrial application, etc.). For instance, (non-altered) human nucleic 'gene' sequences are patentable *as they exist in the human body and expressing the same function*, but isolated from that body: engineered to laboratory form. This at first sight very loose criterion might however not be as weak as it seems in a technology all about finding functions for fractions of the DNA-clew and their interrelation.

2 PIC in Law

The issue of PIC comes up often in the course of medical interventions and donations of body samples: consent to medical intervention, consent to donation (or not, for a certain (research) purpose), consent to research *on* a person, consent to patenting and consent to commercialisation are all affected by different issues and legal rules. A recurring question is that of the feasibility of the integration of all consent-types into one global approach.

PIC is an issue at the centre of many academic publications, yet few jurisdictional decisions have been registered on the matter,[7] and the law seems equally silent.

The Oviedo Convention on Human Rights and Biomedicine establishes the principle that an intervention in the field of health can only be carried out *'after the person concerned has given free and informed consent to it'*. Such consent must be based

5 Whereby 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. (Rule 23 (b) (c) to the EPC and Article 2 (a) Directive 98/44/EC).

6 Rule 23 (c) (a) to the EPC and Article 3 § 2 Directive 98/44/EC.

7 A. TAUBMAN, *Prior informed consent to patent applications by donors of human genetic material*, presentation held at the workshop 'Human Rights in the Patent Procedure', Berne, 28 March 2007, available at: www.nccr-trade.org (last visited June 2007).

upon 'appropriate information' on the purpose and nature of the intervention, as well as on its consequences and risks, and which must be given to the patient beforehand.[8] This principle is extended to research on a living person[9] as well as to removal of organs and tissue from living donors for transplantation purposes;[10] but the Convention remains silent on the matter of consent to patenting. A similar principle is incorporated in the Helsinki Declaration of the World Medical Association.[11] One might argue that the 'appropriate information to the purpose and nature of the intervention' includes the information on an eventual patenting of inventions based upon material removed by the intervention. As we shall see in the section below, however, this not might be easy to realise in practice as, at the moment of the removal, doctors and researchers usually do not yet know whether this material will end up becoming the basis for a patentable invention. In the US Supreme Court of California decision in Moore, nevertheless, such a solution was suggested. Indeed, the Court ruled that although usually used in the context of failure to disclose *medical risks*, the concept of consent to treatment is broad enough to encompass the failure to disclose the *personal interests* of a physician.[12] However, the said concept was not as such separated from medical risks or at least not from *medical interests*. The patient's right to be informed about the economic interests a physician/researcher might have in his body samples and thus also about the

8 Article 5 of the Council of Europe's Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine, Oviedo, 4 April 1997, ETS 164 (Hereafter the Convention on Human Rights and Biomedicine).

9 Article 16 (v) of the Convention on Human Rights and Biomedicine.

10 Article 19 § 2 of the Convention on Human Rights and Biomedicine.

11 Principle 22 of the World Medical Association's Declaration of Helsinki '*Ethical Principles for Medical Research Involving Human Subjects*', Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, as revised by the World Medical Assembly in Tokyo, Japan in 1975, in Venice, Italy in 1983, in Hong Kong in 1989, and Somerset West, South Africa 1996, available at http://www.wma.net/e/policy/b3.htm (last visited June 2007), which reads: 'In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed."

12 Thereby, among others, referring to Court of Appeal of California, *Magan Medical Clinic v. California State Bd. Of Medical Examiners*, 1967, 249 Cal. App. 2d 132: 'Certainly a sick patient deserves to be free of any reasonable suspicion that his doctor's judgment is influenced by a profit motive'.

economic value of the samples *in se* was recognised only to the extent it affects the medical judgment of the doctor: *'Accordingly, we hold that a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic,* ***that may affect his medical judgment****'* (emphasis added).[13][14]

Prior informed consent is also established under the 2005 UNESCO Declaration on Bioethics and Human Rights, which rules similarly that 'medical interventions' and 'scientific research' must be carried out with *'prior, free and informed consent of the person concerned, based on adequate information'*. Such consent should be 'express' and can be withdrawn *'for any reason without disadvantage or prejudice'.* The UNESCO Declaration, finally, incorporates a specific tenet applicable in cases where research is carried out on a group of persons or a community, ruling that in no case can a collective agreement or the consent of a community leader be a substitute for an individual's informed consent. [15]

Article 15 of the Convention on Biodiversity establishes that *access* to genetic resources 'shall be subject to prior informed consent of the Contracting Party providing such resources'[16]. The Convention, however, is generally held not to be applicable to *human* genetic resources and works in a different context.

Prior informed consent to patenting, concretely, has mainly been discussed in relation to issues of 'traditional knowledge', but has been enacted into hardly any applicable legal provisions. The TRIPS Agreement, Paris Convention and

13 Supreme Court of California, *John Moore v. the Regents of the University of California (et al.*), 9 July 1990, No S006987, 51 Cal. 3d 120, at III, A, § 10.

14 In making its final decision, the Supreme Court of California held that physician Golde who planned research on Moore's cells even before performing the splenectomy upon him, and did not inform his patient at all thereof, even when he explicitly inquired about it, did not fulfil his legal obligations. However, researcher Quan, the Regents of the University of California, the Genetic Institute and Sandoz Corporation, were not held responsible by this judgment, for they are not physicians and only these stand(s) in a fiduciary relationship to the patient, in casu Moore. Secondary liability was not accepted.

15 See Article 6 of the UNESCO Declaration on Bioethics and Human Rights, 19 October 2005, Adopted 'by acclamation' at the 33rd session of the General Conference of UNESCO.

16 Article 15 of the Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, United Nations Treaty Series 143 (1993).

WIPO's Substantive Patent Law Treaty being silent on the matter, PIC to patenting is left open to regional and domestic regulation.

At first glance, the European Union has apparently taken a different approach from the United States (where the matter was set aside by the Landmark decision in Moore) by enacting a PIC by human donors-requirement into the 1998 Biotechnology Directives: *'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'* (Recital 26; emphasis added).[17]

The weak legal value of this provision reduces the EU PIC-requirement to little more then a symbolic piece of legal literature, however. A 'Recital' in an EU Directive has no binding force whatsoever on EC-member countries and the terms used, moreover, are extremely feeble. Recital 26 has no mention of the form in which PIC should be given, does not require any mention in the patent application and does not even actually require consent to be given, but only that a donor must have had 'an opportunity' to do so.

The provision came only at a fairly late stage of negotiations on the Directive, in 1997, under the general influence of the recently adopted Oviedo Convention on Human Rights and Biomedicine and the concrete impact of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission. The latter construed PIC as an ethical principle: *'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*

17 Recital 26 Directive 98/44/EC reads: *'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'.*

origin, having been retrieved without respecting the principle of consent will not fulfil the ethical requirements'.[18]

So far, even though the matter was incorporated into the Directive under pressure specifically from Belgium and Denmark;[19] only Italy has implemented a PIC provision in its national patent law.[20]

Lacking an explicit legal basis in the majority of countries to enforce PIC, the use of the *ordre public* and morality-provision as widely implemented in national patent laws across Europe and in the European Patent Convention has been suggested as a potential gateway to PIC. The said provision excludes inventions from patentability whose *commercial exploitation* would be contrary to the 'ordre public' or 'morality'.[21,22] *Ordre public* being a concept mainly dealing with security-aspects of inventions; it is the morality provision that is at stake here. The proof of whether the commercial exploitation of a certain invention goes against European morals is however very difficult to make under the existing European Patent Office jurisprudence. The commercial exploitation, it was found at the present workshop, may well be contrary to *ordre public*/morality if the process of developing the product has been tainted by moral deficiencies (in casu, ultimately, lack of

18 GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY TO THE EUROPEAN COMMISSION, *Opinion N° 8: Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, 25 September 1996, at 2.4, available at: http://ec.europa.eu/european_group_ethics/docs/opinion8_en.pdf (last visited June 2007).

19 See P. SAELEN, *Biotechnologische uitvindingen, octrooien en informed consent*, Vlaamse Raad voor Wetenschapsbeleid, 2002, at p. 172, available at: http://www.vrwb.be/MFiles/Studiereeks5.pdf (last visited June 2007).

20 Article 5 of Decreto Legge 10 gennaio 2006: *'la domanda di brevetto relativa ad una invenzione che ha per oggetto o utilizza materiale biologico di origine umana deve essere corredata dell'espresso consenso, libero e informato a tale prelievo e utilizzazione, della persona da cui è stato prelevato tale materiale, in base alla normativa vigente'*.

21 Cf. Article 27 § 2 TRIPs Agreement; Article 1709 § 2 of the North American Free Trade Agreement (NAFTA); Article 6 (a) of the Bangui Agreement; Article 6 § 1 Directive 98/44/EC; and Article 53 (a) EPC, which reads: '*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'*.

22 Cf. Recital 39 Directive 98/44/EC: *'Whereas ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of invention in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention'*.

informed consent)[23]. Under EPO case law, however, one would have to show that the commercial exploitation of an invention based upon someone's donated body samples is wrong '*founded on the **totality of the accepted norms which are deeply rooted in**,…, **the culture inherent in European society** and civilisation'*.[24] The question is how to prove this; could human rights play a role here?

It was in fact Belgium which suggested explicitly enumerating the commercial exploitation of inventions lacking PIC as being contrary to ordre public and morality under the EU Biotechnology Directive. Later, this option was also considered under Belgian patent law but neither at the EU level, nor in domestic regulation, did the proposal make it through the legislative process.

3 PIC in Practice

Prior informed consent of human donors can be divided into two categories: *individual* consent and *collective* consent. In the latter case, one specifically thinks of indigenous communities researched upon for the specific genetic features which they share. Here, the question is: who should consent? Should it be the state in which they live (in which case a problem might arise in relation to cross-boundary share of genetic specificities), the group, the leader, or each individual? This concern is not limited to indigenous communities, but must also be considered in the family-context: the question often arises of whether consent is up to the individual or should also be given by those family-members sharing the characteristics. For example, can a son give consent to research on his genetic material without his parents being involved?[25]

23 M. SCHEFER, *Human Rights and Patenting the Results of Research on Human Material*, Paper presented at the NCCR Workshop 'Human Rights in the Patent Procedure', Berne, 28 March 2007, at p. 9.

24 Technical Board of Appeal of the European Patent Office, *Plant cells/PLANT GENETIC SYSTEMS*, 21 February 1995, T 356/93, Official Journal of the European Patent Office (1995) 545.

25 See: F. MEIENBERG, *Access to Human Genetic Resources Results from a Transnational Stakeholder Dialogue*, presentation held at the workshop 'Human Rights in the Patent Procedure', available at: www.nccr-trade.org (last visited June 2007).

A practical issue, also, is to know the best moment to require and give consent. The incorporation of consent to medical intervention, research, patenting and commercial exploitation into a single agreement might not be the best option in terms of 'informed' consent, but might nonetheless be the most appropriate from the practical point of view. The Group of Advisers on the Ethical Implications of Biotechnology to the European Commission, for instance, advised that a person from whom retrievals are performed must be able to give free and informed consent thereto; 'informed' meaning in particular 'on the potential patent application on the invention which could be made from the use of this element'.[26] At that moment, however, hardly anyone knows what the outcome of the research performed on the donated body samples will be, let has a concrete patent application in mind.[27] On the other side, the possibility of obtaining consent later on is limited by the fact that body samples usually go into databases where they become, for privacy reasons, untraceable to the original donor. Prior informed consent would hence need to take place before the samples are placed into databanks. This reasoning is reinforced by the uncertainty created in heads of research projects over the patentability of the outcome of their research if consent is only assured at the latest stage. Today, however, whereas most databanks need and do work with a PIC form, this rarely covers consent to patenting as well.[28,29]

Finally, research is often undertaken on human bodies donated for research *post mortem*; the question then is when and by whom should consent be given to patenting if this is not done by the donor him or herself.

Prior informed consent to patenting covers the paradox that it is often the patients affected with certain diseases who push for research to be started on the

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26 GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY TO THE EUROPEAN COMMISSION, *Opinion N° 8: Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, 25 September 1996, at 2.4, available at: http://ec.europa.eu/european_group_ethics/docs/opinion8_en.pdf (last visited June 2007).

27 See: D. MONARD, *Identification of new targets through analysis of human genetic material and steps to patentable inventions*, presentation held at the workshop 'Human Rights in the Patent Procedure', available at: www.nccr-trade.org (last visited June 2007).

28 At the workshop, a Dutch Alzheimer databank was cited.

29 The issue of anonymous databanks was said also to affect the possibility of being able to withdraw consent to research 'at any time' as guaranteed under the Oviedo Convention on Human Rights and Biomedicine (Article 5) and under the Helsinki Declaration (Principle 22).

causes and cures for their illness and, at that time, concentrate only on convincing research institutes, rather than thinking about any eventual patents.[30] One of the best known cases in this respect, as regards indigenous communities, is that of the Hagahai people from Papua New Guinea who themselves sought help for a specific disease that was affecting them. When the US National Health Institute thereupon applied for patent protection for the cell line developed from their genetic donation, controversy was so strong that they decided to abandon the patent.[31]

Canavan disease/ Greenberg

Shortly after his first birthday, Jonathan Greenberg was diagnosed with the rare *Canavan* disease: a fatal genetic disorder. A few years later, his younger sister, Amy, was diagnosed with the same condition. Amy and Jonathan's parents, thereupon, not only found a researcher, Dr Matalon, willing to conduct research aimed at finding the mutated gene responsible, but also organised tens of thousands of dollars in donations, including a large amount of personal money, and moreover managed to provide blood, urine and biopsy samples from other children with *Canavan* disease and their parents. When the gene was finally isolated, a patent was granted to the *Miami Children's Hospital Research Institute*, employer of the researcher, in 1997. The hospital then decided to make a charge for the test developed on the basis of the gene sequence(s) of US$ 12.50 per unit. Shortly afterwards, the families who had initiated the research reacted by expressing their strong disappointment: *'We gave our samples to be use for the public, if they told us they*

30 See: D. MONARD, *Identification of new targets through analysis of human genetic material and steps to patentable inventions*, presentation held at the workshop 'Human Rights in the Patent Procedure', available at: www.nccr-trade.org (last visited June 2007).

31 See: WIPO, *Bioethics and Patent Law: The Cases of Moore and the Hagahai People*, WIPO Magazine, September 2001, available at: http://www.wipo.int/wipo_magazine/en/2006/05/article_0008.html (last visited 15 June 2007).

wanted to patent it, we probably would have found another researcher who had the same goals as we did'. [32]

AIDS/ Erich Karl Fuchs

Although Erich Karl Fuchs regularly had unprotected sexual intercourse with various people infected with HIV, repeated AIDS-tests showed him to be HIV-negative. In 1994, Mr Fuchs, on his own initiative, contacted the *Aaron Diamond AIDS Research Center* in New York where researchers agreed to study him and acknowledged the impossibility of the HIV virus being able enter his cells. When this characteristic was discovered to be linked to a hereditary gene blocking the porthole into white blood cells to the virus and when thereafter the so called 'HIV-resistance gene' was successfully isolated, the Aaron Diamond Center's researchers were granted a patent on a test aimed at identifying the presence of the specific gene in human beings. Mr Fuchs, who with his *personal initiative* and *specific genetic structure* had initiated the whole process, however, remained completely excluded from participation in reaping the subsequent benefit: *"I just wanted to do something good, but once money came into the picture, why not have it be shared with me?"* [33]

In this regard, it seems one must distinguish between donors of rare genetic material having specific genetic characteristics and donors of common genetic material. Especially in relation to cell lines the threshold to create patentable cell lines might not be very high once a specific cell type has been accessed (cell lines are in a culture, to produce them under controlled circumstances).

Patentable inventions of biological material are always a mixture between the inherent characteristics of the material and the information discovered about it by the 'inventors' – the applicants. The donor is however unable to 'disclose' the often very complex information rendering his donation patentable. The proportion of biological material v. information might differ a little from one invention to

32 G. KOLATA, *A Special Report: Who Owns Your Genes?*, New York Times, 15 May 2000.
33 G. KOLATA, *A Special Report: Who Owns Your Genes?*, New York Times, 15 May 2000.

another; the principle remains the same however. It seems that from a human rights or human dignity angle (as explained below) PIC should however not be limited either to certain types of donors or to certain types of inventions.

Hairy cell leukaemia/John Moore

In 1976, US citizen John Moore was diagnosed with the rare 'hairy cell' leukaemia (cancer). During his subsequent visit to the University of California Los Angeles (UCLA) medical centre, on 5 October 1976, blood, bone marrow aspirate and other samples were removed from Moore's body, and thereafter the diagnosis was confirmed. Only three days later, Moore agreed in a written consent to the removal of his spleen, in order to slow down the progress of the disease. The responsible physician, even before carrying out the splenectomy, agreed with a researcher at UCLA to give him portions of Mr Moore's spleen which they knew could be of great value in a number of scientific and commercial activities. Both Moore's physician and the UCLA researcher were thus fully aware of the uniqueness of Moore's spleen and also of the possible economic benefit of research performed on it. However, Moore was never informed either of the research that was planned on the spleen or of the financial interests of the researchers, and not even of the 'donation' of his spleen by the physician to the UCLA researcher.

Between 1976 and 1983, upon request of the physician who held it 'necessary' for Moore's health and well being, Moore continued to make regular visits to UCLA (from his home in Seattle (Washington)). At each of these visits, samples of blood, blood serum, skin, bone marrow aspirate and sperm were withdrawn. In response to his questions, Moore was told this could only be done at UCLA.

Meanwhile, around 1979, a cell line was established from Moore's 'T-lymphocyte' cells, for which an application for patent protection was made in 1981, citing both the physician (Mr Golde) and the researcher (Mr Quan) as inventor and called the 'Mo cell line'. This application also included several methods for using the cell line to produce lymphocytes.

Simultaneously, the physician Mr Golde became a 'paid consultant with a right on 75 000 shares of common stock' at the Genetics Institute, who paid him and the Regents of the

University of California, moreover, a fee of US$ 330 000 over three years in return for exclusive access to the Mo cell line and the products of the research performed thereupon, in order to commercially develop the Mo cell line and derived products. In 1982, the 'Sandoz Pharmaceuticals Corporation' was added to the agreement, increasing the compensation by a further US$ 110 000.[34]

In relation to indigenous communities a communication problem is often the source of trouble and also of abuses. The difficulty in explaining what exactly genetic research is; what exactly patents are about, is often hard to overcome. How does one explain what genetic information is to tribes in the Amazon? The argument that 'if they could understand, they would agree', as made by certain pharmaceutical companies in the past, might not however be the most honest one.[35]

Another issue is what should be the consequences for patent applications made regarding inventions that did not respect a PIC-requirement: should this affect the patentability or the enforcement of the patent? Should it be linked to damages without touching on the value of the patent?[36] This also needs to be linked to the TRIPS-compliance of an eventual PIC-requirement: Is it possible for instance to implement an additional patentability requirement for PIC under the TRIPS Agreement?

The final question is whether PIC really is an issue of patent law at all, or rather one of civil, constitutional or criminal law. This issue was what motivated Germany not to implement Recital 26 of the EU Biotechnology Directive into its national patent law.[37] In this respect it can also be observed that consent to

34 Supreme Court of California, *John Moore v. the Regents of the University of California et. al*, 9 July 1990, No S006987, 51 Cal. 3d 120.

35 See: F. MEIENBERG, *Access to Human Genetic Resources Results from a Transnational Stakeholder Dialogue*, presentation held at the workshop 'Human Rights in the Patent Procedure', available at: www.nccr-trade.org (last visited June 2007).

36 See J. KOOPMAN, *Prior informed consent in patent law: On the asymmetries between international legal regimes*, Presentation held at the workshop 'Human Rights in the Patent Procedure', Berne, 28 March 2007, available at www.nccr-trade.org (last visited June 2007).

37 DEUTSCHER BUNDESTAG, *Entwurf eines Gesetzes zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen*, 15 October 2003, Drucksache 15/1709, at p. 8.

patenting does not entail one's consent to the commercialisation of the invention. Many patents do not ultimately give rise to commercialised inventions. In fact, most do not, and patenting as such does not allow commercialisation anyway. The lack of PIC to patenting and the impact thereof on public opinion can however undermine trust in biotechnological research, which is already at quite a low point in Europe.

4 PIC and Human Rights

Both the Convention on Human Rights and Biomedicine and the UNESCO Declaration on Bioethics and Human Rights establish a human rights-linked PIC-requirement, yet neither deals with the human rights angle of PIC to *patenting* specifically. In many cases, the need for PIC can be both strengthened from the point of view of certain human rights and weakened from the point of view of others. The 'battle of human rights' in relation to PIC seems especially to relate to the human right to dignity and privacy versus the right to health and freedom of research, for instance; but also to human rights pertaining to cultural identity and community or human rights pertaining to natural wealth, resources, etc.[38] The following section discusses the human rights guarantees that could motivate a PIC-requirement to be implemented in patent law.

4.1 The Right to Property

The right to property is enshrined in several international conventions, including the first protocol to the European Convention on Human Rights.[39] Property rights

38 See J. KOOPMAN, *Prior informed consent in patent law: On the asymmetries between international legal regimes*, Presentation held at the workshop 'Human Rights in the Patent Procedure', Berne, 28 March 2007, available at www.nccr-trade.org (last visited June 2007).

39 Article 1 of Protocol I to the Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocol No. 11, Rome, 4 June 1950, 213 U.N.T.S. 262, available at: http://www.echr.coe.int/NR/rdonlyres/D5CC24A7-DC13-4318-B457-

were found suitable in the context of appropriation of traditional knowledge by third persons (companies). The question here however is of a different nature: i.e. to what extent can it be applied to the human body and donations of samples from it?

The human body being excluded from financial gain under the UNESCO Declaration on Bioethics and Human Rights, the right to property cannot cover the material interest of an individual in sharing in financial profits generated by marketing a patent based on research with material from his or her body, according to Schefer.[40] The question remains however of what its role could be apart from the financial aspect; looking at PIC purely.

If they are not covered by property rights, what status is to be accorded to body samples? In the US Moore case, one tried to construe theft of body samples for the donor had not been informed about the planned use in research of his spleen which had been removed for medical reasons. To prove this (the tort of conversion in the US), one must however first prove property. The Supreme Court of California denied this and refused to recognize property rights of the donor over his body samples *after* their donation. One might argue, however, that the property rights a donor has *before* removal of the samples allow him to choose among the permissible uses to which the samples may be put *after* removal.[41] The problem

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5C9014916D7A/0/EnglishAnglais.pdf (last visited June 2007), which reads: *'Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.*

The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties'.

40 M. SCHEFER, *Human Rights and Patenting the Results of Research on Human Material*, Paper presented at the NCCR Workshop 'Human Rights in the Patent Procedure', Berne, 28 March 2007, at p. 3-4.

41 This was argued by Broussard, concurring and dissenting in the Moore decision: *'Although the majority opinion suggests that there are "reasons to doubt" that a patient retains "any" ownership interest in his organs or cells after removal, the opinion fails to identify any statutory provision or common law authority that indicates that a patient does not generally have the right, before a body part is removed, to choose among the permissible uses to which the part may be put after removal. On the contrary, the most closely related statutory scheme – the Uniform Anatomical Gift Act – makes it quite clear that a patient does have this right',…, 'If defendants had informed plaintiff, prior to removal, of the possible uses to which his body part could be put and plaintiff had authorized one particular use, it is clear under the foregoing authorities that defendants would be liable for conversion if they disregarded plaintiff's decision and used the body part in an unauthorized manner for their own economic benefit'.* This was also argued by dissenter Mosk, referring to prior case law of the Courts of Appeal of California which held that one must assess ownership or right to possession of the property *at the time of the conversion* (Cf.

would remain however that by consenting to patenting, one does not consent to patenting the donated body sample but to patenting the invention based thereupon.

4.2 The Right to Human Dignity

Human dignity is a recurring argument in many debates. In international law, it is the central theme of many preambles but rarely a direct provision. The EU Biotechnology Directive for instance, refers to human dignity in Recital 16, saying 'patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person[42].'

The concept of human dignity can be generally defined as isolating the human being from its environment to look at it '*in se*', separately from third persons and society. In Article 2 of the Oviedo Convention on Human Rights and Biomedicine, we find an application thereof, reading: *'The interests and welfare of the human being shall prevail over the sole interest of society or science'*. Similarly, Article 3 of the 2005 UNESCO Declaration on Bioethics and Human Rights reads: '*Human dignity, human rights and fundamental freedoms are to be fully respected. The interests and welfare of the individual should have priority over the sole interest of science or society'*.

Two basic principles are often derived from human dignity. In France, for instance, human dignity has been divided, in law, to cover: '*le principe d'inviolabilité'* and *'le principe de non-patrimonialité'*. Whereas the first ensures protection against assaults to one's body, the second is meant to establish the basic idea that the human body cannot be the subject of a private right; that the human body cannot

Court of Appeal of California, *Baldwin v. Marina City Properties Inc.*, 1978, 79 Cal App. 3d 393, at 410).

42 Recital 16 Directive 98/44/EC: *'Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented'.*

be 'on the market'.[43] This latter principle of non-commercialisation of the human body has been enshrined in many conventions, including the Oviedo Convention on Human Rights and Biomedicine which states: *'The human body and its parts shall not, as such, give rise to financial gain'*.[44] The Group of Advisers on the Ethical Implications of Biotechnology to the European Commission similarly asserted that on basis of the principle of non-commercialisation of the human body no remuneration can be accorded to the donor of body samples.[45] The donation of body samples must be based on the generosity of the donor, the Advisers said.[46]

The situation is different however for third persons making inventions based upon such donation: they do not commercialise the human body as such. Hence the patenting of biotechnological inventions would be exempted from being contrary to the principle of non-commercialisation of the human body.

The issue at stake here however is not so much whether a donor is entitled to a piece of the economic cake, but more of whether he should be able to give his consent to the patenting of the said inventions. The Group of Advisers on the Ethical Implications of Biotechnology to the European Commission denied, as mentioned above, a right to remuneration in favour of the donor, but nonetheless recognized the donor's right to consent.[47][48] In this respect, human dignity could

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43 Cf. S. DEGORRE, *La protection juridique des inventions biotechnologiques*, at p. 12-13, available at : http://eurasante.com/polebio/etude11.html (last visited April 2007).

44 Article 21 'Prohibition of Financial Gain'.

45 GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY TO THE EUROPEAN COMMISSION, *Opinion N° 8: Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, 25 September 1996, at 2.3: *'The human body, at different stages of its constitution and development, as well as its elements, do not constitute patentable inventions. Such an exclusion does not come only from the usual conditions of patentability, but it is also inspired by the ethical principle of non-commercialisation of the human body. Therefore no patent can be given on the human body or on its elements. Also it follows that no remuneration to the person from whom the samples are retrieved, or to his/her eligible party, can be allocated'*.

46 GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY TO THE EUROPEAN COMMISSION, *Opinion N° 8: Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, 25 September 1996, at 1.7: *'The collection or sampling of elements from a human being relies on the consent, cooperation and generosity of the person collaborating in the research. It 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'*.

47 GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY TO THE EUROPEAN COMMISSION, *Opinion N° 8: Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, 25 September 1996, at 1.7.

require PIC to patenting because it safeguards the right of individuals to decide themselves to become involved in enterprises to the benefit of third parties.[49] This is underscored by Principle 8 of the Helsinki Declaration, which emphasises that special attention is required to those 'who will not benefit personally from the benefits of the research'.

A human dignity approach seems to stand at the other end of the spectrum of the basic philosophy underlying the patent system: utilitarianism. Considerations of human dignity therefore seem to lead to a negative reply to one of the major arguments against PIC, namely that research and hence society as a whole would be disproportionally burdened in relation to the benefit PIC has for individual persons. This is nonetheless the argumentation applied in the US Moore case: *'What Moore is asking us'*, the Supreme Court of California ruled, *'is to impose a tort duty on scientists to investigate the consensual pedigree of each cell sample used in research. To impose such a duty, which would affect medical research of importance to all of society, implicates policy concerns far removed from the traditional, two-party ownership disputes in which the law of conversion arose'*.[50]

4.3 The Right to Privacy

The right to privacy in the context of health is generally assured under Article 10 of the Oviedo Convention on Human Rights and Biomedicine[51] and Article 8 of the

48 This is in line with François Meienberg's argumentation on the reported workshop, saying: 'Subjects must be completely free to say "no" to the research, and no attempt should be made to coerce, manipulate or "buy" them into participation'; See F. MEIENBERG, *Access to Human Genetic Resources Results from a Transnational Stakeholder Dialogue*, presentation held at the workshop 'Human Rights in the Patent Procedure', available at: www.nccr-trade.org (last visited June 2007).

49 M. SCHEFER, *Human Rights and Patenting the Results of Research on Human Material*, Paper presented at the NCCR Workshop 'Human Rights in the Patent Procedure', Berne, 28 March 2007, at p. 9.

50 Supreme Court of California, *John Moore v. the Regents of the University of California (et al).*, 9 July 1990, No S006987, 51 Cal. 3d 120, at III, B, § 2.

51 Which reads: *'1. Everyone has the right to respect for private life in relation to information about his or her health. 2. Everyone is entitled to know any information collected about his or her health. However, the*

UNESCO Declaration on Bioethics and Human Rights.[52] It is one of the fundamental principles of the European Convention on Human Rights (Article 8) and of the International Covenant for Civil and Political Rights (Article 17).

By preventing the state from collecting personal information about an individual without his/her consent, privacy rights would provide an appropriate human rights basis for PIC in relation to patenting according to Markus Schefer. Privacy rights not only cover the *taking* of physical material, but also the *use* that may be made of the material. This latter is not covered by consent to research alone. Deciding to grant a patent has an impact on how personal information on an individual (in casu genetic information) will be used and needs therefore to be seen in the light of privacy rights.[53] In this respect, a 1986 California Court of Appeal's decision ruled: *'A patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress'*.[54] In the later US Moore case (1989), nonetheless, the privacy argument that *'if the courts have found a sufficient proprietary interest in one's persona, how could one not have a right in one's own genetic material, something far more profoundly the essence of one's human uniqueness than a name or a face?'*[55] was refused by the Supreme Court of California using the strongly criticized argument that *'lymphokines, unlike a name or a face, have the same molecular structure in every human being and the same, important functions in every human being's immune system'*.[56] Both arguments might be incorrect, however. Firstly, it can be argued whether someone's name or image really is less important, from a privacy point of

wishes of individuals not to be so informed shall be observed. 3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.'

52 Reading: *'In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected'.*

53 M. SCHEFER, *Human Rights and Patenting the Results of Research on Human Material*, Paper presented at the NCCR Workshop 'Human Rights in the Patent Procedure', Berne, 28 March 2007, at p. 4.

54 California Court of Appeal, *Bouvia v. Superior Court*, 1986, 179 Cal. App. 3d 1127. Cf. also New York Court of Appeal, *Schloendorrf v. Society of New York Hospital*, 1914,105 N.E. 92, at 93: *'Every human being of adult years and sound mind has a right to determine what shall be done with his own body'*.

55 Supreme Court of California, *John Moore v. the Regents of the University of California (et al.)*, 9 July 1990, No S006987, 51 Cal. 3d 120, at III, B, 1, § 5.

56 Supreme Court of California, *John Moore v. the Regents of the University of California (et al.)*, 9 July 1990, No S006987, 51 Cal. 3d 120, III, B, 1, § 5.

view, than one's genetic functioning. Secondly, one cannot say every human being has the same molecular structure.

Finally, the right to privacy has also a drawback in relation to PIC. The idea of incorporating an Article 8bis into the EU Biotechnology Directive, for instance, instead of the later drafted Recital 26, was blocked for it would be contrary to the protection of privacy rights. In fact, the planned article was drafted to require the name and address of the donor to be mentioned in the patent application.[57] This was found to be a violation of privacy rights despite the fact that this information would not be made public by the patent office.[58]

4.4 Conclusion

When discussing prior informed consent, the different stages at which this can apply must be disentangled. Whereas c*onsent to medical interventions* is widely established in international law and *consent to research* is regulated as well; *consent to patenting* and *consent to commercialisation* of inventions based upon the donated human genetic material is subject to little or no regulation.

Using human rights to assess the general desirability of patenting biotechnology might not lead us much further. In a general assessment, human rights might cut both ways. Even in limited areas of patent law such as PIC, the limits of human rights in assessing the utilitarian-based patent system are evident.

The right to privacy, the right to human dignity and the right to property might be involved in discussing PIC to patenting. However, it is the overall protection that counts in assessing human rights; hence the different rights that might apply must be balanced with one another. Similarly, the patent system is intended to benefit society at large, even if this might entail individual deprivation.

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57 See P. SAELEN, *Biotechnologische uitvindingen, octrooien en informed consent*, Vlaamse Raad voor Wetenschapsbeleid, 2002, at p. 171, available at: http://www.vrwb.be/MFiles/Studiereeks5.pdf (last visited June 2007).

58 See EUROPEAN COMMISSION, COM (97) 446def. – 95/0350(COD), 11 October 1997.

Practical obstacles might become apparent when considering the implementation of PIC. The first question to be answered is at what stage the consent should be given. This is important from a privacy point of view too; since donations mostly go into databases where they become untraceable to their donor. If however the consent must take place at an early stage; researchers might not be able to inform the donor as to what precisely will happen to his or her sample and the PIC might turn out not to be 'informed'. A uniform consent (to medical intervention, research, patenting and commercialisation) might hence not be desirable; yet a later and separate consent might not be a solution either. Similarly, as regards indigenous communities, it is not always possible to inform them on the concrete research that will take place or on what exactly 'patenting' means. Furthermore, in communities, families, or even territories, it is not always clear who should give the consent, how many people should consent, and whether group consent is enough.

The right to privacy, the right to human dignity and the right to property might have angles calling for PIC to patenting; yet whether this would justify the eventual burden on research and hence society as a whole remains doubtful.