BANKING OF HUMAN MATERIALS, INTELLECTUAL PROPERTY RIGHTS AND OWNERSHIP ISSUES:

INTERNATIONAL POLICY POSITIONS AND EMERGING TRENDS IN THE LITERATURE

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INTRODUCTION

The therapeutic utility of donated human tissue has long been recognised. Prior to and during the second World War, the development of routine tissue banking, especially of blood banks, gained momentum[1]. Tissue banks now exist for a variety of regenerative bodily substances and non regenerative tissue such as blood, sperm, skin, bone marrow, cells, eyes and bones[2].

Canadian society has generally perceived the gratuitous alienation[3] of body parts by individuals as "praiseworthy"[4]. This is in contrast to lucrative alienation which raises questions particularly where third parties are involved. Indeed, the issue of economic "worth" and interest in products developed from donated cells and tissues seriously strains the altruistic model[5]. The treatment of body parts and products as objects available for commerce, could be considered as the "commodification" of the human body and as an affront to respect for human dignity. Yet, only in very rare cases will an individual have cells containing the unique properties which, after biotechnical transformation, might lead to commercially exploitable products. In the event of such commercial breakthroughs however, a total prohibition on researchers and sponsors from recovering their investment of time, monies and ingenuity through eventual financial profit might ultimately discourage research leading to therapeutic developments profitable to the whole of society. Several recent examples illustrate the notion of the body/person as not merely a commodity but as a "natural resource", available for exploitation.

The central issue may be neither that of alienation of tissue *per se* nor even the possibility of economic reward but rather that of public confidence. As noted,"[i]f biotechnologists fail to make provision for a just sharing of profits with the person whose gifts made it possible, the public's sense of justice will be offended and no one will be winner."[6] Indeed, the larger policy questions of the role of industry as corporate "citizens" and of researchers within a publicly funded health care system has been neglected in favour of the more obvious and immediate issues of conditions of sampling or donation and payment for donation. Even if these latter issues are resolved, the more

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1 Law Reform Commission of Canada, *Procurement and Transfer of Human Tissues and Organs*, Working Paper 66, (Ottawa: Minister of Supply and Services Canada, 1992) at 23 [hereinafter LRCC].

2 For an overview of the purposes and operation of these banks see *ibid.* at 22-9.

3 For an overview of the ethical issues surrounding the sale-gift debate in Canada, see *ibid.* at 39. See also authors cited at *infra*, note 42.

4 *Ibid.* at 57.

5 *Ibid.* at 39; Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Commission on New Reproductive Technologies* (Ottawa, Minister of Government Services Canada: 1993) at 718 [hereinafter RCNRT].

6 T. H. Murray, Congressional Testimony in 1985, In: OTA, *ibid.* at 67.

general policy questions remain.

Once tissues and substances are removed from the body, who has rights, if any rights exist? Who has intellectual property rights - the patient/research participant, the researcher/institution, or industry, or both? Though generally classified as "gifts" of human tissue between the donor and recipient, Canadian common law does not deal specifically with the legal regime of removed tissues, substances and body parts nor with the issue of whether intellectual property rights may be granted with respect to third parties such as industry. In requiring that informed consent be obtained not only for research on any human material but also before any tissue removed from a person in the course of treatment be used for research[7], the Quebec Civil Code partially addresses these issues by considering the issue to be one of personality rights. Even so, for the most part, individuals, researchers and investors in Canada are left without explicit legislative or even ethical guidance.

The wide range of means and procedures by which human materials come to be banked further exacerbates this uncertainty. For example, in the case of DNA banks, samples are sometimes donated for storage by individuals or are stored as part of a research project. In such cases, individuals are most likely to have consented to the storage of their material or are aware of the practice. Samples will most likely be stored in a linked fashion thus allowing for identification of the sample following certain procedures. In most cases however, samples will be routinely sent for storage in banks by medical practitioners sometimes for pathological purposes, other times for simple conservation such as tumor banks. In such cases, consent for further use of the sample is usually not obtained. The bank may be uncertain as to whether they can be used. If samples have their identifiers removed or simply linked to a geographic region would further use without consent be possible?[8] This spectrum of sources of stored human material and the varying scopes of informed consent means that collections of samples cannot be treated as homogenous, free to be used for any type of research or without any conditions.

Internationally, the need to protect and compensate researchers for their innovative work leading to therapeutic applications and products that benefit society has long been recognized[9].

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7 Under the 1994 Civil Code of Quebec, article 22 provides that: "A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purposes of research." It remains unclear however whether this article applies to research using samples that have been anonymized.

8 B.M. Knoppers & C.M. Laberge "Research and Stored Tissues: Persons as Sources, Samples as Persons?" (1995) 274:22 JAMA 1806-1807; E.W. Clayton et al., "Informed Consent for Genetic Research on Stored Tissue Samples" (1995) 274:22 JAMA 1786-1792; J. Sugarman et al., "Ethical Aspects of Banking Placental Blood for Bone Marrow Transplantation" (1995) 274:22 JAMA 1783-1785. American College of Medical Genetics (ACMG), "Statement on Storage and Use of Genetic Materials" (1995) 57 Am. J. Hum. Genet. 1499-1500.

9 The 1948 *Universal Declaration of Human Rights,* GA Res. 217/A, 3 U.N. GAOR Pt. 1, UN Doc. A/810 (1948)(preamble), article 27, acclaims the right of everyone "freely ... to share in scientific advancement and its benefits". The *International Covenant on Economic, Social and Cultural Rights*, (1976) 993 U.N.T.S. 3, which came into force in 1976, more specifically recognises at article 15(b), the right of everyone "to enjoy the benefits of

Irrespective of the country or of the applicable legal regime, however, traditional attitudes whereby individuals had little interest in their removed bodily materials, appear to be progressively changing. In certain European countries, the ethical and policy discourse has long been underway[10]. Policy positions from international, regional and national bodies have been developed on various aspects of the use of human tissue and body parts indirectly addressing or founding their position on a presumption of a legal relationship of a person with respect to his/her body parts, tissues and cells once they are removed from the body. More explicit and specific policy positions have also been developed on the separate issue of intellectual property rights in human tissues or in products derived from human tissues. The question of legal status (property or person) has always influenced how researchers interact with individuals who provide the material necessary for research endeavours. It also affects any claims an individual might have in eventual commercial products. The current trend towards a more informative and detailed consent undermines the personal vs. property rights debate in the banking arena in that such consent can flow from the application of either approach. The person vs property classification may however, remain relevant to intellectual property issues. Moreover, the issue of the role of the biotechnology industry and of the researcher in society cannot be ignored. The legal and bioethics literature on these issues and in particular on the controversial patent issue has been growing and serves to broaden our understanding of emerging trends.

This study aims at surveying the emerging trends in the published literature (Section 1) as well as the different international, European and national published policy positions (Section 2) on the issues of ownership and intellectual property rights in banked human material. Extensive focus will given to documents discussing the relationship between individuals (or sample "sources"[11]) and their banked human material, and any claims "sources" may have over patented products derived from their biological material. Other equally important issues raised by the banking of human materials, such as the right to privacy and confidentiality, and access to samples, will only be explored to the extent that they relate to the main topic. In addition, the highly technical issue of intellectual property protection of the results of biomedical research will not be analysed exhaustively and extensively but only to the extent that the issue reflects the current debate on patent protection of genes of unknown function.

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scientific progress and its applications". For an interesting study of the economic dynamics (between researcher, academia, government and industry) of the genotechnology industry see M.J. Malinowski & M.A. O'Rourke, "A False Start?: The Impact of Federal Policy on the Genotechnology Industry" (1995) Yale J. Reg. (Forthcoming); For the perspective of industry, see G. Poste, "The Case for Genomic Patenting" (1995) 378 Nature 534-536.

10 See *infra*, Section 2.1.

11 See *supra*, note 6.

SECTION 1 - EMERGING TRENDS IN THE LITERATURE

In the context of this study, the terms "personal rights" and "property rights" approach reflect two different philosophical approaches of the relationship between a person and her or his body parts and material once they are removed from the body. In referring to these two approaches, one is not referring to explicit and comprehensive legal regimes but rather to philosophical bases that form the opposing ends of a scale along which are identified diverse legal regimes. Both the personal rights and the property rights approaches are based on certain preconceptions about the issues of the status of the human person and of human material and its commercialisation and patentability. In order to discern emerging trends and to understand why various policy approaches have been developed, then, we shall briefly overview the literature on the personal and property rights approaches, the proposed alternatives and the policy issues surrounding patenting.

Section 1.1 - Approaches to Ownership of Human Tissue

The legal relationship between a person and her or his bodily material once they are removed from the body, are generally of two types: a personal rights (§ A) or a property rights (§ B) approach.

§ A - Personal Rights Approach

A personal rights approach reflects both the classical Common Law and Civil Law enshrinement of the principle that the human person is not a commodity subject to property rights[12]. Thus, in general terms, the legal status of human material may be negatively defined as being neither the person nor a commodity that can be appropriated, but rather a part of a person. It is this relation it maintains with the person from whom it originated that warrants that the integrity of the person still apply to the material once removed from the body. In a personal rights approach, an individual right to integrity includes respect for bodily material once removed from the body and still identifiable to that person. The mechanism employed to ensure respect and protection of the integrity of the person and of bodily material is informed consent. As a component of a person's integrity, personal dominion over bodily material will be ensured by requiring that the informed

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[12] For brief descriptions of these classical principles in common law see: LRCC, *supra*, note 1; M.M. Litman, & G.B. Robertson "Reproductive Technology: Is a Property Law Regime Appropriate?" in *Overview of Legal Issues in New Reproductive Technologies* (Volume 3 of the Research Studies, Royal Commission on New Reproductive Technologies) (Ottawa: Minister of Supply and Services Canada, 1993) at 243. B.M. Dickens "The Control of Living Body Materials" (1977) 27 University of Toronto Law Journal 142. And in Civil Law see: J.-L. Baudouin, "La personne humaine au centre du droit québécois" (1966) 26 Revue du Barreau 66; J.-L. Baudouin & C. Labrusse-Riou, *Produire l'Homme: de quel droit?* (Paris: Presses Universitaires de France, 1987) at 185-7. See also: Ontario Law Reform Commission (B.M. Knoppers ed.), *Genetic Screening: An Analysis and Proposal for Legislative Reform in Ontario*, see chapter *Property Rights and Genetics*, (1996)[forthcoming]; M. Hirtle & B.M. Knoppers, "Civil Law, Property Rights and Human Genetic Material" (1996) [forthcoming].

consent of the person from whom the material originated be secured and by providing remedies for any harm resulting from non compliance.

Yet, since the current legal doctrine of informed consent "fails to require disclosure regarding what will happen to the patient's body parts after they have been removed from her body"[13], an expansion of the informed consent doctrine[14] has been proposed in order to ensure respect for the person's integrity in removed bodily material. Hence, it is argued that a person's right to self-determination encompasses a "dignitary interest in one's body and extracorporeal body parts"[15]. This includes the right to control what happens to excised tissues and cells, an interest wholly distinct and independent from property rights[16]. An expanded doctrine of informed consent would impose a duty on the physician to disclose not only the risks and benefits associated with a certain medical treatment, "but also the proposed use, if any, of the patient's body parts."[17] The provisions of the new Civil Code of Quebec on consent, treatment and research[18] constitute an expansion of the informed consent doctrine with respect to bodily integrity and privacy since informed consent will need to be obtained prior to the subsequent use of any bodily material removed form the body during medical care.

In addition to respect for the inviolability and integrity of the person, additional sources of personal control over the disposal of bodily material and information are founded on respect for fundamental rights and freedoms such as the rights to liberty and privacy as found under public law[19]. Indeed, the right to privacy provides protection for genetic material and information[20] since

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13 S.N. Perly, "From Control Over One's Body to Control Over One's Body Parts: Extending the Doctrine of Informed Consent" (1992) 67 New York University Law Review 335 at 337. For a discussion of these issues see also G. Dworkin & I. Kennedy, "Human Tissue: Rights in the Body and its Parts" (1993) 1 Medical Law Review 291.

14 "The doctrine [of informed consent] protects a patient's right to self-determination - the right to possession and control of her own person - by mandating that a physician seek and secure a patient's informed consent before commencing an operation or other course of medical treatment." Perly, *ibid,* at 336-337.

15 *Ibid.*

16 *Ibid.* at footnote 13. Perley distinguishes his proposal from that of other commentators which suggest an extended informed consent doctrine but rely upon recognition of property rights.

17 *Ibid.*

18 See below Section 2.1, § C.

19 Such protection is afforded through the Canadian *Charter of Rights and Freedoms*, Part 1 of the *Constitution Act, 1982*, Schedule B of the *Canada Act* (U.K.), 1982, c.11, section 8. See *R.* v. *Dyment* [1988] 2 S.C.R. 417. See also B.M. Knoppers, *Human Dignity and Genetic Heritage, Protection of Life Series Study Paper* (Ottawa: Law Reform Commission of Canada, 1991) at 38. These fundamental rights are also found under Civil law regimes, for example in the Quebec *Charter of Human Rights and Freedoms*, S.Q.1975, c. 6, R.S.Q. c. C-12. See H. Guay, B.M. Knoppers, "Information génétique : qualification et communication en droit québécois" (1990) 21 R.G.D. 545 at 562.

it protects against unwarranted intrusions on the body as well as unauthorised procedures to obtain information about a person.

§ B - Property Rights Approach

Strong arguments have also been made in favor of recognition of proprietary interests in extracorporeal material[21]. It has been submitted that a property framework may be the most efficient way of protecting rights of patients and of research subjects since property law provides precise rights of control and thus would recognize people's interest in controlling what happens to their body parts[22]. Principles of equity and fairness would be better served and unjust enrichment prevented[23]. Characterizing body parts as property does not mean however, that they must be

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For an overview of the various approaches under Civil Law see M. Hirtle & B.M. Knoppers, *supra*, note 12.

20 *R.* v. *Dyment, ibid.* Protection is also afforded under the rights to integrity and to autonomy. H. Guay & B.M. Knoppers, *ibid.*, at 562-566. See also E. Deleury & D. Goubau, *Le droit des personnes physiques*, (Cowansville: Les Éditions Yvon Blais, 1994) at 137-138.

21 For a common law perspective in favor of property rights see: R. Hardiman, "Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue" (1986) 34 UCLA Law Review 207; I.J. Churchill, "Patenting Humanity: The Development of Property Rights in the Human Body and the Subsequent Evolution of Patentability of Living Things" (1994) 8 I.P.J. 249; B.G. Hanemann, "Body Parts and Property Rights: A New Commodity for the 1990s" (1993) 22 Southwestern University Law Review 399; J.M. Gilmour, "Our Bodies: Property Rights in Human Tissue" (1993) 8:2 CJLS 113; W. Greenberg & D Kamin, "Property Rights and Payment to Patient for Cell Lines derived from Human Tissues: An Economic Analysis" (1993) 36:8 Soc. Sci. Med. 1071; 1. Davies, "Live Donation of Human Body Parts: A Case for Negotiability" (199) 59:2 Medico-Legal Journal 100; B.M. Dickens, "Living Tissue and Organ Donors and Property Law: More on *Moore*" (1992) 8 Journal of Contemporary Health Law and Policy 73; L.B. Andrews, "My Body, My Property" (October 1986) Hasting Centre Report 28. For a civil law perspective in favour of property rights, see: N. Mazen, "Réflexions juridiques sur le matériel génétique de l'homme" in R. Drai & M. Harichaux, *Bioéthique et Droit*, (Paris: Presses Universitaires de France, 1988); J.-C. Galloux, "Réflexions sur la catégorie des choses hors-commerce: l'exemple des éléments et des produits du corps humain en droit français" (1989) 30 Les Cahiers de droit 1011; J.-C. Galloux, "De la nature juridique du matériel génétique ou la réification du corps humain et du vivant" (1989) 3 Revue de la Recherche Juridique 517; N. Lenoir, "La protection des données issues des recherches sur le vivant" (1994) 28:3 Bulletin du droit d'auteur 3; M. del Corral, "Aspects juridiques de la protection du génome humain" (1994) 28:3 Bulletin du droit d'auteur 13; G. Kutukgjian, "La brevetabilité des gènes et des séquences de gènes humains" (1994) 28:3 Bulletin du droit d'auteur 26.

22 Andrews, *ibid*, at 29.

23 In pursuing similar interests of justice and equity, B. Hoffmaster, "Between the Sacred and the Profane: Bodies, Property, and Patents in the *Moore* Case" (1992) 7 I.P.J. 115-148, suggests that instead of trying to solve the tissue ownership issue, the broader issue of entitlement to a share of the profits should be addressed. He proposes a legislation licensing scheme for the sharing of profits with those that made the research possible.

completely transferable as restrictions on alienability may be imposed[24]. In this line of thought, a study paper presented to the Royal Commission on New Reproductive Technologies, maintains that rejection of the property approach to control over one's extracorporeal material stems from misconception of the modern concept of property[25]. The legal concept of property refers not to material objects but to a bundle of rights, the "rights of control and domination over both tangible and intangible things or spheres of activity."[26] Viewed in terms of control over one's body, property rights enhance personal dignity rather than diminish it.

Prior to the French legislation of 1994[27], several French commentators on civil law had proposed a property rights approach to control over human genetic material. Accordingly, human genetic material is the person's property and may be the object of commercial transactions, even if they are gratuitous[28]. Individuals maintain personal control over removed material from their bodies. Thus, abandonment or donation of tissue or bodily material may not be presumed but rather requires intentional abandonment or donation[29]. Another author proposed that the legal regime of human genetic material be based on the legal regime of assigning property to a person, that is, that property has a formal assignment[30]. Biological material is naturally assigned to a person's body.

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24 Andrews, *supra*, note 22 at 29. See also J. Horton, "A Personhood Analysis of Property Rights in the Human Body" (1995) 11:2 C.I.P.R. 213-231.

25 Litman & Robertson, *supra*, note 13. It is interesting to note that these authors do not suggest a property rights approach to human material (in this case fetuses and embryos) but rather a *sui generis* approach. See below section 1.1 § C.

26 *Ibid.* at 243.

27 See *infra* note 92.

28 Mazen, *supra*, note 21 at 204, 207: "We believe it is wrong to claim that the human body as a whole and particularly genetic material are unavailable and excluded from all legal agreements. At the most, they enjoy a specific legal protection because of the cause which renders illegal any act that is contrary to public order and good morals." [Our translation] See also Byk, *infra*, note 47 at 303-4, states that extra-corporeal DNA becomes a *res* but that only the physical element is a matter of property, the informational element being the common heritage of mankind.

29 Mazen, *ibid.* at 200, 204, 207.

30 Galloux (1989), *supra*, note 21. Characterizing genetic material as a thing in no way determines the legal *regime* applicable to it, that is whether it may be appropriated or be an object of commercial transactions. Galloux bases his analysis of the legal *regime* of genetic material on the legal process of assigning property to a person. The concept of extra commerciality of the human body, essential to the protection of the dignity of human beings, cannot be legally coherent and useful unless it is absolute. And yet in practice, this condition is never satisfied. Accordingly, Galloux's theory proposes that a temporary absolute character of extra-commerciality be recognized and that notions of assignment be attached to body parts. Biological material is naturally assigned to a person's body. A person may, if he or she desires, put an end to the natural and original assignment of his body parts or products, just as he may consider such assignment to continue despite their removal from the body and even during their conservation by a third party.

Even if removed from the body and detained by third persons, the natural assignment of human genetic material to the person will change only after the expressed consent of that person. Only when that human material is no longer assigned to a person may it be the object of commerce[31].

§ C - Alternative Approaches

Several interesting alternative approaches have been proposed by Canadian authors. In 1989, Marusyk and Swain proposed a three-tiered legal classification of human substances[32]. The first level looks at the human body as a whole (including the *persona*). Thus the sum total of tissues, organs and genetic material that create a unique individual would "fall under the classification of property rights in that person" as long as the parts remain in that person. The second level of the legal structure covers *res nullius*, things without an owner. Bodily material removed from the body in a way that no longer serves the original possessor would fall into this category. Such extracorporeal material would become a corporal moveable owned by no one and ownership could be acquired by the first person to take possession of the material. The third tier of the legal structure characterizes bodily material permanently removed from the body as *res communes omnium,* the common property of all. This approach would prevent human material from becoming a marketable commodity but would allow a product derived from human material through labour and technology to generate property rights[33].

A somewhat similar approach to the three-tiered legal structure has been proposed by civil law commentators and may be translated as a theory of gradual distancing[34]. This theory is directly rooted in Quebec civil law. It suggests that the human body be considered on three levels. When the body is a comprehensive entity, it follows the personal interests of the person. The second level of distancing, refers to body parts removed from the body that may be "alienated" and thus are no longer "parts of persons" but have become things. The gratuity of the alienation reflects the respect due to these bodily parts such as organs[35] . At the third level of distancing, it is maintained that as

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31 *Ibid.*

32 M.S. Swain & R.W. Marusyk, "An Alternative to Property Rights in Human Tissue" (September/October 1990) Hasting Center Report 12; R.W. Marusyk & M.S. Swain, "A Question of Property Rights in the Human Body" (1989) 21:2 Ottawa Law Review 351. This approach has previously been summarized in Ontario Law Reform Commission *supra*, note 12.

33 Swain & Marusyk (1989), *ibid* at 381.

34 J. Goulet, "Appropriation of the Human Being: An Essay on the Appropriation of the Human Body and its Parts" in *Overview of Legal Issues in New Reproductive Technologies* (Volume 3 of the Research Studies, Royal Commission on New Reproductive Technologies) (Ottawa: Minister of Supply and Services Canada, 1993) 595 at 606; This theory was analysed in M. Hirtle & B.M. Knoppers, *supra*, note 12.

35 Goulet, *ibid.* at 608.

the distance increases between the extracorporeal material and the person from whom it originated, the restrictions imposed on the circulation of the human material would decrease accordingly[36]. General rules of property law and ownership would govern removed body parts once they are at the third level of distancing.

Finally, a report presented to the Royal Commission on New Reproductive Technologies proposed a unique, *sui generis* regime for the qualification of the juridical character of an object[37]. A *sui generis* interest need not have any particular characteristics as the utility of this category is precisely that courts may develop the law relating to a particular object on a case-by-case basis, "without the fetter of proprietary or other preconceptions."[38] However, "in practice ... *sui generis* interests, as they relate to objects, will always have proprietary characteristics. Some degree of control will be conferred on someone."[39] Maintaining that a property rights discourse should not be used with respect to human genetic material for symbolic as well as political reasons, the *sui generis* regime was submitted since it does not reject property principles, some of which are useful in defining the type of control over human material, and would afford courts latitude in interpretation without "evoking an unwarranted and unnecessary emotional debate."[40]

It should be noted that although possible economic value that is, commercialism, and property overlap, the former should not automatically be associated with the latter. Moreover, underlying the debate on the applicable legal regime is that of sale or gift of human material[41].

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36 *Ibid.* at 609: "Applying the principle of this theory, it must be agreed that, unless it is separated only temporarily for curative purposes, a part removed from the human body with the consent of the person concerned becomes a thing, an object that can be appropriated, movable property that is initially owned by the person from whom it originates but can be alienated to any other person to whom it is properly assigned."

37 Litman & Robertson, *supra*, note 12 at 247: "This classification is resorted to when the implications of ascribing an object to an established legal category is considered inappropriate or, at least, not wholly appropriate." In the case of human material, a *sui generis* regime has the advantage of recognizing their unique nature (i.e. distinct from ordinary things or from persons) and avoiding the often repugnant commodity property discourse, while allowing recourse to proprietary or other principles in defining and establishing personal interests over removed bodily material.

38 *Ibid.* at 247-8. Litman and Robertson describe, at 244-245, that proprietary preconceptions, or standard proprietary incidents, include extensive and not mutually exclusive rights, powers, immunities, priviledges and obligations, such as: right of possession, right of exlcusion, power of alienation, liberty to use, enjoy and manage, right of destruction and injurious use, and the right to the fruits and profits. Proprietary interests may be composed of all of these incidents collectively of a fewer number of these.

39 *Ibid.* at 248.

40 *Ibid.* at 268.

41 The status of human material and of the regime that applies to it (personal or property rights) is also relevant to the issue of procurement of human tissue that involves, however, other elements that fall outside the scope of the following study. On the issues of sale or gift of human tissue see, respectively, L.B. Andrews, *supra*, note 22; T. H. Murray, "Gifts of the Body and the Needs of Strangers" (April 1987) Hastings Centre Report 30.

Whether the gift philosophy prevails or rather the possibility of selling one's human material, underscores the role of the citizen in society, that is contributing freely to the common good or seeking to "profit" from one's materials. Whether or not the legal regime espoused is one of personal rights or of property rights may however be irrelevant as is evident in the contentious issue of patenting.

Section 1.2 - Approaches to Intellectual Property Protection

In recent years, the issue of patenting human genes has become increasingly controversial. The potential commercial exploitation of research in human genetics adds a certain urgency to the need to find a suitable means of protecting research results and stimulating such research while considering industrial and academic interests as well as the attendant controversial moral and ethical concerns surrounding the use(s) of human genetic material.

At the outset of the controversy, is the debate over the most suitable legal form of eventual intellectual property protection of human genetic material. The most widely sought protection has been that of patent rights, although strong arguments have been made in favour of copyright protection[42] and a hybrid or *sui generis* protection[43] . During a 1995 UNESCO international workshop on legal systems of protection of research results in genetics, consensus seems to have been reached by the international commentators in favour of patent protection[44] for the results of human genetic research. Opting for protection through the patent system, appears to be in accordance with growing practice[45]. In fact, as we will see below, under current European and US.

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[42] M. del Corral, *supra*, note 22; D.M. Hogle, "Copyright for Innovative Biotechnological Research: An Attractive Alternative to Patent or Trade Secret Protection" (1990) 5:1 High Technology Law Journal 75; N.M. Derzko, "Protecting Genetic Sequences under the Canadian *Copyright Act*" (1993) 8 I.P.J. 31.

[43] P. Gannon & T. Guthrie & G. Laurie, "Patents, Morality and DNA: Should There Be Intellectual Property Protection of the Human Genome Project?" (1995) 1:4 Medical Law International 321 at 338-9; J.H. Barton, "Adapting the Intellectual Property System to New Technologies" (1995) 10 Int. J. Technology Management 151 at 161.

[44] UNESCO, *International workshop on legal systems of protection of research result in genetics* , Paris 30-31 January 1995. Also to this effect see, R.L. Baechtold *et al.*, "Property Rights in Living Matter: Is New Law Required?" (1991) 68 Denver University Law Review 141; K.H. Murashige, "Intellectual Property and Genetic Testing" in *The Genetic Frontier: Ethics, Law, and Policy* (Washington, DC: American Association for the Advancement of Science, M S. Frankel and A.H Teich, 1994) at 182-3. For an overview of patent law application to human genetic material see T. Caulfield, K. Cherniawsky, E. Nelson, "Patent Law and Human DNA: Current Practice and Future Problems" (1996) [Forthcoming]. Malinowski & O'Rourke, *supra*, note 9; Poste, *supra*, note 9.

[45] See D. Butler, "Patent System Gets Vote of Support from Gene Workers" (1995) 374 Nature 376; H. Gavaghan, "NIH Wins Patent on Basic Technique Covering All *ex vivo* Gene Therapy" (1995) 374 Nature 393; D. Mackenzie, "Patents on Life Sneak Through the Back Door" (1994), New Scientist, 14 May, 6; A. Coghlan, "Outrage Greets Patent On Designer Sperm" (1994) New Scientist, 9 April, 4; R. Herman, "One Patenting Gene's Astounding Success Story" (1992) *Washington Post Health*, 16 June; C. Anderson, "EC Look to Animal Patents" (1991) 353

patent laws, inventions derived from or containing human genetic material are generally considered as patentable subject matter by patent offices. In addition, human genes and DNA sequences of demonstrated purpose as well as related processes are patentable[46].

Despite this seemingly established practice, patent applications on DNA sequences remain controversial. The gene patenting controversy arises from international tension symptomatic of the opposing views and attitudes of government agencies (mostly US and European), researchers, industries, non governmental organisations and lay persons[47], based not only on the property-person, sale-gift dichotomies, but also on differing interpretations of the actual and potential reach of patent law. While differences in US. and European patent laws may be at the source of some difficulties encountered in attempting to resolve this controversy, in general, competing arguments as found in the literature may be summarized under three headings: ethical, industrial policy, and legal.

Nature 8; A. Coghlan, "Genome Funds Wasted On Patents" (1991) New Scientist, 7 September, 22; M. Sun, "Part of AIDS Virus Is Patented" (1988) 239 Science 970; C. Ezzel, "AIDS Envelope Protein Patent" (1988) 331 Nature 649.

46 A. Pompidou, "Research on the Human Genome and Patentability - The Ethical Consequences" (1995) 21:2 Journal of Medical Ethics 69; Judge C. Byk, "Patenting Human Genes" (1994) 5:4 Inter. J. of Bioeth. 301 at 305; Murashige, *supra*, note 45 at 188. Well known examples of such patents are those on cell lines derived from genetic material from John Moore and from the Hagahai people in Papua New Guinea. The patent application was dropped on the cell line derived from a Guaymi Indian woman from Panama and apparently dropped on that from an indigenous person form the Solomon Islands. See UNESCO, *Bioethics and Human Population Genetics Research, supra*, note 6. See also Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (London: Nuffield Council on Bioethics, April 1995) at 86 for additional examples.

47 See, for example: RAFI Communique 1995, *supra*, note 6; A. Coghlan, "Licensed to Sell the Stuff of Life" (1995) New Scientist, 11 Feb, 12. M. Ward, "Europe's Unknown Patent Future" (1995) 13 Bio/Technology, January, 21; D. Dickson, "British MPs Likely to Oppose Gene Patents" (1995) 373 Nature 550; S. Lehrman, "Coalition Plans Challenge to Genetic Patenting in the US" (1995) 375 Nature 268; R. Stone, "Sweeping Patents Put Biotech Companies on the Warpath" (1995) 268 Science 656; R. Stone, "Religious Leaders Oppose Patenting Genes and Animals" (1995) 268 Science 1126; F.B. Charatan, "US Religious groups oppose gene patents" (1995) 310 BMJ 1351; A. Coghlan, "Sweeping patents shocks gene therapists" (1995) 1 April, New Scientist 4; "Broad Coalition Challenges Patents on Life: Blue Mountain Declaration" (June, 1995); RAFI Communique, "The Patenting of Human Genetic Material" (Jan/Feb 1994); RAFI Communique, "'Gene Boutiques' Stake Claim to Human Genome" (May/Jun 1994); D. Gershon, "US and British Researchers Agree Not to Seek Gene Fragment Patents" (1994) 367 Nature 583; D. Dickson, "HGS Seeks Exclusive Option On All Patents Using Its cDNA Sequences" (1994) 371 Nature 463; E. Marshall, "Biotech Leaders Give Patent Office a Litany of Complaints" (1994) 266 Science 537; A. Abbott, "Protein Gene Faces Challenge In Court" (1994) 371 Nature 645; D. Dickson & D. Butler, "EU States Back Biotech Patent Reform" (1993) 366 Nature 713; T. Wilkie, "Charities Join Forces Against Patenting of Human Genes" (1993) The Independent, 17 November, 10; D. Dickson, "UK Clinical Geneticists Ask for a Ban on The Patenting of Human Genes", (1993) 366 Nature 391; C. Mailwain, "OTA Panel Opens Inquiry into Patenting of Genes" (1993) 362 Nature 386; C. Anderson, "Gene Wars Escalate as US Official Battles NIH Over Pursuit of Patent" (1992) 359 Nature 467; C. Anderson, "Gene Wars Escalate as US Official Battles NIH Over Pursuit of Patent" (1992) 359 Nature 467; C. Anderson, "NIH cDNA Patent Rejected; Backers Want To Amend Law" (1992) 359 Nature 263.

§ A - Ethical Concerns

Opposition to the patenting of human genetic material is often based on the recognition of rights of ownership, that is exclusive rights of exploitation, over human biological material that are an intrinsic part of human beings[48]. Strong ethical arguments against patenting genes are also based upon the premise that genes are the common heritage of mankind[49] and as such, may not be appropriated. Further arguments of privacy[50] and distributive justice[51] have also been raised. Interestingly, ethical concerns in favour of patenting have also been raised. Based on concepts of fairness and efficiency[52], not rewarding researchers for work which eventually benefits society as a whole is deemed unethical. Controversy may stem from different perceptions of what it is that is being patented[53]: life forms, genetic information, or an innovative process. In the event of genes of unknown function the distinction may be even harder to draw. As we will see below, however, the greatest challenge of the gene patent controversy is ensuring that these ethical concerns are considered.

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48 Westminster Institute for Ethics and Human Values & McGill Centre for Medicine, Ethics and Law, *Ethical Issues Associated with the Patenting of Higher Life Forms*, December, 1994, at 79ff.

49 B. Looney, "Should Genes be Patented ? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement" (1994) 26 Law & Policy in International Business 231 at 236-7; Pompidou, *supra*, note 47 at 70; A. Khan, "Faut-il breveter le génome humain?" (1991) Médecine/science 960 at 961; Gannon, *supra*, note 44 at 324ff.; Del Corral, *supra*, note 22 at 15. For a discussion on the arguments invoking the human dignity doctrine see T. Peters, "Intellectual Property and Human Dignity" in Frankel and Teich, *supra*, note 45 at 219; Byk, *supra*, note 47 at 304; See also a discussion on the doctrine if the common heritage of mankind as applied to human genetics: B.M. Knoppers, *supra*, note 19.

50 Looney, *ibid.* at 238: "Patenting genes and gene sequences may interfere with privacy rights in that it permits an interference with a bodily part....[Genes] are in a zone of privacy that may be violated by assignment of gene patent rights to others. A collective privacy right may also be patented by gene patenting."

51 *Ibid.* at 239-40:

> "The ability to identify gene sequences has been made possible by the scientific and financial contributions of peoples around the world, all of whom are entitled to benefits from these advances" ... "Distributive justice requires that less developed countries not be excluded from the benefits of gene research. ... Gene patenting is ethically suspect if it concentrates genome benefits in those few countries fortunate enough to have the resources to obtain gene patents, when all human should enjoy such benefits. Thus, under principles of distributive justice, all the world's citizens are entitled to genome research and its benefits, unencumbered by intellectual property rights."

52 *Ibid.* at 240-243. See also Poste, *supra*, note 9.

53 Westminster Institute for Ethics and Human Values & McGill Centre for Medicine, Ethics and Law, *supra*, note 48.

§ B - Industrial Policy Concerns

Industrial policy arguments foresee several possible outcomes for gene patenting. A recent study notes that willingness in the United States to recognize and protect intellectual property rights in technological advances is a manifestation of the desire to advance genotechnology in the US[54]. However, these authors recognize that "[t]o the extent that the PTO has de facto relaxed its requirements for genotech inventions and will issue more questionable patents, the rest of the industry bears the burden of either litigating the validity of these patent or entering into license agreements with those who hold them."[55] The validity of such patent applications remain unclear and controversial, as the unsuccessful NIH gene patent application, followed by that of the UK Medical Research Council, exemplifies[56]. More importantly, the impact of gene patenting applications on the dissemination of genomic information and on international cooperation and collaboration is troublesome[57].

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54 Malinowski & O'Rourke, *supra*, note 9.

55 *Ibid.*

56 The policy discourse justifying the NIH patent application on gene sequences, talked of the promotion of technology transfer and product development by awarding exclusive licenses to US companies to give them an extra edge in commercial product development. Companies were opposed to such a strategy viewed as increasing obstacles in product development rather than as an incentive. See B. Healy, "Special Report on Gene Patenting" (1992) 327:9 The New England Journal of Medicine 664.; R. Eisenberg "A Technology Policy Perspective on the NIH Gene Patenting Controversy" (1994) 55 University of Pittsburgh Law Review 633 at 635ff; R. Eisenberg, "Genes, Patents, and Product Development", (1992) 257 Science 908; R.G. Adler, "Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization" (1992) 257 Science 908; P. Aldhous, "MRC Follows NIH On Patents" (1992) 356 Nature 98. Malinowski & O'Rourke, *supra*, note 9, "Simply stated, while the United States through the NIH may have "jump started" the genotech industry by encouraging early patenting of discoveries, it has succeeded primarily in sowing confusion and mounting litigation. These controversies demonstrate that the PTO's application for statutory standards in the context of genotechnology should be scrutinized for consistency with traditional application standards and the fundamental objectives of the patent system to ensure that policy objectives underlying those standards are not lost."

57 See Eisenberg (1994), *ibid.* at 641ff; R.S. Eisenberg, "Patenting the Human Genome" (1990) 39 Emory Law Journal 721 at 74ff; Healy, *ibid.* at 666; Khan, *supra*, note 49 at 961. Murashige, *supra*, note 44 at 193ff; J. Overhauser, "Intellectual Property and Genetic Testing: A Scientist's Perspective" in Frankel and Teich, *supra*, note 44 at 211-212; For a discussion of this issue in general, see R.S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 The University of Chicago Law Review 1017; See also Adler, *ibid.*; J. Carey, "The Gene Kings" (1995) Business Week, 8 May, 72; G. Bylinsky, "Genetics: The Money Rush is On" (1994), Fortune, May 30, 94.

§ C - Legal Concerns

Turning to the legal debate as found in the legal literature, the determination of whether genes are patentable rests on two criteria: the first is the threshold criterion of patentable subject matter; and, the second, the technical criteria that refers to novelty, non-obviousness and utility (usefulness being the European counterpart) of any inventions[58]. Of upmost interest for our purposes is the latter criterion. Several commentators have argued that the main issue will be to determine the degree of utility necessary for patenting. Here the debate turns on whether gene sequences of unknown function may be patented[59]. Distinctions between fundamental and applied research are also at issue[60]. Fundamental research has long been categorized as knowledge belonging to the public domain, "freely available for further use"[61], and thus unlike applied research, not patentable. Research in biotechnology, however, may be difficult to clearly categorize. It has also been suggested that human genes lack the novelty required[62] and that awarding patents over genetic material could hinder downstream patent applications over products eventually derived from genetic sequences[63]. Other commentators argue that human genes will probably meet all the technical requirements[64] and that the "true" issue at stake is the threshold criterion of patentable

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58 Looney, *supra*, note 49; For a discussion on this last criterion of utility see R.S. Crespi, "What's the Use in Patent Law"(1993) 11 Tibtech 407.

59 Healy, *supra*, note 56 at 665ff.; N.H. Carey & P.E. Crawley, "Commercial Exploitation of the Human Genome: What are the Problems?" in Ciba Foundation Symposium, *Human Genetic Information: Science, Law and Ethics* (Chichester, UK: John Wilezandsons, 1992) at 133; Barton, *supra*, note 43 at 166; Crespi, *ibid.* at 407-408; T.J. White, "Intellectual Property and Genetic Testing: A Commentary" in Frankel and Teich, *supra*, note 44; Overhauser, *supra*, note 57 at 209; Peters, *supra*, note 49 at 216; Pompidou, *supra*, note 46 and Byk, *supra*, note 46, argue that human genetic material is not patentable per se but that their functions or application will be patentable; see also Adler, *supra*, note 57 at 910; D.J. Kevles & L. Hood, *Code of Codes: Scientific and Social Issues in the Human Genome Project* (Cambridge: Harvard University Press, 1993).

60 Under US law, it was settled that while naturally occurring phenomena are not patentable subject matter, genetically engineered living organisms may be so. "*Chakrabarty* reiterates the historic substantive distinction between discovery and invention. Discovery of a naturally occurring phenomeon, despite the fact that it may require a large investment, is not patentable while invention -- human-engineered transformations of natural substances-- may be. Thus, pursuant to existing PTO policy and established law, patent protection will apply to "those organisms that an inventor has altered in a new and useful way or to genes when they have been isolated as synthetic molecules, *a form in which they do not occur in nature.*" Additionally, however, it appears that, even in cases in which a researcher only determines the sequence of DNA, which seems to resemble a "discovery" rather than an invention, a patent may still issue." [Footnotes omitted] See Malinowski & O'Rourke, *supra*, note 9.

61 Caulfield *et al.*, *supra*, note 44.

62 Eisenberg (1990), *supra*, note 57 at 723-724.

63 Carey & Crawley, *supra*, note 59 at 141-2; Kevles & Hood, *supra*, note 59 at 315; Adler, *supra*, note 56 at 912.

64 Carey & Crawley, *ibid.*; Looney, *supra*, note 49 at 248.

subject matter[65]. In fact, two American analysts recently wrote:

> "Less certain is whether patent protection will be available for the discovery of a gene sequence or partial sequence. In the notorious genotech patent controversy involving the NIH's application for patents on partial gene sequences, the PTO rejected the applications based upon lack of utility, novelty or non obviousness -- not for lack of statutory subject matter. This reflects either the PTO's willingness to avoid the issue of statutory subject matter in this context or a substantiation of the contention that the historical distinction between discovery and invention has been eroded to a nullity."[66]

In addressing whether genes are patentable subject matter, the differences between the US. and European patent laws are manifest. European patent laws explicitly provide a criterion for exclusion from patentability for *ordre public* (public order) or morality motives, an ethical criterion that falls under the evaluation of the patent office[67]. In contrast, US. patent law only has provisions with specific exclusions from patentable subject matter[68] and no such ethical criterion. Ethical

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65 Looney, *ibid.*, at 235; Khan, *supra,* note 50; Pompidou, *supra*, note 46.

66 Malinowski & O'Rourke, *supra*, note 9. [footnotes omitted]

67 Article 53a) of the European Patent Convention: "European patents shall not be granted in respect of: (a) 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 contrary merely because it is prohibited by law or regulation in some or all of the Contracting States." See: G. Paterson, *The European Patent System* (London: Sweet & Maxwell, 1992) at 68; M. van Empel, *The Granting of European Patents* (Leyden: A.W. Sitjthoff, 1975) at 350; H.-R. Jaenichen, *The European Patent Office's Case Law on The Patentability of Biotechnology Inventions* (Koln: C. Heymanns Verlag, 1993) at 333; See also Looney, *supra,* note 49 at footnote 128: "European patents shall not be granted in respect of ... inventions the publication or exploitation of which could 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...".

68 Under US patent law, the subject matter for patent protection must be any machine, article of manufacturer, process or composition of matter. Exclusions cover, for example, products of nature. However, US patent law has been interpreted in a way that there will be patents on products of nature if the invention is new, useful and falls into categories of patentable subject matter as set forth in section 101 of the Patent Act. See Eisenberg (1990), *supra*, note 57 at 722-8; E.F. Enayati, "Enemies to Innovation: Protecting Biotechnology Inventions" (1989) 5 Computer and High Technology Law Journal 435 more generally on US patent law requirements. See also: Looney, *supra,* note 49 at 252. For a brief overview of the patentability of living matter see Baechtold *et al.*, *supra*, note 44 at 143ff; L.L. Greenlee, "Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years" (1991) 68 Denver University Law Review 127; Also see Murashige, *supra*, note 44 at 187, who examines whether genes constitute a discovery or an invention. "In general, it has been possible to obtain composition-of-matter patents on materials that exist in nature so long as they can be claimed in a *form* different from that in which they exist there." US Case law indicates a liberal approach to the threshold requirement. See *Diamond v. Chakrabarty,* 447 U.S. 303 (1980) in which living organisms, in this case an oil-eating bacterium, could be patented the articulating a broad standard for patentable subject matter covering "anything under the sun that is made by man" at 309; Also indicative of this liberal position is the 1988 US patent granted over the Harvard Oncomouse, a genetically altered mouse to facilitate cancer research. The European Office also granted a patent in 1992 which is now being opposed in the EPO and proceedings are expected to continue in November 1995. See Nuffield, *supra,*

considerations are only implicitly considered and consequently, as has been noted in US. patent law, "the threshold test [...] fails as an ethical safeguard"[69]. While then, the role of ethical analysis differs, several commentators on both the European and US. patent systems believe this will have little effect on the issue of gene patenting. Indeed, several have concluded that under current legal threshold requirements, genes seemingly constitute patentable subject matter in both Europe and the US.[70]. Furthermore, it has been suggested that the public order exclusion in the European Patent Convention was not designed for the resolution of such controversial issues and that the European Patent Office may in fact not be the appropriate body to undertake such complex universal pressing ethical analysis[71].

In short, as concerns human genetic material, the current literature holds that the patent law framework does not explicitly address important ethical concerns. A growing consensus seems to be that patent law is unable to serve as a tool to solve the controversy because of the limited attention paid to the underlying ethical and policy concerns[72]. Indeed, governmental intervention

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note 46 at 90 for an overview of the European procedures. Finally, see *Ameng, Inc. v. Chughai Pharmaceutical Co., Ltd*, 927 F.2d 1200, 1203 (Fed. Circ. 1991), *cert. denied*, 112 S. Ct. 169 (1991), which clarified that genes and gene sequences are patentable subject matter if they are novel "purified and isolated" sequences derived from the original product of nature.

69 Looney, *supra*, note 49 at 257.

70 Carey & Crawley, *supra*, note 59; Looney, *ibid*, at 258 footnote 111 and 128 for EU; In Canada the conclusions are to the same effect see J.D. Morrow, "Patentable Subject Matter: Emerging Technologies" in *Patent Law of Canada* (Scarborough, Ontario: Carswell, 1994) at 25.

71 See A. Pompidou, *supra*, note 46; See also Nuffield, *supra*, note 46 at 89 for the history of public order exclusion: "[T]he "*immoral*" inventions which the legislation contemplated at that time included such things as instrument of torture and letter-bombs - which were so clearly immoral as to require little detailed consideration of the meaning of the exclusion...The Guidelines for Substantive Examination in the European Patent Handbook provide that an invention is "*immoral*" if the general public would consider it so abhorrent that patenting would be inconceivable. There are no express guidelines which go beyond this general statement, and the EPO has stated that it considers it the responsibility of individual patent examiners to determine on the facts of each case whether a given invention is "*immoral*", or not. As mentioned above, until very recently, the morality requirement was a relatively obscure provision which was rarely invoked. it has now come to prominence in the context of patents relating to human parts and transgenic animals." And further on the report continues "[T]he EPO... acknowledges that it is not the right institution to decide fundamental ethical questions. It confirmed that its general approach to the immorality exclusion in Article 53(a) of the European Patent Convention would remain that as set out in the EPO Guidelines and that the exclusion would be narrowly construed and applied in only the clearest cases".

72 Looney, *supra*, note 49 at 251; K.M. Cherniawsky & P.J.M. Lown, "New Reproductive Technologies: Commercial Protection" in *Overview of Legal Issues in New Reproductive Technologies* (Volume 3 of the Research Studies, Royal Commission on New Reproductive Technologies) (Ottawa: Minister of Supply and Services Canada, 1993) 303 at 345; Pompidou, *supra*, note 47; Gannon, *supra*, note 43 at 327; Churchill, *supra*, note 21 at 272; Healy, *supra*, note 56 at 668.

on national and international levels has been called for in order to reach an international consensus that might take several forms. One suggestion is to establish an international registry system, a "Human Genome Trust", to monitor genome progress and ensure collective "ownership" while permitting the co-existence of commercial development incentives[73]. Other propositions call for international agreements on a range of issues such as data sharing or limiting protection to the "moral" recognition of scientists who "discover" gene sequences[74]. As early as 1992, it was suggested that international agreements affirm that any rights to patented sequences be enforced only when the biologic function becomes known[75].

Working toward such agreements will be difficult and time consuming, as exemplified by the recent rejection of the European Directive, as explained below[76]. However, the alternative case-by-case analysis by patent offices and subsequent case law may prove to be not only equally time consuming but also expensive. A policy or legislated resolution process would allow for extensive debate over these sensitive issues. This process has begun.

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[73] Looney, *supra*, note 49 at 235-6, 267ff.

[74] Gannon, *supra*, note 43 at 338.

[75] Healy, *supra*, note 56 at 668.

[76] See *infra*, note 135.

SECTION 2 - COMPARATIVE OVERVIEW OF POLICY POSITIONS

International and regional instruments/documents seldom bind national governments. Only national legislation or statutes (where they exist[77]), are binding. The absence of enforcement procedures further undermines the authority of these international and regional instruments. For example, while international conventions adopted by the United Nations bodies bind member States upon their signature and ratification, difficulties in ensuring their enforcement make the actual legal strength of these instruments quite limited. Moreover, declarations adopted by the United Nations bodies are not legally binding upon member states but rather have a moral pursuasive force[78]. At the European level, the only body that binds member states is the European Parliament. Hence, had the draft European Directive of the Parliament on the legal protection of biotechnological inventions[79], been adopted, member European nations would have been bound by it and be required to modify or interpret their national legislation accordingly.

The reports of governmental commissions, agencies or working groups, recognized international, regional or local organizations, expert committees, and workshops, constitute the main source of policy positions. The common thread of all these texts is the formulation of recommendations following deliberation and study.

Thus, the vast majority of documents surveyed here, are not binding on governments. They find their value in the discussion and consensus work of groups of experts resulting in recommendations that have moral persuasion and normative influence since they reflect a consensus position. Such texts and their recommendations may also influence the legislative bodies during the drafting of legislation. In countries where legislation already exists, they may indicate possible interpretations or desirable amendments. This is especially true of instruments developed by bodies set up by governments either at the international, European or national levels. For example, even though the Council of Europe does not have legislative power to bind European nations by the recommendations[80] it adopts, it does reflect a consensus agreed upon following deliberations of experts from every member country, hence its moral strength. In contrast to the non binding nature of its recommendations, however, the Council of Europe's *Draft Bioethics Convention* will be upon

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77 We are aware of legislation on the issues related to the current discussion in France, *infra*, note 91.

78 See for example, once or if it is adopted, the UNESCO *Outline of a Declaration on the Human Genome and its Protection in Relation to Human Dignity and Human Rights*, (UNESCO, IBC Subcommittee, September 1995)[Hereinafter UNESCO]. See P.M. Dupuy, *Droit international public*, Précis Dalloz, (Paris: Editions Dalloz-Sirey, 1992) at 24-25.

79 See below section 2.2 §B.

80 See *infra*, note 85.

adoption (since it is a convention), binding upon member states that sign and ratify the convention. Finally, at the national level, study papers and reports from commissions generally have consultative and interpretative force. The influence of these policy positions should not be underestimated in that they are often considered as "soft law" and as sufficient to provide normative guidance along with prevailing professional codes of ethics and practice guidelines. The perspectives found in these policy positions on the issues of property and persons with respect to the status of human genetic materials (2.1) and once banked with respect to possible intellectual property rights (2.2) reveal a gradual convergence toward similar solutions although coming from different positions.

Section 2.1- Perspectives on Property and Person Issues

Like in the general literature, the questions: "What is the legal basis for the right of the individual to determine what happens to his or her body?" "May human materials removed from the body be considered property, or ought they still be considered as part of the body and thus, of the person and controlled by that person's personal rights?", dominate policy discussions around the world.

With a few notable exceptions[81], these policy texts do not generally address the issue of ownership of bodily material by explicitly stating whether they adopt a property rights or a personal rights legal regime. Indeed, option for one or the other regime can only be inferred from the position taken on commercialism as the personal rights approach generally forbids any monetary compensation for human materials. Exceptions do exist, however, and commercial transactions are sometimes allowed under a personal rights approach while they are forbidden in a property rights regime. A survey of international (§ A), regional (§ B) and national policy positions (§ C) and legislation relevant to the transfer and banking of human material, will clarify the different positions.

§ A - International Positions

Among the few international organisations that have made statements on the status of human material, the tendency has been to present general policy positions rather than precise statements. In its 1991 *Guiding Principals on Human Organ Transplantation*[82], the World Health Organization

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81 For example see, the French bioethics legislation, *infra*, note 91; the statement by the American Society of Human Genetics, *infra*, note 115; and the *Genetic Privacy Act and Commentaries*, *infra*, note 115.

82 World Health Organization, *Human Organ Transplantation*, A Report on Developments Under the Auspices of WHO (Geneva: WHO, 1991) Guiding Principle 5. The World Health Assembly endorsed these principles the same year. See Forty-fourth World Health Assembly. Forty-fourth World Health Assembly, Resolution WHA44.25 as cited in (1991) 42:3 Int. Dig. Hlth. Leg. 389-413. In 1989, the Forty-second World Health Assembly adopted

adopted the position that the human body and its parts could not be subject to commercial transactions. Therefore, any giving or receiving of payments for organs as well as any other commercial dealings in human tissues and cells should be prohibited by member states. With regard to human material used for genetic research, several other international bodies[83] have endorsed the spirit of a personal rights approach in one's bodily material and information derived therefrom by asserting the importance of respecting the will of persons participating and their right to decide on the extent of participation. Recently, the International Bioethics Committee of UNESCO reiterated that "the human genome is a fundamental component of the common heritage of humanity"[84] but did not include a specific statement on commercialisation in its proposed *Outline of a Declaration on the Human Genome and its Protection in Relation to Human Dignity and Human Rights*. The preamble, however, incorporates a reference to general patent law principles and thus seemingly, does not exclude eventual commercial applications.

§ B - Regional Positions

At the regional European level, the Council of Europe has adopted a similar position in its recommendation on genetic testing and screening for health care purposes. It would require a person's permission for the further use of any sample collected for a specific medical or scientific purpose[85]. But in contrast to the UNESCO International Bioethics Committee, the 1995 proposed *Draft Bioethics Convention*, explicitly affirms the principle of non-commercialism of the human body and its parts and substances[86]. In addition, it states that the human body, its parts, organs and tissues may not be a source of profit through the trade of body parts for neither the individual source

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resolution WHA42.5 specifically preventing the purchase and sale of human organs and calling upon Member States to take appropriate measures to prevent such trafficking.

83 World Medical Association, "Declaration on the Human Genome Project (1992)" (1993) 44:1 Int. Dig. Hlth. Leg. 150; World Health Organization, *Hereditary Diseases*, WHO Technical Report Series (Geneva: 1995) [forthcoming]; UNESCO, *supra*, note 78.

84 UNESCO, *ibid.*, section 1.

85 Council of Europe, C.M., 470th meeting, *Adopted*, Rec. R(92)3 on Genetic Testing and Screening for Health Care Purposes, princ 13 (a): "Samples collected for a specific medical or scientific purpose may not, without permission of the persons concerned or the persons legally entitled to give permission on their behalf, be used in ways which could be harmful to the persons concerned".

86 Council of Europe, *Draft Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Bioethics Convention and Explanatory Memorandum* (Strasbourg: July 1994) art. 11 as amended in February 1995 [Council of Europe, P.A., First part of its session (30 January - 3 February) on the draft Bioethics Convention, *Adopted*, Opinion No. 184 on the Draft Bioethics Convention] [hereinafter *Draft Bioethics Convention*].

of the human material, nor for any third parties such as hospitals[87]. However, the proposed prohibition would not extend to the sale of tissue that is part of a medical device nor to tissue considered as waste, such as hair and nails[88].

The Working Group on the ethical, social, and legal aspects of the European Commission's Programme on Human Genome Analysis[89], briefly addressed the more specific issue of ownership of materials collected for human genome analysis recommending that the issue be solved at the international level. Its 1991 report enunciated the guiding principle that "data and materials must be readily available to *bona fide* researchers" and that material be available at a nominal charge to cover the cost of distribution[90].

§ C - National Positions

Several European nations have taken specific positions on the ownership of bodily material once removed from the body. In France, bioethics legislation[91] adopted in July 1994 follows the position of the National Ethical Consultative Committee for the Life and Health Sciences[92] affirming the non-commercialisation of the human genome or of any parts of the person. This legislation most definitely adopts a personal rights approach as it clearly states that the human body

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87 *Draft Bioethics Convention, ibid.* at 24.

88 *Ibid.*

89 European Commission, Working Group on the Ethical, Social and Legal Aspects of Human Genome Analysis, *Report of 31 December 1991*, (WG-ESLA), also in (June 1993) Bull. Med. Eth. 19. [hereinafter WG-ESLA].

90 *Ibid.* at 10-11.

91 *Loi n° 94-653 du 29 juillet 1994 relative au respect du corps humain*, J.O., 30 juillet 1994, 11056 also in "Law No. 94-653 on respect for the human body" (1994) 45:4 Int. Dig. Hlth. Leg. 498 [hereinafter Loi No. 94-653]; *Loi n° 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal*, J.O., 30 juillet 1994, 11060 also in "Law No. 94-654 on the donation and use of elements and products of the human body, medically assisted procreation, and prenatal diagnosis" (1994) 45:4 Int. Dig. Hlth. Leg. 473 [hereinafter Loi No. 94-654].

92 Comité consultatif national d'éthique pour les sciences de la vie et de la santé, *Avis sur l'application des tests génétiques aux études individuelles, études familiales et études de population (Problèmes des "banques" de l'ADN des "banques" de cellules et de l'informatisation des données)*, Avis du 24 juin 1991: "Le genome d'un individu, parce qu'il relève de son être plutôt que de son avoir, ne peut pas être l'objet de commerce, tout comme les autres composantes physiques de sa personne. Cette "non propriété" ne s'oppose pas à une recherche ou analyse des éléments constituant le génome." It further affirmed this principle in another opinion by asserting that "all information contained in the human genome belongs to the common heritage of mankind; it is a field of knowledge that cannot be subjected to monopoly." See French National Ethical Consultative Committee for the Life and Health Sciences, "Opinion on the Non-Commercialisation of the Human Genome", as cited in (1993) 44:1 Int. Dig. Hlth. Leg. at 130.

and body parts may not be subject to patrimonial rights[93]. Individuals maintain control over removed materials through the requirement of obtaining informed consent for the collecting of identifiable samples and the right to revoke such consent at any time[94].

Prior to the adoption of these bioethics laws, a report by the French Ministry of Higher Education and Research on *The Intellectual Protection of the Results of Research on the Human Genome, Cell Collection and DNA Sequencing Data, (1994),* also based its recommendations on the principle of "non-proprietorship of the elements and products of the human body"[95]. Hence, not having any property rights in body parts, individuals should "donate" such substances and would be protected through consent procedures. In addition, this report clearly denied to every person involved in the collection of samples (donor, investigators or promoters), any proprietary rights in the material although the promoter (granting agency) would have other rights with respect to the collection[96].

In 1995, the Nuffield Council on Bioethics, of the United Kingdom, published a report on the ethical and legal issues raised by the use of human tissue in medical research[97]. In accordance with most European policy positions, commercialisation of tissue procurement should be prohibited except for certain removed body products such as hair and nails that may be bought and sold since they are common waste products[98]. The Nuffield Council does not explicitly establish whether a person from whom tissue is removed retains any claim over the tissue. The report recalls that, in addition to rights over the actual removed tissue, "a person may also claim an entitlement to share in any benefits arising from the exploitation of the tissue removed and, where relevant, any consequent intellectual property rights. Abandonment and donation, however, do not ordinarily give rise to intellectual property rights."[99] However, it recommended that any claim over removed tissue should be examined on the basis of the consent given to the procedure resulting in the

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93 Law No. 94-653, *supra*, note 91 art. 1: "Le corps humain, ses éléments et ses produits ne peuvent faire l'objet d'un droit patrimonial".

94 Law No. 94-654, *supra*, note 91 art. 2.

95 Ministry of Higher Education and Research, *Report of the Study Group on the Intellectual Protection of the Results of Research on the Human Genome, Cell Collection, and DNA Sequence Data* (Paris: June 10, 1994) at 11.

96 *Ibid.*, at 21: "Like its individual elements, the collection is not considered to be commercially exploitable; it does not confer ownership rights to any of the persons involved, whether donors, promoters, or investigators; in return, the results of research carried out using such a collection are protected conforming to the general guidelines concerning intellectual property."

97 Nuffield Council on Bioethics, *supra*, note 46 at 67ff.

98 *Ibid.* para. 13.24.

99 *Ibid.* para. 9.18.

removal of the tissue and not on the basis of a property claim. It further specified that consent to medical treatment should be regarded as entailing the abandonment of any tissue removed. Finally, the Report noted that even though a property approach seems to have been endorsed in other UK. legislation, for example, that pertaining to human tissue, organ transplantation and anatomy, any tissue removed from donors is given free of all claims[100].

As early as 1989, the Health Council of the Netherlands addressed the issue of cell banks in a large study on issues in human genetics[101]. The Health Council while in favour of the adoption of a code of conduct setting out the legal position of the "donor" also sought to ensure that no unnecessary barriers to the use of banked cells for research were created. Furthermore, it recommended that written agreements should be made at the time of collection of samples setting out the specific rights of the donor, including, time of storage, use of material, confidentiality, withdrawal of consent, etc. In so far as consent procedures are favoured and no mention is made of any proprietary rights in banked material, can we infer that these early recommendations endorsed a personal rights approach to bodily materials?

In 1994, the Health Council of the Netherlands[102] seemingly rejected the notion of property rights over the human body as a whole[103]. It considered that human tissue removed from the body as having a distinct "legal position"[104]. In addressing this issue of the "legal position" of human

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[100] *Ibid.* see para. 9.5, 9.9 & 13.26 at 131.

[101] Committee of the Health Council of the Netherlands, *Heredity: Science and Society*, (The Hague: Committee of the Health Council of the Netherlands, 1989).

[102] Health Council of the Netherlands, Committee on Human Tissue for Special Purposes, *Proper use of Human Tissue* (The Hague: Health Council of the Netherlands, 1994).

[103] *Ibid.* at 32:

"Various views have been expressed over the years regarding the legal basis for the individual's right to determine what happens to his or her body. The notion that the body is an integral part of the person implies that it has a special position in law. Certainly the living body is not seen merely as a thing: the body is a means of existence, not an item of property."

[104] *Ibid.* at 35:

"The notion expressed above that the law of property has no relevance to the body as a whole is associated with the view that material which has been removed from the body has no legal existence in its own right: the process of separation makes it the property of the person from whom it has been taken. In this view ownership may be transferred, as happens when blood is given to a blood bank. In special cases such as that of sperm (unlike blood, hair or urine) a refinement is introduced, in that the *personal rights* of the donor continue to play a background role (author's emphasis).

Waste or surplus material used to be seen as medical waste which the patient was deemed to have surrendered. As medical advances have increased the usefulness and value of such material here too a refinement has been introduced: the removal of material does not imply that the doctor or hospital concerned becomes its owner. In this view the patient is considered to retain ownership of any material removed at surgery, with surrender by the patient being assumed only in the case of material which is destroyed or which is to be used in some way

tissue removed from the body, this report of the Health Council of the Netherlands centered its reflection on how an individual's right to self-determination might best be protected: through property law, contract law, or that of constitutional law protecting rights of the person[105]. Although the Health Council did not take an explicit position on the legal status of human tissue, it did state that individuals have the right to determine what happens to identifiable material as a "personal right". Moreover, in commenting on its earlier 1989 report, it reiterated that "should exceptional cases arise in which [cell material] is identifiable, then the principle of non-commercialism means that the "donor" has no claims to any revenue that may be earned."[106]

In 1993, the Norwegian government issued a report on *Biotechnology related to Human Beings*[107] which was partially enacted into legislation[108] the following year. No specific provisions discuss banking. Even though current Norwegian transplant legislation does not contain a ban on commercial exploitation of organs or parts of organs[109], the 1993 report of the Norwegian government considered its stance to be in accordance with the European *Draft Bioethics Convention*[110] thus, endorsing the position that there be no commercial exploitation of such materials[111].

In the United States, the existence of possible legal claims of individuals whose tissue have been removed, has been particularly controversial. *Moore* v. *Regents of the University of California*[112] is a landmark case on this issue. In 1991, the Supreme Court of California overruled

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known to the person from whom it was taken. If residual material is to be used for the purposes of which patients are unaware, then - as the argument runs - they should at least be informed and given the opportunity to object."

105 *Ibid.* at 35.

106 *Ibid.* at 42; see also at 13 for principle of non-commercialism.

107 Norway, Ministry of Health and Social Affairs, *Biotechnology Related to Human Beings, Report no 25 (1992-1993) to the Storting on Biotechnology related to Human Beings* (Oslo: Ministry of Health and Social Affairs, 1993) [hereinafter *Report No. 25*].

108 Norway, "Act relating to the Application of Biotechnology in Medicine" (June-July 1994) Bull. Med. Eth. 8.

109 *Report No. 25*, *supra*, note 107 at 83.

110 *Supra*, note 87.

111 *Report No. 25*, *supra*, note 107 at 84.

112 *Supra*, note 6. Moore was affected with a rare form of leukemia and had a splenectomy in the course of his treatment. For quite some years he continued giving bodily samples which he believed to be for the purpose of monitoring his condition. Without his consent, Moore's doctor and another researcher used his cells to develop a number of new pharmaceutical products which resulted in profits of several billion dollars. Moore sued the University and the

the Court of Appeal's recognition of Moore's proprietary interest in his cell line. The California Supreme Court granted Moore relief based on the doctor's breach of "fiduciary duty to disclose facts material to the patient's consent, or alternatively, on the performance of medical procedures without first having obtained the patient's informed consent."[113] In doing so, it examined the policy implications of recognizing individual property rights in cells, substances and body parts against the need to pursue medical research, advance scientific knowledge, and provide incentives for biotechnology industry.

Various policy positions in the United States demonstrate how controversial this topic has come to be. In fact, as early as 1987, the American Society of Human Genetics stated that "[b]anked DNA is the property of the depositor unless otherwise stipulated. Therefore, the word "donor", which implies a gift, is inappropriate."[114] A similar "property" position was also adopted in a proposed 1995 *Genetic Privacy Act* which provides that "an individually identifiable DNA sample is the property of the sample source,"[115] who has the right to order the destruction of the sample. Distancing itself from the preceding positions, a recent report commissioned by the National Institutes of Health and the Centre for Disease Control and Prevention[116] endorses a personal rights approach and discusses the components of an expanded informed consent. A recent statement by the American College of Medical Genetics (ACMG)[117] on storage and use of genetic material, adopts a similar approach. Avoiding all property-person discourse the ACMG statement makes recommendations on the scope of informed consent recognizing sample "sources'" right to control the outcome of their removed bodily material.

Turning finally to the Canadian context, the only legislation that deals with the status of human materials is the Civil Code of Quebec. It adopts a personal rights approach[118], that in fact

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researchers as well as the two pharmaceutical companies. The basic issue raised in this case was whether or not a person has proprietary interest in and hence the right to commercially exploit his or her body.

[113] *Ibid.* at 150.

[114] American Society of Human Genetics, "DNA Banking and DNA Analysis: Points to Consider" (1987) American Journal of Human Genetics 781.

[115] G.J. Annas & L.H. Glantz & P.A. Roone, *The Genetic Privacy Act and Commentary* (Boston: 28 February 1995), s. 104(a) [hereinafter *Genetic Privacy Act and Commentary*]

[116] E. W. Clayton et al., *supra*, note 8.

[117] ACMG, *supra*, note 8.

[118] The Civil Code of Quebec being a comprehensive code, placing provisions dealing human material in the "Book on Persons", "Title Two - Certain Personality Rights", is clearly indicative if the legislators intent to consider human bodily material as parts of persons and not as things to be appropariated. Other elements, such as the prohibition of remuneration for tissue donation and classical principles of integrity and dignity of the person, endorse the personal rights appoach. The issue of claims to intellectual property rights or share of profits is not covered except to the extent

constitutes an expansion of informed consent. Article 22 reads as follows: "A part of a body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purposes of research." Hence, according to this provision, all types of research be it on nominative, anonymous or anonymized samples, requires that specific consent be obtained for the use of removed material until recently considered as waste.

Few reports deal directly with the issue of the legal status of human material removed from the body. In 1992, the report of the Law Reform Commission of Canada on the *Procurement and Transfer of Human Tissues and Organs*[119] (in conformity with most provincial legislation), recommended the general principles of altruism, voluntarism, gratuity and universality[120]. More specifically, the Law Reform Commission recommended that the purchase or sale of human bodies, organs and other non-regenerative tissue should constitute a criminal offence[121]. No mention was made however, of regenerative tissue. Finally, in cases where health providers, hospitals or researchers develop a commercial interest in a patient's tissue or cellular matter or where the development of any such interest is reasonably foreseeable, the health providers, hospitals or researchers should be obliged to disclose such an interest to the patient prior to obtaining his consent[122]. The Law Reform Commission recognized that the issue of who should have commercial and patent rights to therapeutic products developed from human cells remains uncertain.

Closer to the issue of use of human genetic material, the 1991 Science Council of Canada report on genetics in Canadian health care, similarly endorsed the philosophy of gift-based donorship and warned against its possible undermining by the recognition of property rights in genetic material. Without taking a position on this debate, the Science Council emphasized that "even if genetic material were deemed property, the donor's claim in any commercial profits might be limited to the value of the tissues when they were removed."[123] Moreover, "extension of the donor philosophy would mean that genetic material could not be sold, and donors would not have commercial interest in products developed using their tissues."[124] It remains critical, however, "that

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of compensation for the research participant. Art. 25 C.C.Q. states: "Any experiment may not give rise to any financial reward other than the payment of an indemnity as compensation for the loss and inconvenient suffered".

119 LRCC, *supra*, note 1.

120 *Ibid.*, Rec. 2 at 171-2.

121 *Ibid.*, Rec. 11 at 184.

122 *Ibid.*, Rec. 13 at 188.

123 Science Council of Canada, *Genetics in Canadian Health Care*, Report 42,(Ottawa: Minister of Supply and Services Canada, 1991) at 75.

124 *Ibid.*

in all cases, individuals have control over the use of their tissues, including use in research or in the development of commercial products."[125]

These two reports, together with comments by the Royal Commission on New Reproductive Technologies[126], indicate that Canadian policy discourse generally endorses a personal rights approach to human genetic material via the endorsement of expanded informed consent. This approach is also reflected in current positions on banked human genetic material as recently stated by the Quebec Network of Applied Human Genetics of the FRSQ[127] .

Section 2.2- Banked Materials and Patents

The issue of patenting human genetic material has raised greater debate at the international and national levels than has the legal status of such material. In fact, the Human Genome initiative has inspired or compelled a number of international and national bodies to make policy statements on the "patentability" of the human genome or more simply, of genes. Since the gene is the basic unit of life, positions on patenting the human genome may be determinant of the patentability of other bodily parts and tissue. Moreover, an examination of the international (§ A), regional (§ B), and national (§ C) position on patenting reveals that a clarification of patenting issues may well put the property-person debate to rest.

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125 *Ibid.*

126 RCNRT, *supra*, note 5. Although this report dealt with gametes, zygotes, embryos or fetuses, the principles put forth are relevant to our discussion. See 718:

> "As we have discussed, we believe that certain aspects of the human experience must never be commercialized. Among the activities that we see as ethically unacceptable on the basis of the principle of non-commercialization are the buying and selling of gametes, zygotes, embryos, or fetuses, and the use of financial incentive in preconception or adoption arrangements. To allow commercial exchanges of this type would undermine respect for human life and dignity and lead to the commodification of women and children."

127 See Réseau de génétique humaine appliquée du Fonds de recherche en santé du Québec, "Énoncé de principes: Médecine génétique et recherche génomique" (1995) 8 *Recherche en Santé* 30-34, principle II.2 "*Participation Without Prejudice. Option to Give Genetic Material*: The participant has the right to choose whether or not to give genetic material. He equally has the right to choose whether tissue removed in the course of care will be allowed to be used for genome research." [Our translation] The principles also propose that participants have the option to contribute to research on other phenotypes and transmission of their samples to other research centres. Participants may also choose whether or not they wish to be recontacted to obtain research results. Such a personalistic approach was proposed as early as 1989 in B.M. Knoppers & C.M. Laberge "DNA Sampling and Informed Consent" (1989) 140:9 C.M.A.J. 1023-1028. This position was reiterated in B.M. Knoppers & C.M. Laberge, *supra*, note 8.

§ A - International Positions

At the international level, two positions have been endorsed with respect to the patentability of the human genome or parts of it. The first, simply states that no patents should be given[128]. The second position qualifies this "blanket" refusal by maintaining that no patents should be allowed on genes *per se*, but accepts that uses or applications of genes or sequences can be patented[129]. A 1995 statement by the international Human Genome Organization[130] (HUGO) further clarified the issue of patentability of DNA sequences by distinguishing between different steps in the research process of molecular biology and by qualifying what is "discovered" at each step. Thus, HUGO recommended that routine procedures such as sequencing expressed sequence tags or genes should not be patentable[131], while the "more difficult and significant discoveries"[132] of determining the underlying biological functions should receive patent protection.

§ B - Regional Positions

At the regional European level, a 1991 Working Group of the European Commission[133] opposed patenting the human genome or any part of it since granting patents for DNA sequences with unknown utility could have an inhibitory effect on research[134]. Again, this would not exclude patent protection of products or processes that are the result of innovative research. It is also interesting to note that an earlier 1988 draft directive of the European Parliament and Council, aimed at providing clear guidelines without modifying existing legislation on the patentability of

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[128] World Medical Association, *supra*, note 83 at 151: "The information [acquired from mapping the human genome] should be general property and should not be used for business aims. Therefore no patents should be given for the human genome or parts of it."

[129] WHO, *supra*, note 83; The Human Genome Organization, "HUGO Position Statement on cDNAs: Patents", (1992)[hereinafter HUGO 1992]; C.T. Caskey *et al.*, "HUGO Statement on Patenting of DNA Sequences" (April 1995) Genome Digest 6 [hereinafter HUGO 1995]; First South-North Human Genome Conference, "Declaration on Patenting of Human DNA Sequences" (1993) 44 :2 Int. Dig. Hlth. Leg. 362: "... we urge that consideration be given to avoiding the patenting of naturally occurring DNA sequences".; International Council of Scientific Unions, "Statement on Gene Patenting (June 1992)" in (1993) 44:2 Int. Dig. Hlth. Leg. 363.

[130] HUGO 1995, *ibid.* at 8-9.

[131] *Ibid.* at 9.

[132] *Ibid.*

[133] WG-ESLA, *supra*, note 89.

[134] *Ibid.* Rec. vii.

human genes, was finally rejected in 1995[135]. This directive sought to prohibit patenting of elements of the human body as such, but allowed patenting of inventions that included elements of the human body modified in such a way that they could no longer be directly linked to a specific individual. As a consequence of the rejection of the Directive, applications for gene patents in Europe will remain subject to national law and to a case by case interpretation by the European Patent Office under the unchanged European Patent Convention[136].

§ C - National Positions

At the national level, the clearest position on whether genes should be offered patent protection, is found in French legislation. In 1994, the French legislature enacted amendments to its intellectual property code declaring unpatentable "...the human body and its elements and products, as well as knowledge of the total or partial structure of a human gene"[137] (since contrary to public order). Earlier national reports in France had already come to this position[138].

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[135] On this initiative see Nuffield Council on Bioethics, *supra*, note 46 at 85:
"The draft European Directive on the legal protection of biotechnological inventions was first proposed by the Commission to the Council of Ministers in November 1988 (European Commission, Office for Official Publications (1988) Proposal for a Council Directive on the legal protection of biotechnological inventions COM(88) 496 final - SYN 159). There then followed a lengthy period of consultation, and in October 1992 the European Parliament approved the draft in its first reading, with 45 proposed amendments. The Commission then put these amendments (although doubts existed as to whether a quorum was present). The amendments were rejected by the Council of Ministers and a Conciliation Committee began to meet on November 1994 to see whether a compromise could be achieved. On 23 January 1995 a compromise was apparently achieved between the Council and the Parliament but on 1 March 1995 the Parliament rejected the draft Directive by a vote of 240 to 188 with 23 abstentions."

[136] See D. Dickson, "European Parliament Rejects Bid to Stem Confusion Over Gene Patents" (1995) 374 Nature at 103. The EPC contains a provision prohibiting patenting on any invention considered to be against *ordre public* (public order). It remains unclear whether this provision suffices to reject patenting of genes. It is interesting to note that "the European Patents Office procedure offers a "one-stop" system for acquiring a bundle of national patents - but the validity of an individual patent remained open to challenge in national courts." See A. Rodgers, "Update on European bioethics and patent talks" (1995) 345 Lancet 916.

[137] Law No. 94-653, *supra*, note 91 art. 7:
"The following shall not be patentable: (a) Interventions whose publication or realization would be contrary to public order and morality, the realization of such an invention not being considered as such solely because it is prohibited by a legislation or regulatory provision; in this connection, the human body and its elements and products, as well as knowledge of the total or partial structure of a human gene, may not, as such, be subject of a patent".

[138] See Ministry of Higher Education and Research, *supra*, note 95, s. VI; Comité consultatif national d'éthique pour les sciences de la vie et de la santé, *Avis sur la non-commercialisation du génome humain*, Rapport, Paris, 2 décembre 1991, also in (1993) 44(1) Int. Dig. Hlth. Leg. 130.

In 1994, the Danish Council of Ethics produced a report that specifically addressed the issue of patenting human genes[139]. It endorsed the position that patents should not be allowed on human genes in naturally occurring form, allowing, however, patenting of the information content of DNA sequences, in the manufacture of a specific product[140]. The Danish Council further proposed that a forum be established in order to continuously monitor developments in the legal protection of biotechnical inventions.

The Norwegian Ministry of Health and Social Affairs in its 1993 report on *Biotechnology related to Human Beings,* did not recommend that human cells and genes be explicitly excluded from patent protection but only that current patent criteria be applied. In the Ministry's view, "genes that have no known function will not be patentable in Norway because they do not fulfil the requirements for patentability."[141] Thus, the simple application of the current Norwegian law was deemed sufficient to decline patents on human genes and cells.

In the United Kingdom, the 1995 report of the Nuffield Council on Bioethics extensively covered the issue of patentability of inventions derived from human tissue with particular reference to the "immorality exclusion" criteria (public order) of the European Patent Convention[142]. The Nuffield Council remarked that "human genes, human cells, and the products and processes derived from them are already patentable (and patented) under European patent law"[143] since they have not been excluded on the basis of immorality, restrictively interpreted by the European Patent Office. However, the Report noted that oppositions to awarded patents had been filed and that a body of opinion believes that the immorality exclusion deserves clarification[144]. Indeed, the rejection of the European draft Directive in 1995 as mentioned above, exemplifies the continuing controversy over this issue. Because of this situation, the Nuffield Council made several recommendations. First, the notion of invention requires that "some technical intervention should have taken place that justifies the granting of an intellectual property right."[145] Second, the Nuffield Council recommended that in the interpretation of the exclusion based on immorality (public order), account be taken of ethical factors and sensitivities in the patenting of inventions derived from human

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139 Danish Council of Ethics, *Patenting Human Genes- A Report*, (Copenhagen: Danish Council of Ethics, 1994).

140 *Ibid.* at 35.

141 *Report No. 25, supra*, note 108 at 84.

142 For a description of the "immorality exclusion" see Nuffield, *supra*, note 47 at 89ff.

143 Nuffield Council on Bioethics, *supra*, note 47 at 94.

144 *Ibid.*

145 *Ibid.* at 98.

tissue."[146] Finally, it recommended that clarification of the immorality exclusion be attempted once more in a protocol that could be adopted under the European Patent Convention.

Later in 1995, in a report on human genetics[147], the UK. House of Commons Select Committee on Science and Technology made a recommendation precluding patenting of gene or gene fragments of unknown function concluding that only a combination of a gene and a known utility which is novel and not obvious should be patentable in the context of that utility. In addition, a combination of the same gene and a further novel utility should also be patentable. Interestingly, the Committee considered that the exclusion from patentability on the grounds of immorality should remain "narrowly construed, rarely applied, and then only in extreme cases."[148] The increased importance given to the concept of human dignity by the European Parliament was not deemed "inconsistent with the proper use of patenting in creating conditions in which new therapies can be developed to relieve suffering and improve the quality of life."[149] Concern was raised, however, that patent examiners apply the novelty and utility criteria too loosely with over-generous patents being granted. Due to the absence of provisions in the European Patent Convention to challenge the scope of patent claims, the Committee called for review of grounds under which opposition to patents may be filed[150].

In the United States, there is no such exclusion based on the notion of public order. Rather, the debate has focused on the question of sharing of profits gained through patent protection and only to a lesser extent on the patentability of inventions derived from human tissues[151]. In 1991, however, the NIH patent applications for thousands of partial complementary DNA sequences of unknown function raised much polemic in scientific, industrial and lay groups[152]. The NIH policy

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146 *Ibid.*

147 House of Commons Select Committee on Science and Technology, *Human Genetics: The Science and its Consequences,* Third Report of the Science and Technology Committee 1994-95, 6 July 1995, at para 205.

148 *Ibid.* at para 195.

149 *Ibid.*

150 *Ibid.* at para 195.

151 See for example OTA, *supra*, note 6. The US. Supreme Court ruling in *Diamond* v. *Chakrabarty*, *supra*, note 68 at 49-50 makes it clear that "the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability, as long as the invention is the result of human intervention." In another case, *In re Bergy*, 596 F. 2d 952 (CCPA 1979) at 49 50, the U.S. Court of Customs and Patent Appeals ruling suggests that "a purified strain of naturally occurring organisms is statutory subject matter unless precluded under the "product of nature" doctrine." Under the product of nature doctrine, "a cell or other substance occurring in nature is not patentable unless it is given a substantially new form, quality or property not present in the original."

152 On this application see: Eisenberg (1992), *supra*, note 56; Eisenberg (1994), *supra*, note 56; Adler, *supra*, note 56; Gannon *supra*, note 43.

justification for such an application was that patent protection would promote product development by US. industries through the granting of exclusive licenses over DNA sequences[153]. The scientific community opposed this application considering it an obstacle to technology transfer and product development rather than an incentive. The NIH patent application was denied since it lacked patentable novelty and utility, the functions of the cDNA being unknown[154]. In spite of this ruling, as the above survey of the literature demonstrates, the debate on the issue of granting patent protection over human genetic material with no known function continues.

Finally, in Canada, few policy statements have been made on this issue. In its report on tissue procurement and transfer, the 1991 Law Reform Commission report asked "whether there is something intrinsically wrong with patenting human life, particularly human life forms. That human life forms have formally been patentable subject-matter in Canada since the early 1980s may suggest that it is not."[155] In contrast, the 1993 report of the Royal Commission on New Reproductive Technologies considered that the patenting of human cell lines raises some concern and, as already mentioned, asks for further study[156]. In addition, the commissioners held that human zygotes, embryos, and fetuses are inappropriate subject matter for intellectual property protection[157]. In its general principles regarding intellectual property rights, the Canadian Genome Analysis and Technology Program (CGAT) does not consider the issue of gene patenting. CGAT simply states that researchers supported by the program may seek intellectual property protection for their

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153 Eisenberg (1992), *ibid.;* Eisenberg (1994), *ibid.*

154 NIH has not appealed the decision of the U.S. Patent Office. NIH policy behind the application for patents was to promote technology transfer of fundamental research to researchers in U.S. industries so that product development be enhanced through exclusive access to raw material. See Looney, *supra*, note 49, at 256-157; Eisenberg (1994), *ibid.* ; Late in 1994 the US. Patent and Trademark Office announced new guidelines for the examination of biotechnology patent applications focusing on the utility requirement. See BNA's Patent, Trademark & Copyright Journal, (1995) 49:1210 at 223- 244.

155 LRCC, *supra*, note 1 at 124. Also see Canadian Patent Office, *Manual of Patent Office Practice* (Ottawa: Consumer and Corporate Affairs, 1990): In the chapter on Utility and non-statutory subject matter: art. 12.03.02: "Living Matter: Inventions for new microbial life forms such as bacteria, yeast, moulds, fungi, actinomycetes, algae, cell lines, viruses and protozoa may be patentable. Processes for producing and utilizing microbial life forms may be patentable. ... Inventions for new plants and animals are not patentable. Processes for producing plants and animals which require significant technical intervention by man may be patentable. Traditional biological breeding process used for the production of plants and animals are considered essentially natural biological processes and are not patentable." Art. 12.03.01: "Examples of non-statutory subject matter. (a) Plants and animals are not patentable subject matter. (b) Subject matter being a process of treating living humans or animals by surgery or therapy is excluded by section 2". It is however interesting to note that prior to the reform of the Patent Act were excluded from patentable subject matter " an invention that has an illicite object in view...".

156 RCNRT, *supra*, note 5 at 723 -724.

157 *Ibid.* at 722-723.

inventions providing that publication is not denied[158].

In short, intellectual property rights for persons who contribute their human genetic material to research that eventually leads to inventions awarded patent protection is still under discussion. Potential claims to a share of patent profits by contributors may be summarized in two general tendencies as found in policy positions according to the person-property dichotomy. Under a personality rights approach, where human material is usually considered as extra-commercial, a person has no right to claim a share of profits derived from patents on inventions containing their bodily material. However, during the process of obtaining informed consent from the sample "sources", some have suggested that the person should be informed of whether a share of any potential profits can be expected by the researcher, the institution and possibly by the participant[159]. Accordingly, under this approach, contractual institutional arrangements could be drawn up in which the person's right to a share of eventual profits derived from patents is ensured through the informed consent mechanism. Similarly, under a property rights approach, *ab initio* proprietary interests in the removed material could extend beyond the raw material to include rightful claims of a share of profits on any patented inventions containing the sample, provided that there is no legal authority to the contrary[160]. Individual "bargaining" or exploitation under these approaches cannot be ruled out. In any event, another possibility would be to provide a percentage of eventual profits not to the individual participant or patient but to a non profit foundation or organization whose goal is to educate and help lay members with that disease. Hence, the issue of whether individuals maintain any claims over profits derived from removed bodily material remains unclear and merits continued discussion.

Whatever the type of arrangement convened with respect to sharing profits from patent protection, there will be implications for individuals who contribute their bodily material, to researchers as well as to institutions where research is conducted[161]. For example, will the remote hope of obtaining a share of profits influence individual's informed consent? Will researchers who offer a share in their potential profits be considered as imposing undue inducement on their potential sample contributors? How and under what form will profits be redistributed? In large research projects, how will the value of one person's genetic material be evaluated with respect to other people's material also studied? What will the institution's duty be in such a context? Are there other models for potential profit sharing that are not patent law based? Finally, how will any

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158 Canadian Genome Analysis and Technology Program, "General Principles Regarding Intellectual Property Rights" (1995) 3:1 Genexpress 12.

159 See for example Clayton et al., *supra*, note 8, recommendation A2; ACMG, *supra*, note 8 recommendation B2.

160 For example, in the *Moore* case, *supra*, note 6, the Supreme Court of California rejected any recognition of proprietary interests of Moore in his removed bodily material that might have allowed him to claim a share of the profits gained from the patent.

161 See the highly divergent current approaches to consent and sampling in the results of a 1995 Canadian survey in T. Caulfield, ed., *Legal Rights in Human Genetic Material*, forthcoming, 1996.

compensation scheme realistically be implemented?

CONCLUSION

Whether drawing its origins from the sale-gift debate that has dominated the organ transplant debate for years, or from the property-person debate in the legal literature on other human tissue, it is evident that the advent of DNA banking has forced a re-examination of the issues. While the dichotomy is still philosophically relevant, the solutions proposed share common elements: expanded forms of control through a more extensive and detailed informed consent procedure, through access, storage and destruction options and through the provision of explicit written policies and choices for possible research. The issue of possible commercialism through payment for procurement or even through a sharing of eventual profits is then secondary in importance. With the future expansion of international and North American "biotech" industry into Canada, other ways than possible (and generally highly hypothetical) individual financial rewards of returning benefits to scientific research, to the patient associations and the research participants need to be developed with the stakeholders.

Moreover, the issue of patentability is international. While the exact form of such expanded consent and sharing of profits is largely culturally dependant and should remain so in order to respect cultural diversity, patent law with respect to human genetic material is definitely an international issue. An explicit national, regional and international reaffirmation of patent law principles together with a clarification of how they apply to the specific situation of "uses" discovered for human genes may be the first step towards a necessary consensus that respects research participants and scientific endeavour.

** Addendum: Three-way European discussions, between the the European Parliament, the European Commission and the Council of Ministers, are to take place in January 1996 to decide whether to propose a new draft directive on the issue of patenting biotechnologies. This initiative follows from the unexpected rejection, in March 1995 by the European Parliament of the previous directive. The new draft directive is not yet publicly available[162].

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[162] A. Abbott, "Europe tries again on biotechnology patents" (1995) 378 Nature 328.