

Civil law reflections on the use of human biological material

Li Westerlund & Annina H Persson

Faculty of Law, Stockholm University, Stockholm

Introduction

Recently there has been an upsurge of commercial interest in the activities of biotech enterprises. This has been reflected on the world's stock markets, where biotech enterprises have been numbered among the star performers, but economic and medical successes have given rise to a number of legal problems, one of the most important legal issues being who should derive economic benefit from the successes of biotech development. Is it only biotech companies and shareholders, society and its institutions, or could it possibly be that the person originally providing the biological material is also entitled to a share in the economic benefits? This latter question is connected with the question of who is entitled to the material and, accordingly, has free disposal of it. Who, for example, is entitled to the millions of tissue and cell specimens which are stored in special "biobanks"¹ in our Swedish hospitals?² How is this material being collected and how will it now be used?³ Can the material change hands? What are the possessor's possibilities of disposing of it? Can the possessor carry out any research whatsoever on the material, and if so, how will the information obtainable from the material be used? Does it make any difference whether the biological material comes from a living or a dead person? What about the right of use and disposal where embryos and zygotes are concerned? Can a person whose material is used without his consent sue for damages?

The legal position on biobanks does not seem altogether clear. This is due to the absence of a uniform, coherent regulation of permissible procedures for the collection, storage and use of biological material.⁴ In addition to the problem of ownership/right of disposal of this material, there are many unresolved questions, e.g. the question of whether it is possible for private undertakings to set up biobanks and if so what happens to corporate tissue banks in the event of bankruptcy.⁵ This latter question is especially acute, since privately owned biobanks already exist.⁶

Purpose and extent of the analysis

The purpose of this study is to investigate some of the questions mentioned above.⁷ In particular we shall be considering who can be deemed entitled to the products derived through biotechnology from human material. The analysis will take as its starting point the laws variously dealing with different kinds of biological material and the rules of civil and penal law in general. The analysis will also include an account of the legal position in the light of the Council of Europe Convention on human rights and biomedicine.⁸ That convention, it is true, has yet to be ratified by Sweden, but this may happen within the not too distant future.⁹ In this connection it is also of interest to consider the Convention specifically linked to this European Convention on biomedicine, especially the 1950 European Convention for the

Protection of Human Rights and Fundamental Freedoms (ECHR)¹⁰, hereinafter called the European Convention.

In the event of biological material being deemed property in the sense of the European Convention, the legal assessment of the question of ownership in Swedish law will be affected. The shaping of future legislation on biological material and its handling will then be an urgent task for the legislator, given that the European Convention already acquired the status of Swedish law on 1st January 1995.¹¹ This incorporation in itself makes the provisions of the Convention directly applicable by Swedish courts and, accordingly, makes it possible for an individual person to have his case tried. If, then, the biological material in the biobanks mentioned above should constitute property in the sense of the European Convention, the legal position on the material collected in the biobanks will have to be defined as soon as possible, so that afterwards it can be decided what regulatory measures may need to be taken concerning utilisation of that material.

The right as such, viewed separately from the actual right of use

When discussing the right to biological material, it is important to distinguish between the right as such and the purely factual possibility of exercising the right, which may be limited, e.g. by legislation regulating use for various reasons. Limitation of the exercise of the property right need not, for example, come into conflict with the European Convention if prompted by a public interest. Thus the line of demarcation is of importance when analysing whether biological human material can be deemed to constitute a property right under the European Convention or a right of ownership as construed by Swedish law. Legally speaking, rights of this kind may conceivably exist in spite of the material, purely as a matter of fact, not being allowed to generate an economic return, owing to rules based on considerations other than those of ownership. For the purpose of the analysis, a distinction has to be made between a potentially basic economic value and a purely factual economic value. A heart may have an economic value in the sense of persons in need conceivably being willing to buy one for transplant purposes, at the same time as such transactions are prohibited under rules basically intended to protect the well-being of the country's inhabitants. The actual occurrence of trade in human organs is a fact pointing in favour of this argument.

Collecting the material

As remarked earlier, there are millions of tissue and cell specimens stored in our hospitals. This material can have been removed from a human being in order, for example, to make a diagnosis, to treat the patient or for transplant donation.¹² Pathology Departments all over Sweden have been saving tissue specimens from human beings ever since the 1940s, and in some cases longer still.¹³ In some places in Sweden there are tens of thousands of blood samples which have been donated for various projects. Tissue specimens from post-mortem examinations are also stored in these biobanks.¹⁴ Sperm banks and banks containing fertilised eggs are other examples of human biological material kept in store. All these biobanks contain material which has been gathered over a long period of time, frequently without consent being obtained from the donor.¹⁵ The donor has perhaps assumed that the material would be destroyed after the treatment was concluded, and is thus unaware that the material was meant to be saved and perhaps used in further research. Thus there may be people who have supplied human biological material without being sufficiently informed about the purpose and nature of the specimen. Possibly they also failed to receive the information that

should have been given to them concerning the consequences and risks which the taking of the specimen would entail. If, on the other hand, the donor received this information and consented, without further specification, to the sample being preserved for future research, one may ask whether he understood what he was consenting to, since no one at the time of the specimen being taken could predict the course of biotechnological development and, accordingly, the potential use of the specimen.¹⁶

Material from a living donor

The first thing to investigate is the condition under which hospitals and research institutions have obtained biological material, since this has a bearing on the question of who has the right of disposal over it. In principle, the taking of samples has always been subject to consent.¹⁷ The present rules of the law on health and medical care, therefore, are relatively precise concerning the situation requiring consent, also in relation to the type of material. Consent can be written or verbal, depending on the situation involved.¹⁸

In our opinion, the rules imply that, if a person has consented to an intervention and on that occasion has supplied biological material which is later stored, for example at the hospital, for subsequent re-transfer to the patient, then the right to dispose of the material remains all the time with the patient. Thus he can decide whether the material is to be destroyed after the treatment has been concluded, and the right of disposal over the material cannot in this case be transferred to the hospital.¹⁹ Consequently a patient's consent to an organ being taken for transplantation to another person means that the patient consents to the material being transferred to the recipient. Since the donor has no legal possibility of demanding the return of the transplanted organ, he has thus surrendered the right of disposal over the material in favour of the recipient.

This argument, however, is open to some doubt, because biological material is sometimes taken for transplantation without being transferred to the recipient directly. Instead it is stored at the medical institution for a fixed or indeterminate period until the right recipient turns up.²⁰ Even in this case, however, the donor has probably surrendered his right of disposal over the material in favour of the medical institution. If the patient provides biological material for research, the same argument should be applicable. If the patient has consented to the material being used in a research project, then by doing so he has surrendered his right of disposal. Since the consent makes such an important difference to the question of who has the right of disposal, it is of the utmost importance for the patient to know what he is consenting to.

Material from a deceased donor

In the case of an organ or tissue transplant from a deceased donor, it is the donor's attitude to the question of donation before his death which matters. Thus Section 3(1) of the Transplant Surgery Act allows biological material to be taken for transplantation or some other medical purpose from a deceased person if that person has consented to the intervention or it can otherwise be ascertained that the measure would be in accordance with the deceased person's attitude.²¹ Biological material may not be taken, however, if the deceased person has objected in writing to such a measure or has spoken against it, or if there is any other reason to suppose that the intervention would be contrary to the deceased person's standpoint, Section 3(2).²² One interesting point in this connection is that the deceased person can make his donation subject to conditions. He/she can, for example, stipulate that certain organs or biological

material may not be taken. As in the case of living persons, a deceased person, if it is his will, retains the right of disposal over the material. On the other hand the deceased donor can never prohibit or consent to the biological material being given for the benefit of a certain person or group of persons of a particular nationality or particular ethnic origin. In such cases there is an impediment to the intervention.²³ On the other hand, if a deceased person has expressed no objection to biological material being taken, the right to disposal may *ipso facto* be deemed to have passed to another.²⁴

Material from embryos etc.

If the biological material is tissue from an aborted embryo, it is the woman who carried the embryo who must consent to tissue from the embryo being used for medical purposes; Section 11 of the Transplant Surgery Act.²⁵ When the materials are to be taken, the woman may stipulate that tissue from the embryo may only be used for a specific purpose. Thus she can exclude a certain use of the material and thus has the right of disposal over the material. If the woman has consented to the material being used in a particular way, however, she cannot subsequently make the use of the tissue subject to further conditions. Her right of disposal has then passed to another party. If the biological material concerns experiments on fertilised eggs for research or treatment purposes, consent is again required.²⁶ Since fertilised eggs are normally stored to be reinserted in the woman donating them, the right of disposal over the material remains with the donors all the time.²⁷ Thus they must be able to decide whether the material is to be destroyed after the treatment has been concluded.²⁸ It should be noted that the Transplant Surgery Act does not apply to the transfer of gametes or organs producing them.²⁹

The Council of Europe Convention on human rights and biomedicine

Summing up, we may note that the laws which have now been mentioned usually require consent to be obtained whether the biological material is to be used for treating the patient himself or for some other purpose. These provisions, however, should be compared with the corresponding articles of the Council of Europe Convention on human rights and biomedicine.³⁰ That Convention also distinguishes between different situations and between different types of material, and it makes provision concerning both when organs and tissues may be taken and consent to their being taken.³¹ Without going any further into the specific rules on the possibilities of taking biological material, we may note briefly that the above mentioned provisions and articles generally stipulate consent where the biological material is to be used for a purpose other than treatment of the patient himself. Thus the stipulation of consent makes an important difference to a question of who may dispose of the material supplied and how. Neither the Convention nor the above mentioned laws, however, tell us what may be done with material that has been taken without consent.³² Can the material be used for research when the original biological material was taken for the treatment of a patient? ³³ One may further ask what one is allowed to do with material where consent has indeed been given but can hardly be said to include the measure now contemplated. Can consent be revoked? Can material be used if the donor is dead but the donor's relatives may come to be affected?³⁴

The right of disposal over the material

The debate on biological material has included a discussion concerning its ownership. It has been asked who owns the material and the information which the material contains. This debate has proceeded in two different directions.³⁵ Firstly, it has been argued that the public or private medical institution, doctors and others collecting the material are its rightful owners. In the other direction it is argued that it is the patient himself who owns his body and its constituent parts. The fact of the material being in a biobank does not alter this fact, and the bank has only certain rights over the material it possesses. It has further been discussed to what extent the owner of the specimen is entitled to dispose of the material as he himself sees fit. For example, is the possessor at complete liberty to sell the material within the country and abroad? Lastly it has been discussed whether the researcher who has used the material in the biobanks has thereby acquired some right of user over it.

To be able to tell who owns the material and who is entitled to use it, and if so what this right of user implies, one must, in our opinion, begin by asking what this so-called right of ownership amounts to. In addition one should state the criteria whereby a person can be deemed to have a right of ownership to an object of value. In addition, one has to ask whether human biological material is in the first place an objective value which can be owned like any other object. If biological material cannot be a subject of ownership in Swedish property law, then the question finally arises whether the material comes within the scope of any other fundamental right.

The concept of ownership in Swedish law generally

The extent of ownership, the concept and its implication have always been a controversial political issue in Swedish law.³⁶ This has resulted in the ownership concept being variously defined and understood by the legislature and jurisprudence at different points in time. In modern Swedish doctrine, ownership is functional, a utilitarian or purpose-related concept which can be used for resolving various conflicts.

Ownership can only be defined in a negative sense. In other words, the owner may use his property as he likes, in the absence of restrictions entailed by law or by agreements which he himself has entered into.³⁷ There are no direct rules of law describing the meaning or true existence of the right of ownership, except for Chap. 2, Section 18 of the Constitution Act and suchlike provisions defining the powers of the owner. Provisions of this kind decide, for example, the conditions on which an owner can exercise his right of ownership in an object as a basis for his obligations.³⁸ Summing up, the content of ownership is a question of political expediency.³⁹ Thus ownership is invested with the content which, from the viewpoint of legal policy, is judged suitable for the attainment of certain purposes.

One closely related question in this context is when the right of ownership passes from one person to another. In property law one finds that there is no special statutory provision as to when the title to an object passes, for example, from vendor to purchaser. The absence of a statutory provision, however, does not mean that ownership is regarded as something which entirely of itself 'passes' from vendor to purchaser.⁴⁰ Instead attention is made to focus on the many different legal consequences associated with the point in time at which title is transferred, and on trying to determine the commencement of those consequences. It is stated in the doctrine that the transfer of title does not hinge on a particular point in time but on the successive transfer of different components of title from vendor to purchaser.⁴¹ Thus different legal consequences pass at different points of time and in turn are linked to certain legal facts. In the purchase of personal property, certain legal consequences

are always attached to the contract. This applies above all to legal consequences affecting the relative obligations of the parties. Other legal consequences, applying to property relations between the parties, are on the other hand attached to tradition.⁴² Thus the legal consequences materialise at certain specified points of time between the conclusion of the contract and the completion of the purchase.⁴³

Criteria of a right of ownership

Since the implication of ownership cannot be substantially determined, the criteria of a right of ownership are likely instead to be determined according to the visible powers which a person may exercise over an object of value. What, then, are the powers of which rights in general are made up? These powers, according to Hessler, are of three kinds, *viz.*:

1. *The exercise*, meaning the material or actual power/s or possibility/possibilities of action which may be termed the content of the right. 2. The power of *legal disposal* of the right, i.e. of transferring it, pledging it and so on, and 3. the 'power' consisting in the right constituting *a basis of obligation* on the part of the entitled party, i.e. being included in his property as an asset and thereby forming a basis of the obligations which he incurs.⁴⁴

If applying, for example, the first power associated with ownership, one finds, in Hessler's opinion, that normally, at least, the object here, quite directly, is the economic benefits. One owns a car, a piece of real estate. And power-wise ownership, in principle, encompasses all the possible causes of action with regard to an object which the legal order permits. Within the framework of what is permitted or not prohibited, the owner of a car may do what he likes with it.⁴⁵ Applying the second power of ownership, one finds that an owner has the most far-reaching right as regards the possibilities of transferring the object. Sometimes the owner is the sole person legally capable of pledging an object. Applying the third power of ownership, one finds that the best and safest way of showing that the right is included in someone's property is possession of the object. Through possession one shows one's ownership of the asset.

Biological material as property

As stated earlier, in order to determine the legal status of human material, we have to analyse the true content of the right, i.e. the individual rights and legal dispositions of which property protection consists. The first question to be answered is whether one can own one's body and its parts.

Ownership can be asserted in both real and personal property. Personal property is taken to include chattels, non-freehold buildings, shares and other securities, intellectual property rights etc. Animals are deemed chattels, i.e. choses in possession.⁴⁶ To what category, then, do human beings or the human body belong? In our opinion, human beings would not seem to belong to any particular category. Instead the literature argues that every person is a legal subject.⁴⁷ A person cannot be the object of any other person's right of ownership.⁴⁸ This also applies to deceased persons.⁴⁹ Then what about the ownership of parts of a person's body? It is asserted that parts of a living person (hair, beard etc.) belong to the person from whom they have been separated, unless that person has abandoned them. The same probably also applies to other material, e.g. blood and internal organs removed in the course of surgery.⁵⁰ In the case of deceased persons it is maintained that just as the ownership of the hair, beard etc. of a living person can pass to someone else, however, the same applies concerning the same kind of biological material from a deceased person.⁵¹ Since an invention can be based on biological material of human origin and then patented, the implications of a

patent right in this respect should be underscored. The object of a patent right is generally of an intangible character. The object of the exclusive right is the technical information, an idea, and not the object in the form of a product or a procedure, even though the exercise of the right means preventing others from making commercial use of the information by manufacturing, offering etc. the patented product or procedure. Comparing ownership with intellectual property law, one finds in both cases that the possessor has an exclusive right of disposal to and over the object.⁵² The difference between the two rights, however, is that the rights of disposal over the intellectual property right can be retained and transferred at one and the same time.⁵³ When discussing the ownership of biological material, one should further remember to distinguish between *the material* as such, its physical existence, and the *information* which the material may contain.⁵⁴ The information in the material is something which all human beings carry about with them. Therefore it would not seem possible to assert a right of ownership in the information as such. The right of ownership – if there is one – could only apply to the material itself, not to the information. The only question is what counts as information and what counts as material. A human gene which all human beings are equipped with can, for example, be patented.⁵⁵ Is, for example, the gene giving rise to certain forms of cancer to be counted as material or as information in the material?

Summing up, the legal position appears to be as follows. Nobody can own a living or dead body. On the other hand, a right of ownership can be claimed in body parts. It follows that the material belongs to the person it has been taken from and, accordingly, that consent is required.⁵⁶ Application of the general principles of property law does not furnish any guidance as to when the ownership of human material passes from one person to another. How, then, does this assertion relate to the general criteria of ownership?

As regards the first power, *exercise*, we can begin by discussing what the possessor of a body may do with it, within the scope of what the legal order permits. True, nobody can own a living or dead body, but in practice it is still the possessor who to a great extent decides what is to happen to the body. As regards the second power, that of *legal disposition*, we may discuss when the possessor can exercise this right. Since body parts are clearly transferable, one naturally asks when this transfer can take place. As regards the third power, *the object as a basis of the obligations which the possessor incurs*, we have to investigate whether the body really is such an asset. If body parts can be sold then they are of course an asset. One asks, however, how body parts can be an asset when current law seems to reject commercial trade in human organs. We shall now turn to investigate these questions.

Exercise

As mentioned earlier, we can discuss what the possessor of a body may do with it, within the scope dictated by the legal order. The basic principle seems to be that the possessor can in principle do what he likes with his body. One may abuse it and torment it without society interfering. One is entitled, by self-mutilation, to make oneself ineligible for military service and one is entitled to attempt or carry out abortion on oneself.⁵⁷ One is even entitled to take one's own life.⁵⁸

Man's right to subject his own body to illness, risks etc., however, has been limited in certain respects. A person committing a serious form of substance abuse can be placed in coercive care. A minor can be placed in care, and for this to happen it is sufficient for the parents to be incapable of providing for his needs; there is no stipulation that the minor should be incapable of looking after himself. Then again, even if one wishes to harm oneself, one may not drive one's motor vehicle exactly as one pleases.⁵⁹ Nor may one use narcotic drugs.⁶⁰ Lastly, one may not take part in competitive matches, demonstration matches or training

matches in professional boxing.⁶¹ Society has also imposed limits on what anybody else can do to a certain person, even though that person has consented.⁶² A woman, for example, may not consent to genital mutilation.⁶³ Nor, for example, may a person consent to being murdered or severely assaulted. Consent, then, does not exempt the culprit from criminal liability. On the other hand, certain medical interventions can be classed as assault. In such cases, however, there is no question of hospital staff incurring liability if the patient consented to the intervention. Nor can the hospital staff be held liable in cases where the patient was unconscious and thus incapable of giving consent, so long as the staff can plead that the intervention was an emergency action.⁶⁴

Thus there are a number of enactments indicating what the possessor of a living body may do with it, but what about a dead body? Initially we may note that Chap. 2, Section 6 of the Constitution Act and Chap. 3 of the Penal Code only apply to living persons. This means that a deceased person can never be assaulted.⁶⁵ Furthermore, no one can commit a crime of property by unlawfully removing a dead body or removing a part from a dead body. On the other hand, the person committing this act can be found guilty of an offence against the sanctity of the grave⁶⁶ or possibly of unlawful dispossession.⁶⁷ From birth to death, every person has legal capacity. Once dead, however, a human being is no longer deemed to be a legal subject, and accordingly he loses his legal capacity. Thus the deceased person can no longer acquire any rights. The rights which the deceased person formerly possessed now pass to another person or cease to exist entirely.⁶⁸ It should be noted, however, that the fact of the deceased person no longer being a legal subject does not mean that he becomes a legal object. Thus neither the dead body nor parts of it can be a subject of ownership, with one exception.⁶⁹

Legal right of disposal over one's own body

The second important question to answer is whether the owner can legally dispose of his right, e.g. by assigning it. Thus, applied to the human body, the question is whether the possessor can sell his body or parts of it.⁷⁰ The Government Commission report accompanying the Transplant Surgery Act, however, states that the notion of part of a living person being regarded as a commodity which can be bought or sold is quite alien to most people in our country.⁷¹ The notion of trade occurring in parts of a dead person's body is equally foreign.⁷² On the other hand the doctrine states that, even though there can be no claim to ownership of the person's body or parts of it, a person has the right to disposal over it within certain limits.⁷³

As has already been made clear, Sweden has a number of laws regulating what can be done with a living and dead body respectively.⁷⁴ Most of these laws deal with medical procedures such as transplant surgery⁷⁵, post-mortem examination⁷⁶, criteria for the establishment of death⁷⁷, artificial insemination⁷⁸, research using fertilised ova⁷⁹ etc. What, then, is one allowed to do with a dead body? All the statutory text has to say on this point is that certain procedures with dead bodies are forbidden.⁸⁰ The possibilities of using a dead body for different purposes are limited insofar as the intervention is unsupported by law or statutory instrument.⁸¹

On the other hand it is rather uncertain what applies outside the area regulated by statute. It is an interesting assertion in this connection that relatives or the estate of the deceased person cannot claim ownership of the dead body or parts of it. The dead body is not included in the estate of the deceased person and obviously no economic value can be assigned to it.⁸² The dead body is not to be regarded as a chose in the legal sense. This being so, a person unlawfully removing a dead body cannot be guilty of any crime against property.⁸³ The same applies in the event of someone unlawfully removing a part of the dead

body.⁸⁴ On the other hand it is conceded that, during his lifetime, the individual person may decide a good deal concerning how his body is to be dealt with after he dies. This applies both to burial etc. and the possibilities, after death has occurred, of collecting organs for transplant surgery and of performing post-mortem examinations. Alternatively, some such power of determination is also vested in the relatives. They, on the other hand, cannot “own” a dead body. A right of this kind is only attributed to museums and medical institutions, which can own entire bodies.⁸⁵

The body and its parts – an asset?

The third and last question to answer is whether ownership of the body and its parts is included in the possessor’s property as an asset and thus forms a basis for the obligations which he incurs. From what has now been said, the answer to this question would, initially, seem to be No. On the other hand there is no doubt that a person can cut off his hair and sell it for a certain sum of money to a wig-maker.⁸⁶ Thus it could be argued that a part which has been separated from the body could be given away just like things – choses – generally.⁸⁷

The *travaux préparatoires*, however, appear to distinguish between the situation where the body part can be recreated – as in the case of blood and hair – and a situation where removal entails a lasting detriment to the individual, as for example with the removal of a kidney.⁸⁸ Concerning this latter incidence, it is maintained that if a contract for the sale of a kidney were to come before a court, the court would probably find the contract to be at variance with accepted practice and would therefore void it.⁸⁹ Whether a body part is an asset to the possessor depends on what kind of a body part it is.

The *travaux préparatoires* of the Transplant Surgery Act also discuss the handling of contracts concerning a body part which are already concluded before the part has been separated from the body.⁹⁰ The possibilities are discussed of the entitled party enforcing completion of such an agreement. From the legal analysis, however, it is noted that no distinction is made according to the body part involved. Asserting one’s right as being entitled to the hair which has been sold, e.g. by cutting the hair off the possessor, entails liability for the infliction of bodily injury and is to be regarded as assault if the injured party has not consented. This same goes, of course, for other types of body parts. It does not seem possible for an attempt to be made to enforce performance by executive measures.

We can only conclude that the general rules of civil law concerning gifts and other forms of transfer are subject to substantial modifications in their application to body parts.⁹¹ The question is, however, whether a donation, like a gift, can be made conditionally. Given what has now been said, this would appear to be possible. If the donor has stipulated that the biological material may not be used for anything but a certain purpose, he should be able to insist on the material either being destroyed or returned if the purpose for which it is now intended does not agree with the donor’s wishes.

Given what has already been said concerning the criteria of ownership, the suitability of the concept is open to question when discussing biological material. Since the legal questions with regard to biobanks are above all concerned with rights and obligations⁹², it is, in our opinion, impossible where biological material is concerned to speak of a right of ownership as defined in Swedish property law. The concept of ownership is not applicable, partly because it focuses on choses/objects with related property dispositions and biological material is not to be regarded as such an object. It should also be noted that the concept of possession as used in Swedish property law is also inappropriate in these connections.⁹³

Protection of property

General remarks on protection of property under the European Convention

The protection of property has caused problems in the drafting of universal Conventions, owing to its complicated legal character, which varies from one legal system to another. The difficulty of achieving concrete regulation of this question stems from the political differences associated with the concept of property and protection of property, but the UN Universal Declaration of Human Rights⁹⁴ contains an Article for the protection of property.

Article 17 lays down:

“Everyone has the right to own property alone as well as in association with others. No one shall be arbitrarily deprived of his property.”

No such provision, on the other hand, is included in the International Covenant on Economic, Social and Cultural Rights or the International Covenant on Civil and Political Rights.⁹⁵ Protection of property was omitted from the 1966 Conventions because the Commission was unable to agree on the text of such an Article.⁹⁶ The European Convention, adopted in 1950, did not contain any provision on property protection either. Despite the great difference of opinion concerning the framing of the provision, one was adopted in the first additional protocol to the Convention.⁹⁷ As mentioned earlier, the Convention provision with its additional protocol on protection of property can have a bearing on the determination of the legal status of biological material directly emanating from the human body. That question, however, has not been the subject of any judicial decision.

Sweden has a large number of biobanks containing material which was taken and stored before the requirement for consent actually began to be applied. As has already been shown, the individual cannot be deemed to have a right of ownership in his biological material as the concept is defined in Swedish law. On the other hand there is cause to investigate whether one may still have a basic title to the biological material emanating from one's own body. Any such right will not necessarily be as far-reaching as a right of ownership where the possibilities of economic disposal are concerned.

Since the legal outcome of an adjudication under the Additional Protocol to the European Convention may be relevant to material in biobanks taken before consent was actually stipulated, we shall examine the criteria for the right to property more closely. As regards material taken after consent began to be applied to sampling, the question is less interesting. There is a purely practical explanation for this. If a property right to the material were to prove to exist for the individual person, such a right would be deemed, by reason of the consent, to have passed to the sampler, at all events in the form of a dispositive right to use the material for research to a varying extent.

Internationally regulated property rights

In addition to a defined universal protection of property, various conventions are declarations containing other provisions which are limited to certain types of property. Rights may be limited both as regards scope and as regards the property rights which can be protected. The right of States to dispose freely of their genetic resources is one such example.⁹⁸ The focus here is on the collective right to certain property. Property rights can also refer to intellectual, industrial and artistic activity, which enjoys special protection under various international conventions.⁹⁹

The right to property and its meaning

The legal basis of the right to property, viewed internationally, has already been presented in general terms. We noted that, both in the UN Universal Declaration and in the European Convention, the right is relatively vaguely and indecisively formulated. For this reason the content of the right cannot be instantly determined. In addition, the European Convention seems to be dynamically interpreted by the Court, which means that new phenomena can be incorporated in a context appropriate to the times.¹⁰⁰

In order to correctly crystallise out the content of the right to property and place it in relation to human material, it has to be analysed in relation to the elements characterising the normative structure of human rights.¹⁰¹ Basically, such a necessary division of the individual elements of the right can be based on subject and object. Every right has a subject, indicated whose right is protected. Similarly, the right applies to an object which stands for the true content of the right, i.e. what is protected and against what.

The question of what is protected has a specially interesting bearing on a potential right of property in the biological material of individual persons. Since the scope of the right indicates the limits of what is protected, it has to be established in order to show whether human material is included or not. In the event of such material being included in the protection of property, the legal status of the right also has to be determined. In such an eventuality, we have to analyse the true content of the right, i.e. the individual rights and legal dispositions which the protection of property comprises. Once again it has to be recalled that a right to property under the Convention is not necessarily the same as ownership in the Swedish legal sense.

Property refers to rights, not to concrete objects (*choses*), but the importance of the property concept varies from one legal system to another, and this is the basic problem when we come to apply the international provisions. Property consists of property rights, which can be either personal or real property. But property is a more extensive concept than ownership and also encompasses other property rights and interests.¹⁰² No clear definition of the concept has been indicated, and so it has to be interpreted in the light of the case law which to some extent clarifies the boundaries of the property concept. Since the scope of the property concept as such has not been very extensively adjudicated, in order to decipher its content we have to fall back on the Commission's decisions concerning refusal or non-refusal.

Personal property

All property rights which are not real property are deemed personal property. A property right may refer to a *chose*, but limited rights in real and personal property – mortgage title, for example – are also included. Property rights remotely connected with concrete objects may also constitute personal property. Payment claims and intellectual property rights are two such examples. Property protection under the European Convention seems to be more extensive than the right of ownership in the Swedish legal sense.¹⁰³ Without any doubt, the right to property is a fundamental human right, but what exactly that right includes is unclear, and so is its concrete implication. Human rights have been dynamically interpreted by the European Court, and their concrete meaning is governed by case law.

The observation that human material can have an economic value is of relatively recent date, and the court has not yet had occasion to decide any question of property rights concerning such material. Consequently no actual decision exists on this point. As regards the object of property, the wording refers to property but without defining it more closely. The

European Court case law illuminating the right, however, indicates an extensive construction of the concept, and in certain respects protection of property has, through interpretation, acquired a more extensive meaning than the actual wording suggests. For this reason, and also considering that the protection of property has not been framed in a Swedish perspective but in a collective European perspective, a restrictive interpretation of the property concept in the European Convention, in accordance with a traditional Swedish legal view, need not necessarily be correct.

The property concept and the concept of ownership have always varied in meaning and most necessarily follow the time in which they are applied. The reality is that human material today has an economic “value” or “interest”, which used not to be the case. This calls for an analysis of the ownership concept in the light of that reality. The content of the property concept as it can be read into the European Convention in its broad sense can influence the meaning of the ownership concept in Swedish law. At all events it is bound to affect the way in which Swedish law regards the fundamental legal status of human material. If such material can be referred to property in its broad sense, there is a strong argument for each individual having some form of power of determination over “his” biological material. The interesting question will then concern the character of this right. To take two examples of property differing in concrete substance, ownership of an object in the Swedish legal sense is a positive right of property, whereas an intangible right in the form of a patent is a negative right in the sense of being a right to prevent others from commercially utilising a technical idea.

Thus the actual content of a property right can vary. Moreover it is quite permissible for the States Parties under the Convention to impede economic use in a purely factual sense, and also, with a public purpose in view, to deprive the individual of his right. This is subject to the deprivation not being arbitrary and to its complying with the law. Consequently the right of property under the European Convention is not an absolute right. Instead the States Parties are permitted, subject to certain conditions, to limit the right of the individual.

A further aspect where pre-existing biobanks are concerned is that a “right” to the material possessed by the bank can possibly be deemed to have passed by custom, prescription or occupation. If so, this would mean that the right of disposal of the original individual had ceased that any claims to compensation had been cut off.¹⁰⁴ An individual person’s property right, should one exist, might possibly be deemed to imply solely a right of excluding the use of the material. In other words, the individual would not have any right to the economic benefits of products developed from the material concerned.

The EC Directive on the legal protection of biotechnological inventions

The Biotechnology Directive¹⁰⁵ governs the patentability of inventions in which genetic material is included, it does not regulate the ownership of genetic material itself. On the other hand, certain more general European aspects and deliberations concerning human genetic material can be deduced from the provisions and preamble of the Directive. It can be noted in this connection that work on drafting a Directive in this field began already in 1988. Thus years of deliberation went into the Directive which was finally adopted. One important distinction with regard to patents is that these are obtainable for inventions but not for discoveries, and the Directive contains certain clarifications on that point.

The potential economic value of the human body and its components was observed in relation to the possibility of patenting inventions based on information in such material. The Directive clarifies the difference between the material as such and patentable inventions in Article 5, which lays down that the human body, at the various stages of its formation and

development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. The Directive also makes clear that an element isolated from the human body or otherwise produced by means of a technical process may constitute a patentable invention.¹⁰⁶ Body parts or genetic sequences as they exist in the human body are not patentable. Thus it is the technical aspect and necessary human intervention to obtain the product as such which decide the distinction between patentable and non-patentable elements of the human body.

The relevant question for this study is whether these can constitute property and, if so, who owns or controls them. The deliberations underlying the adoption of the Directive can be deduced from these Articles, but as regards human material in a purely general sense, the relevant deliberations are if anything apparent from the preamble, and so it is from the preamble that, to some extent, the collective European view of human biological material can to some extent be evaluated.

In connection with the basic principle that the human body and its components as such cannot be patented, the importance is underlined of respecting the fundamental principles safeguarding the dignity and integrity of the person.¹⁰⁷ The importance of research and development in biotechnology is emphasised in this connection. Attention is made to focus on the fact that significant progress in the treatment of diseases can be made thanks to the existence of medicinal products derived from elements isolated from the human body or produced by a technical process emulating the human body. It is declared¹⁰⁸ that research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system. Situations where the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare diseases are also referred to, which indicates the importance attached to progress in this field, in that Member States have a duty in such situations to respond adequately to this problem.¹⁰⁹

The deliberations underlying the Directive clearly show that from a societal point of view research in this field is important and has high priority. At the same time it is also pointed out that the dignity and integrity of the person must not be neglected. A properly balanced solution reconciling these two sometimes contradictory interests is thus seen to be desirable and is positively called for. The question of the fundamental right to each individual's own body and its elements should then be viewed in this context. Similarly, in our opinion, the question must be viewed in the light of the legal reality that today, even in practice, consent is required in order for the material to be used for research and development. This requirement of consent is also internationally rooted in the Council of Europe Convention on Human Rights and Biomedicine, referred to above, which has yet to be ratified by Sweden.

Conclusions

Where biobanks are concerned, there are clearly a number of persons whose interests can come into conflict with each other. It is not yet established how the legislature proposes to balance the conflict of interests¹¹⁰ between the donor, his family, the researchers, the biobank proprietors and industry. The rapid pace of development and the complexity associated with biotechnology also make it difficult to regulate this field effectively by means of traditional legislation.¹¹¹ A person's fundamental right of deciding over their own body is evident from Government Bill 1994/95:148 on Transplants, Post-mortem Examinations etc.¹¹² It is noted that the right of self-determination as to whether a person shall donate his organs can have the effect of restricting the possibilities of carrying out transplant surgery. This highlights the

conflict of interest between individual powers of determination and public interests. This conflict of interests also serves to illustrate the situation whereby, even in the event of ownership being ascribed to the person carrying the genetic material, the State can intervene through legislation and if necessary transfer the right of ownership as such or the right of disposal to another party. The *travaux préparatoires* state that each individual has an interest in being able during his lifetime to decide what will happen to his body after death, and that the focus of attention is on the mental integrity of the person. That interest can be greater still as regards the elements of the body during the person's lifetime, but an economic interest is then added. If it is allowed to operate freely without any rules to restrict the right of disposal over the different elements of the body, the economic interest may be relevant both during a person's lifetime and after their death.

One argument for the right of property viewed from the individual person's perspective is that the individual who has a sought-after genetic material must be entitled to the economic benefits which he can derive from that material in the market. It seems less easy to underpin the argument that as soon as an element has been separated from the body it shall accrue to the party "taking" charge of it. The latter must be separated from the view that the party further developing genetic material or making a commercial product of it shall be entitled to his inventive step. These are two separate questions. This is not to say that the "owner" of a body element shall not be able to share in the economic benefits of an invention, but if so this must be a contractual question between "the owner" and the party using the material, as with all other agreements in property law concerning the transfer of ownership. What is now said applies to the fundamental legal status. In practice, the informed consent, for example, which has to be given before specimens are taken probably means any right of disposal passing to the sampler,¹¹³ who then acquires a legal right of disposal over the sample. Where biological material is concerned, however, it is inappropriate to speak of a right of ownership as defined in Swedish property law. If anything the question is one of a "property right".

Another reflection is that property and ownership are not the same thing. Ownership means that the possessor of this right – which always implies an economic value – is protected from encroachment by other interests. Property and the protection of property as defined in the European Convention mean instead that a person's right to his property shall be left inviolate. Regardless of whether the property has an economic value, a person is entitled to have his property kept inviolate, unless the State finds it necessary to regulate the use of that property out of consideration for the public interest. Consequently one does not own one's body, one has only a right to it.¹¹⁴ This last mentioned right means that a person is entitled to prevent others from using material which comes from that person's body. Thus the right is of a negative kind, namely a right of exclusion. This is supported by the stipulation of consent, which *e contrario* can be interpreted/viewed as the right of each individual to prevent further utilisation of the material.

As mentioned earlier, a person has a right to his body and its elements in the sense of this property having to be left inviolate. This means that individual persons are entitled to exclude, but it does not necessarily imply a right to economic return on the material. Through legislation, however, the State can provide for the material present in Swedish biobanks to be used for research out of consideration for the public interest. How this legislation is to be framed is a political question, but its outermost limits are determined by the European Convention. It should be pointed out that our conclusions concerning ownership and concerning property and property protection imply that only an individualised right can come into question, not a national or collective right to the material present in the Swedish biobanks. Nor is the State, as some kind of proxy for the citizens, entitled to the material as such. But the State can legislate on permissible uses of the material.

As regards the material which is already present in Swedish biobanks and which people have supplied without any proviso concerning its use, we take the following view. The proprietors of the biobanks have acted in the belief that they had a right of disposal over the material. What is more, for a long time nobody has laid claim to the material. Although the main rule is that the donor retains the right of disposal over his body, he can assign that right to another party.

As mentioned earlier, the right of disposal is transferred, e.g. in connection with transplant surgery, to the recipient of the biological material or to the institution receiving the biological material. A rule to the effect that the patient retains the right of disposal over the biological material in all perpetuity implies difficulties with regard to the material which is already present in biobanks and for which no consent has been obtained at all. In certain cases, moreover, consent is unobtainable. Then again, there is the question of how to trace material which has been depersonalised, since it is impossible to find the person who originally provided it.

Summing up, however, our standpoint with regard to the material which is present in the Swedish biobanks and which was collected prior to the stipulation of consent as worded in the Transplant Surgery Act, is that the right of disposal to this material has passed to the proprietors of the biobanks. This conclusion is above all supported by the rules of civil law concerning occupation, since the material has been supplied without any intention of recovering it or disposing of it any further. Thus the individual person cannot be deemed to have any right of deciding or impeding the concrete use of the material. This means that a rule to the effect that consent shall include pre-existing biobanks, so the consent would have to be obtained from donors for every use, is unnecessary and also undesirable because it would create obligations with a retroactive effect. The obligation entailing a retroactive effect is due to a legal stipulation of consent having existed all the time but in certain cases having been ignored when the samples were collected, without any measures being taken by the community.¹¹⁵

Another question concerns the handling of the information which can be associated with the material. Rules exist concerning such information about patients, but this question may need to be reviewed, considering that this type of information nowadays is being set up and systematised in a new way. Problems of integrity occur, especially if information about the patient is connected to the material as such, e.g. in databases, and so do ethical questions, such as the question of whether the patient is entitled to find out what is discovered in the material and may have implications for his health etc.

Actual consequences of a property right

The actual consequence of a property right is that the actual control and use of the biological material is reserved for the individual person from whose body it originates. Accordingly, no one else can lay claim to the material after it has left the body if the property right is not to be deemed to have passed to another or if no one shall be deemed to have acquired a right of disposal in the material. A right of disposal of this kind can be regulated and, for example, made contingent on the extent of consent or on similar legal constructions.

If the stipulation of consent is to be taken to mean that the medical institution storing the material must obtain consent in order to use the material for a purpose other than that for which the material was collected, this can in certain cases impede or prevent the use of the material for research and development. The procurement of genetic information may then be impeded and potentially speaking the possibility of developing future inventions may be adversely affected. It has to be pointed out, in this connection, that in the individual case this

is no “worse” than if the person concerned had never supplied his material in the form of samples, since his genetic material would not then have been available at all.¹¹⁶

As long as the human material remains intact in a person’s body, that person can be said to have a “natural” protection against a third party. It would not seem unfair as a fundamental legal principle to deem that the person whose genetic material is at issue is entitled to decide how it will be used or at all events to prevent its use. What may be debatable, on the other hand, is the right to any economic return on the material. Internationally speaking, we can take the USA as an example where most States have passed legislation forbidding the commercialisation of human organs in accordance with the UAGA.¹¹⁷ Although, then, the right of ownership has powerful status in the USA, the purchase and sale of human organs are to a varying extent prohibited, as are, to a varying extent, the purchase and sale of human tissue.¹¹⁸

It is hard to find tenable basic arguments for the principle that the third person who for various reasons may come by the genetic material shall be entitled to its economic benefit without the person carrying the material having any claim whatsoever. This is not to say that regulation of use cannot be justified for certain public purposes, so that genetic material will be available for research and development in a socio-economically acceptable manner. Genetic material today has a value. In the light of national genetic resources, for example, fundamentally accruing to the State where they occur, and to the possibility of owning real property in the way of choses in possession and choses in action, it is illogical that one’s own genetic material should not basically enjoy such status.

A few practical examples will serve to illuminate the situation. Biotechnical inventions are being patented to an ever-increasing extent, and many of these patents are based on human genetic material. One such patented invention is “erythropoietin”, which is used in the treatment of anaemia. The genetic material needed for manufacturing erythropoietin is present in all human beings, which from a commercial point of view means that the supply is great and the “price” ought to be low or indeed nil. The necessary input material – present in the blood – for manufacturing the product would always be available from somebody. A different situation occurs when, for example, a person has a cell strain which is very unusual indeed and his and perhaps a few other people’s cell strain is needed for manufacturing the product. In a “free market” it can be asked why that person should not be able to negotiate and thus have the possibility of harvesting the economic value of his particular cell strain, just like any other asset, since it is capable of generating great economic values. The extreme instance of a person not consenting to use at all and the material being necessary in order to save present or future patients can always be regulated by means of legislation “expropriating” the material for a certain purpose.

The stipulation of consent before the material is taken could be viewed as a way of streamlining a transfer of a property right/right of disposal, but, as has already been mentioned, consent is fundamentally a problem. It would of necessity precede something, which means that a person with a much sought-after genetic structure would have no chance of knowing his negotiating position in advance. One arrangement is for a person to consent only to research into the sample, while stipulating further consent before the genetic information can be used commercially, e.g. by selling a product in which it is included. The donor would then be able to negotiate for payment. In our opinion, however, it is inappropriate to leave “the market free” for the sale and purchase of biological material. Legislation of the kind occurring, for example, in the USA and prohibiting commercialisation in its true sense may be appropriate. It should be considered whether payment based on the expense to the individual of making his material available for research or to save lives should qualify for compensation.

Summary

1. Where biological material is concerned it is inappropriate to speak of a right of ownership as defined in Swedish property law. The ownership concept does not fit, among other things because it focuses on choses/objects and biological material is not to be regarded as such an object.
2. When discussing intangible rights in the form of patents for biological material, it has been recalled that this is something quite different from the title to an ordinary object. A patent right in human genes, for example, means that one has developed an invention based on the information in the human material. The object of the patent right is a concretised idea, not the right to an individual person's genes.
3. Property and the protection of property as defined in the European Convention means that a person's right to their property shall be left inviolate. This is not to say that one owns one's body, one only has a right to it¹¹⁹ in the sense that individual persons have a right of exclusion. This agrees with the stipulation of consent, which *e contrario* can be interpreted as the right of each individual to prevent further utilisation of the material.
4. Although each individual has a right to his body and its elements in the sense of this property being inviolable, the State, through legislation, can provide that the material existing in the Swedish biobanks may be used for research according to the public interest. How this legislation is to be formed hinges partly on political considerations, but its outermost limits are determined by the European Convention.
5. On the basis of an argument of civil law, we are of the opinion, concerning the material which is already present in the Swedish biobanks and which people have surrendered without any provisos concerning its use, that the right of disposal over the material has passed to the biobank proprietors. From this it follows that retroactive consent is unnecessary.

Legal questions which the legislature should consider

Firstly the legislature must consider whether a right of compensation shall be granted for the use of biological material. We have not found anything in Swedish law to support the view that the person concerned is entitled to compensation for the material being used. In our opinion there are several different standpoints which the legislature can choose from. Either one can adopt the standpoint that compensation shall be paid to "the proprietor" when use takes place. In this way one would permit purchase or sale, lending of the material, temporary encroachment and suchlike on the material, which would entail a right of compensation for the proprietor. The other standpoint is that no compensation at all shall be paid for use. No commercial purchase and sale in return for payment shall be permitted. A variant of this last mentioned alternative would be for the donor of the biological material to permit the biobank to use it freely. The biobank would thus be allowed to use the material in the public interest, i.e. in research for the curing of disease. The biobank proprietors, however, would not be allowed to re-sell the material. On the other hand there would be nothing to prevent the biobank proprietors inventing a product from the material. Then of course they could patent this invention and derive economic benefit from it. The choice of direction is for the legislature to decide, but in our opinion the last mentioned part is probably most in keeping with Swedish legal tradition.

Secondly, the legislature must consider what the stipulation of consent implies. By giving consent, has a person given the use of the right to dispose freely of the material, or does consent mean that the right of disposal exists only within certain frames? As in the above

mentioned case, the legislature has various alternatives to choose from. This question, however, is probably too complex to be answered without a close analysis. The structure of consent will be made the subject of a close analysis within “the Biobank Project”¹²⁰ in the course of work during the coming year.

References:

¹ biobank can be a tissue bank or a collection of blood samples, or the information which has been obtained from such a bank. See Biobankers behandling av personuppgifter, Datainspektionens rapport 2000:1 p. 5, Ahlgren, T., Bankinspektion behövs för biobanker? “Kommersiella intressen skall inte tillåtas inkräkta på etiska värden”, *Läkartidningen*, vol. 96, nr. 13, 1999, p. 1548, Rynning, E., Biobankerna – hög tid för bankinspektion?, *Förvaltningsrättslig tidskrift*, 1998, häfte 6. p. 303. See also *Socialstyrelsens förslag till lag angående biobanker inom hälso- och sjukvården m.m.*, 3 maj 2000, pp. 6, 23, 39, 47, 79.

² See Perkiö, H., Svenskarna har dokumenterats i 80 miljoner paraffinklossar *Landstingsvärlden* nr. 18/99 pp. 14.

³ The material can, for example, be used in a way, which violates the integrity of the person providing the sample. It may also come to be used in a way, which causes the provider to be discriminated against in various respects. See Rosen, E., Genetic information and genetic discrimination how medical records vitiate legal protection, *Scandinavian Journal of Public Health*, vol 27, nr 3, 1999, pp. 166. See also DS 1996:13, pp. 9.

⁴ See *Biobanker i hälso- och sjukvården m.m.* Förslag från Socialstyrelsen, 2000, p. 93.

⁵ See Ahlgren, T., Bankinspektion behövs för biobanker? “Kommersiella intressen skall inte tillåtas inkräkta på etiska värden”, *Läkartidningen* vol. 96, nr. 13, 1999, p. 1548.

⁶ See Rynning, E., *Biobankerna – hög tid för bankinspektion?*, 1998, p. 303. It should be mentioned that the Icelandic parliament (Allting), for example, has already decided to sell the right of disposal over data from an Icelandic gene bank to a business enterprise for a fixed term. See Ahlgren, T., Bankinspektion behövs för biobanker? “Kommersiella intressen skall inte tillåtas inkräkta på etiska värden”, *Läkartidningen*, vol. 96, nr. 13, 1999, p. 1548.

⁷ See also Westerlund, L., & Persson, A., H., *Civilrättsliga reflektioner på användningen av mänskligt biologiskt material*, 2000.

⁸ See Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and Explanatory Report. See [http:// www.coe.fr/eng/legaltxt/164e.htm](http://www.coe.fr/eng/legaltxt/164e.htm) 2000-06-06 and [http://conventions.coe.int/ treaty/en/ Reports/Html/164.htm](http://conventions.coe.int/treaty/en/Reports/Html/164.htm).2000-06-06.

⁹ See Rynning, E., *Biobankerna – hög tid för bankinspektion?* 1998, p. 312.

¹⁰ Convention for the Protection of Human Rights and Fundamental Freedoms FördrS 18-19/1990, adopted 4.11.1950, entered into force 3.9.1953. See also Protocols to the Convention for the Protection of Human Rights and Fundamental Freedoms. FördrS 18-19/1990, adopted 20.3.1952, entered into force 18.5.1954. See also Åhman, K., *Egendomsskyddet. Åganderätten enligt artikel 1 första tilläggsprotokollet till den europeiska konventionen om de mänskliga fri- och rättigheterna*, 2000, pp. 15.

¹¹ See *Lag (1994:1219) om den europeiska konventionen angående skydd för de mänskliga rättigheterna och de grundläggande friheterna* (Act concerning the Convention for the Protection of Human Rights and Fundamental Freedoms). Reprinted in SFS 1998:712.

¹² See Rynning, E., *Biobankerna – hög tid för bankinspektion?* 1998, p. 305.

¹³ See Perkiö, H., Svenskarna har dokumenterats i 80 miljoner paraffinklossar, *Landstingsvärlden* nr. 18/99 p. 14.

¹⁴ See Ahlgren, T., Bankinspektion behövs för biobanker? “Kommersiella intressen skall inte tillåtas inkräkta på etiska värden”, *Läkartidningen*, vol. 96, nr. 13, 1999, p. 1548.

¹⁵ See Holmström, L-G., Det ingen och alla äger, *Landstingsvärlden* nr 18/99, p. 20.

¹⁶ See *Forskningsetiska riktlinjer för nyttjande av biobanker, särskilt projekt innefattande genomforskning*, 1999, p. 2; Ahlgren, T., Nya etiska riktlinjer för biobanker, *Läkartidningen*, vol. 96, nr. 25, 1999, p. 3051.

¹⁷ See Prop. 1981/82:97 pp. 49, 58, and 188. See also Rynning, E., *Samtycke till vård och behandling, En rättsvetenskaplig studie*, 1994, pp. 174, 177. It should be noted, however, that the consent requirement has not always been observed in practice.

¹⁸ See Chap. 2, Section 1 of *Lag (1998:531) om yrkesverksamhet på hälso- och sjukvårdens område* (the Health and Medical Services Professional Activity Act). Sections 2 (2), 5, 6, 7, 8, 9 of *Transplantationslagen (1995:831)* (the Transplant Surgery Act). Sections 2, 2a, and 2b of *Hälso- och sjukvårdslagen (1982:763)* (the Health and Medical Services Act). Cf. Rynning, E., *Mänskliga rättigheter och biomedicin – om Europarådets konvention och svensk rätt*, Ad studium et ad laborem incitavit Elsa Eschelsson, Juridiska fakultetens i Uppsala årsbok, 1997, p. 320. See Prop. 1994/95:148 pp. 31, 79, Cf. SOU 1997:154 p. 422. Cf. Rynning, E., *Samtycke till medicinsk vård och behandling, En rättsvetenskaplig studie*, 1994, p. 125. Cf. SOU 1989:98 pp. 198.

¹⁹ Cf. Statens helsetilsyn. Vedrørende evaluering av lov av 5. august 1994 nr. 56 om medisinsk bruk av bioteknologi – Regulerings av biobanker, point 5.3.1.3. I och III Cf. point 6.2.

²⁰ Cf. Statens helsetilsyn. Vedrørende evaluering av lov av 5. august 1994 nr. 56 om medisinsk bruk av bioteknologi – Regulerings av biobanker, point 5.3.1.3.

²¹ See the statutory text and Prop. 1994/95:148 pp. 23, 75.

²² See also Sections 3 (3) and 4 of *Transplantationslagen (1995:831)* (the Transplant Surgery Act). See also *Lag (1995:832) om obduktion m.m.* (the Post-Mortem Examinations Act). Under Section 21 of this Act, the body of a deceased person may also be used for anatomical dissection for purposes of research or teaching if the deceased has expressly consented thereto. See Prop. 1994/95:148 pp. 100 and *SOSFS 1996:28 om kliniska obduktioner m.m.* (Clinical autopsies etc.), p. 11.

²³ See SOSFS 1997:4, p. 12. *Socialstyrelsens föreskrifter om organ och vävnadstagning för transplantation eller för annat medicinskt ändamål* (Provisions of the National Board of Health and Welfare on the collection of organs and tissue for transplant surgery or other medical purposes).

²⁴ Cf. Statens helsetilsyn. Vedrørende evaluering av lov av 5. august 1994 nr. 56 om medisinsk bruk av bioteknologi – Regulerings av biobanker point 5.4.

²⁵ See Prop. 1994/95:148, pp. 41, 84. Cf. SOU 1991:42 pp. 69. See SOSFS 1997:4, p. 16.

²⁶ See Sections 1 and 2 of *Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med befruktade ägg från människa* (the Fertilised Human Ova Research or Treatment Measures Act). See also Rynning, E., *Samtycke till medicinsk vård och behandling*, 1994, pp. 125.

²⁷ It should be noted that Section 4 of *Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med befruktade ägg från människa* (the Fertilised Human Ova Research or Treatment Measures Act) lays down that a fertilised ovum which has been used for research or treatment may not be introduced into a woman's body.

²⁸ Under Section 3 of *Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med befruktade ägg från människa* (Fertilised Human Ova Research or Treatment Measures Act), a fertilised ovum may be stored in the frozen state for not more than five years or for a longer period as determined by the National Board of Health and Welfare by authority of Section 5 of the same Act. Section 5 empowers the National Board of Health and Welfare, if there are exceptional reasons for doing so, to permit an extension in particular cases of the time limit indicated in Section 3. Under these rules, then, the donor cannot prevent the fertilised ovum being destroyed after five years, unless the National Board of Health and Welfare grants permission for it to be stored longer. See SFS 1998:282.

²⁹ See Section 2 of *Transplantationslagen (1995:831)* (the Transplant Surgery Act).

³⁰ See Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine, and Explanatory Report. See <http://www.coe.fr/eng/legaltxt/164e.htm> 2000-06-06 and <http://conventions.coe.int/treaty/en/Reports/Html/164.htm>.2000-06-06.

³¹ See particularly Articles 18, 19, and 20. Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine, and Explanatory Report. See <http://www.coe.fr/eng/legaltxt/164e.htm> 2000-06-06 and <http://conventions.coe.int/treaty/en/Reports/Html/164.htm>. 2000-06-06. See Rynning, E., *Mänskliga rättigheter och biomedicin – om Europarådets konvention och svensk rätt*, Ad studium et ad laborem incitavit Elsa Eschelsson, 1997, p. 338.

See also *Socialstyrelsens förslag* (Proposals by the National Board of Health and Welfare), 2000, p. 113.

³² Cf. supra p. 4, note 17.

³³ See Rynning, E., *Biobankerna – hög tid för bankinspektion?* 1998, p. 306.

³⁴ See Ahlgren, T., Nya etiska riktlinjer för biobanker, *Läkartidningen*, vol. 96, nr. 25, 1999, p. 3051.

³⁵ See Statens helsetilsyn. Vedrørende evaluering av lov av 5. august 1994 nr. 56 om medisinsk bruk av bioteknologi-Regulerings av biobanker point 5.3.1. Cf. also the legislative proposals by the National Board of Health and Welfare, pp. 30. See also Proposals p. 45. Cf. also Samuels A. JP., *Whose Body is it anyway?*

Medicine, Science and the Law, *The Official Journal of the British Academy of Forensic Sciences*, vol. 39, nr. 4, 1999, pp. 285. See Rynning, E., *Biobankerna – hög tid för bankinspektion?* 1998, p. 306, Lindberg, B., Vem äger provet? *Läkartidningen*, vol. 94, nr. 45, 1997, pp. 4083. See also, concerning the debate in other countries, e.g. Medical Research Council, Human tissue and biological samples for use in research, 1999, pp. 5.

³⁶ Further, for example, to the ownership concept, see Strömholm, S., et al, *Äganderätt och egendomsskydd. Centrala frågor i alla samhällssystem*, 1985, pp. 7; Hessler, H., *Allmän sakrätt*, 1973, pp. 17, Håstad, T., *Sakrätt avseende lös egendom*, 6 uppl., 1996, pp. 23; Malmström, Å. & Agell, A., *Civilrätt*, 16 uppl., 1999, pp. 55, 71, 73, 77, 225; Schmidt, F., *Om ägareförbehåll och avbetalningsköp*, 1938, pp. 84; Sjögren, W., *Anteckningar efter Prof. Sjögrens föreläsningar över den svenska sakrätten*, 1908, pp. 69; Skogh, G. & Lane, J-E., *Äganderätten i Sverige*, 1993, pp. 9; Strömholm, S., *Allmän rättslära*, 6 uppl., 1988, p. 15; Sundberg, J. W. F., *Agges huvudpunkter om den allmänna rättsläran*, 3 uppl., 1980, pp. 78; Undén, Ö., *Svensk sakrätt*, 1995, pp. 57.

³⁷ Restrictions of this kind are contained in *Expropriationslagen (1972:719)* (the Expropriation Act), *Förfogandelagen (1978:262)* (the Emergency Powers Act), *Räddningstjänstlagen (1986:1102)* (the Rescue Services Act) etc. See further, concerning ownership, Undén, Ö., *Svensk sakrätt*, 1995, pp. 57, Hessler, H., *Allmän sakrätt*, 1973, pp. 17. See also Skogh, G. & Lane, J-E., *Äganderätten i Sverige*, 1993, p. 26, Håstad, T., *Sakrätt avseende lös egendom*, 6 uppl., 1996, p. 23.

³⁸ See Strömholm, S., *Äganderätten i idéhistoriskt och internationellt perspektiv, Historiskt och aktuellt. Studier i allmän rättslära*, 1988 p. 124. See also Hessler, H., *Allmän sakrätt*, 1973, p. 20, Håstad, T., *Sakrätt avseende lös egendom*, 6 uppl., 1996, pp. 22; Cf. Rodhe, K., *Handbok i sakrätt*, 1985, pp. 1, 15.

³⁹ See Håstad, T., *Sakrätt avseende lös egendom*, 6 uppl., 1996, p. 23.

⁴⁰ See Hessler, H., *Allmän sakrätt*, 1973, p. 18. See also p. 179.

⁴¹ See Håstad, T., *Sakrätt avseende lös egendom*, 6 uppl., 1996, pp. 209.

⁴² See Hessler, H., *Allmän sakrätt*, 1973, p. 18.

⁴³ See Hessler, H., *Allmän sakrätt*, 1973, p. 179.

⁴⁴ See Hessler, H., *Allmän sakrätt*, 1973, p. 20.

⁴⁵ See Hessler, H., *Allmän sakrätt*, 1973, p. 21.

⁴⁶ See Malmström, Å. & Agell, A., *Civilrätt*, 16 uppl., 1999 p. 59 and p. 76.

⁴⁷ See Malmström, Å. & Agell, A., *Civilrätt*, 16 uppl., 1999 p. 59; Inger, G., *Rätten över eget liv och över egen kropp*, Kungl. Humanistiska Vetenskaps-Samfundet i Uppsala, Årsbok 1985, p. 97. See also SOU 1989:98 p. 68.

⁴⁸ See SOU 1989:98 p. 68. Cf. dock Alexius, K., Något om äganderätt, angrepp på egen rättssfär och en eventuell kriminalisering av prostitution, *SvJT* 1995 p. 599 arguing that a person's right to their own body, generally speaking, is probably of a simple kind, i.e. a non-transferable right of ownership unaccompanied by any unconditional right of disposal over the object.

⁴⁹ See SOU 1989:98 p. 70.

⁵⁰ See SOU 1989:98 p. 68. See also Jareborg, N., *Brotten, andra häftet, Förmögenhetsbrotten*, 2 uppl., 1986, p. 49.

⁵¹ See SOU 1989:98 p. 70.

⁵² See Rehncrona, P. V., *Känneteckensrätt ur ett förmögenhetsrättsligt perspektiv, Variationer på ett obligationsrättsligt tema*, Vänbok till Axel Adlercreutz, 1998 p. 290; Levin, M. & Nordell, P J., *Handel med immaterialrätt*, 1996, p. 19.

⁵³ See Rehncrona, P V., *Känneteckensrätt ur ett förmögenhetsrättsligt perspektiv, Variationer på ett obligationsrättsligt tema*, Vänbok till Axel Adlercreutz, 1998, p. 290, Levin, M. & Nordell, P J., *Handel med immaterialrätt*, 1996, p. 19.

⁵⁴ See Ahlgren, T., Bankinspektion behövs för biobanker? "Kommersiella intressen skall inte tillåtas inkräkta på etiska värden", *Läkartidningen*, vol. 96, nr. 13, 1999, p. 1548.

⁵⁵ Cf. Olsson, H., Kommersielliseringsen av gener – patent på bröstcancer gener pilotfall. *Läkartidningen*, vol. 96, nr. 37, 1999, p. 3920.

⁵⁶ See SOU 1992:16 p. 232, samt Socialstyrelsens förslag, 2000, p. 30.

⁵⁷ See Nelson, A., *Kring födelse och död – några juridiska reflexioner*, Kungl. Humanistiska Vetenskaps-Samfundet i Uppsala, Årsbok 1997, p. 125.

⁵⁸ Cf. 3:1 BrB.

⁵⁹ See Section 1 of *Lag (1951:649) om straff för vissa trafikbrott* (the Penalties Certain Traffic Offences Act).

⁶⁰ See Section 1, point 6 of *(1968:64) Narkotikastrafflag* (the Drug Offences Act).

⁶¹ See Section 1 of *Lag (1969:612) om förbud mot professionell boxning* (the Professional Boxing Prohibition Act).

⁶² See Leijonhufvud, M. & Wennberg, S., *Straffansvar*, 5 uppl., 1997, p. 104.

⁶³ See *Lag (1982:316) med förbud mot könsstympning av kvinnor* (the Genital Mutilation of Women Prohibition Act).

⁶⁴ See Leijonhufvud, M. & Wennberg, S., *Straffansvar*, 5 uppl., 1997, p. 104.

-
- ⁶⁵ See SOU 1989:98 p. 70.
- ⁶⁶ See Chap. 16, Section 10 of *Brottsbalken* (the Penal Code).
- ⁶⁷ See Chap. 8, Section 8 of *Brottsbalken* (the Penal Code). See further Holmqvist, L., & Leijonhufvud, M., Träskman, P O., Wennberg, S., *Brottsbalken. En kommentar Del 1* (1-12 kap.) pp. 366.
- ⁶⁸ See SOU 1989:98 p. 69.
- ⁶⁹ Cf., however, note 85 concerning exceptions for museums and medical institutions.
- ⁷⁰ Cf. Sägänger, J., *Organhandel, Kroppsdelar till salu*, 1994, p. 80.
- ⁷¹ See SOU 1989:98, p. 25.
- ⁷² See *ib.*, p. 25.
- ⁷³ See Machado, N., *Using the bodies of the dead, Studies in Organization, Law and Social Process Related to Organ Transplantation*, 1996, p. 170.
- ⁷⁴ See Machado, N., *Using the bodies of the dead, Studies in Organization, Law and Social Process Related to Organ Transplantation*, 1996, p. 166.
- ⁷⁵ See *Transplantationslagen (1995:831)* (the Transplant Surgery Act).
- ⁷⁶ See *Lag (1995:832) om obduktion m.m* (the Post-Mortem Examinations Act).
- ⁷⁷ See *Lag (1987:269) om kriterier för bestämmande av människans död* (the Human Death Criteria of Determination Act).
- ⁷⁸ See *Lag (1984:1140) om insemination* (the Insemination Act).
- ⁷⁹ See *Lag (1991:115) om åtgärder i forsknings- eller behandlingssyfte med befruktade ägg från människa* (the Fertilised Human Ova Research or Treatment Measures Act).
- ⁸⁰ See SOU 1989:98, p. 70.
- ⁸¹ See, for example, *Begravningslagen (1990:1144)* (the Burials Act), *Begravningsförordningen (1990:1147)* (the Burials Ordinance), *Lag (1995:832) om obduktion m.m* (the Post-Mortem Examinations Act). Cf. also JO:s ämbetsberättelse 1973, p. 292, in which the Parliamentary Commissioner addressed a question concerning a pathologist who had shots fired at dead bodies in order to investigate the harmful effects of certain firearms on human beings. The measure thus taken had no statutory support, nor was it prompted by a public interest of such strength that the procedure could be deemed justifiable. The pathologist was therefore considered guilty of a crime against the sanctity of the grave. See also SOU 1989:98, p. 71 and SOU 1992:16, p. 60.
- ⁸² See Inger, G., *Rätten över eget liv och över egen kropp*, Kungl. Humanistiska Vetenskaps-Samfundet i Uppsala, Årsbok 1985, p. 97. See also SOU 1992:16, p. 66.
- ⁸³ Cf., though, the requirement for unlawful dispossession in Chap. 8, Section 8 of *Brottsbalken* (the Penal Code). I Holmqvist, L., & Leijonhufvud, M., Träskman, P O., Wennberg, S., *Brottsbalken. En kommentar*. In Part 1(chaps. 1-12) p. 367 it is argued that The object of the crime can, but need not, belong to another. It is further argued that the provision protects a person's possession irrespective of what right (ownership, user, no right at all) the possessor has to the object. See also Jareborg, N., *Brotten, andra häftet, Förmögenhetsbrotten*, 2 uppl., 1986, pp. 42, 82, and 122.
- ⁸⁴ See SOU 1992:16 p. 66.
- ⁸⁵ See Jareborg, N., *Brotten, andra häftet, Förmögenhetsbrotten*, 2 uppl., 1986, p. 49. There would not, however, appear to be any impediment to private persons occupying skeletal parts. See *Ib.*, p. 49.
- ⁸⁶ See SOU 1992:16, p. 58.
- ⁸⁷ See *Ib.*, p. 58.
- ⁸⁸ See *Ib.*, p. 58.
- ⁸⁹ See *Ib.*, p. 58.
- ⁹⁰ See *Ib.*, p. 58.
- ⁹¹ See *Ib.*, p. 59.
- ⁹² See Rynning, E., *Biobankerna – hög tid för bankinspektion?*, 1998, pp. 310.
- ⁹³ It should be borne in mind that we are addressing the concept of possession in a civil law perspective only. Unfortunately it is not possible here to discuss any further the possible importance of the possession concept for this type of property seen from the viewpoint of other legal disciplines, e.g. criminal law.
- ⁹⁴ General Assembly Resolution 217 A(III), 10.12.1948.
- ⁹⁵ The International Convention on Economic, Social and Cultural Rights, FördrS 5-6, adopted 16.12.1966, entered into force 3.1. 1976. The International Covenant on Civil and Political Rights. FördrS 7-8/1975, adopted 16.12.1966, entered into force 23.3. 1976.
- ⁹⁶ See further, for the ins and outs of the negotiations, Krause, C., *Rätten till egendom som en mänsklig rättighet, Institutet för mänskliga rättigheter*, Åbo akademi, 1993 pp. 9-20.
- ⁹⁷ Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms. FördrS 18-19/1990, adopted 20.3.1952, entered into force 18.5.1954.
- ⁹⁸ Konventionen om biologisk mångfald Art. 1. Convention on Biological Diversity 5 June 1992. <http://www.biodiv.org/chm/conv/default.htm>.

⁹⁹ E.g. the Paris Convention for the Protection of Industrial Property, adopted 20.3.1883, entered into force 6.7.1884, revised 14.10.1900, 2.11.1911, 6.11.1934, 31.10.1958 and 14.7.1967. The Berne Convention for the Protection of Literary and Artistic Works, adopted 9.9.1886, entered into force 5.12.1887, revised 13.11.1908, 2.6.1928, 26.6.1948, 14.7.1967 and 24.7.1971.

¹⁰⁰ One example is the Court's interpretation of the right to a good living environment as a human right, Cf. Case of Guerra and others v. Italy, 116/1996/735/932 and Case of López Ostra 'v. Spain, 41/93/436/515. See further www.echr.coe.int.

¹⁰¹ See further Krause, C., *Rätten till egendom som en mänsklig rättighet*, 1993, p. 50.

¹⁰² See Krause, C., *Rätten till egendom som en mänsklig rättighet*, 1993, p. 73.

¹⁰³ See, concerning claims on the state and suchlike, Krause C., *Rätten till egendom som en mänsklig rättighet*, 1993, pp. 78 ff. Other intangible rights such as licences and permits are also deemed in certain cases to constitute a property right protected under Article 1, First Protocol. See further Krause, op. cit., pp. 83.

¹⁰⁴ Claims may of course have arisen earlier.

¹⁰⁵ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

¹⁰⁶ Note that certain inventions whose commercial use is at variance with public order or good conduct cannot be patented, e.g. procedures for cloning human beings, procedures for altering the genetic identity of human gametes, and the use of human embryos for industrial and commercial purposes. See further *Socialstyrelsens förslag* (Proposal by the National Board of Health and Welfare), 2000, pp. 97.

¹⁰⁷ Preamble to the Directive, point 16.

¹⁰⁸ Preamble to the Directive, point 17.

¹⁰⁹ Preamble to the Directive, point 18.

¹¹⁰ See *Forskningsetiska riktlinjer för nyttjande av biobanker, särskilt projekt innefattande genomforskning*, 1999, p. 2.

¹¹¹ See Rosen, E., *De lege delenda*, 1999, p. 48. Cf. the statutory regulation of biobanks in Danish law, Hartlev, M., *Den retlige regulering af biobanker, Sundhedsvidenskabelige informationsbanker – biobanker*, 1996, pp. 9.

¹¹² See Prop. 1994/95:148, pp. 23, especially p. 25.

¹¹³ The identity of the sampler is a debated point. The reference can be both to the individual researcher and to other natural and juristic persons.

¹¹⁴ See Åhman, K., *Egendomsbegreppet och människans rätt till sin egen kropp, Lika inför lagen? Rätten ur ett genusperspektiv*, 1999, p. 48.

¹¹⁵ Cf. supra, note 17.

¹¹⁶ To put this question further into perspective, it can be related to intangible rights. Artistic creations bearing the strong imprint of the author's individuality have been deemed by society to need the protection of copyright. Inventions, which in the true sense refer to information concerning the technical idea and are thus characterised by skill and knowledge, are protected by patent. The rights block use by others for a certain length of time, and the time limit has been established in an attempt to strike a balance between the proprietors and a third party in the light of community interest. The personal copyright lasts for the whole of the author's lifetime and for another 50-70 years after his death, whereas a patent is valid for 20 years.

¹¹⁷ The Uniform Anatomical Gift Act. E.g. the following: Vermont; STAT. ANN. § 5246, Utah; UT CODE ANN. § 26-28-2(2)(1998), Pennsylvania, PA STAT. ANN. § 3216(b)(1)-(2), Oklahoma; OK STAT. ANN. § 1-735(1997), North Dakota; ND CODE § 14-02.2-02(3)(1997), New York; NY LAWS ANN. § 4300.2(1997), New Hampshire; NH STAT. ANN. § 291-A:11(1996), Nevada; NV REV.STAT.ANN. § 451.015(1997). Minnesota permits compensation for reasonable expense associated with the intervention, MN STAT. ANN. § 145.422 (1997).

¹¹⁸ Compensation is payable in many cases, but the market is not left free.

¹¹⁹ See Åhman, K., *Egendomsbegreppet och människans rätt till sin egen kropp. Lika inför lagen? Rätten ur ett genusperspektiv*, 1999, p. 48.

¹²⁰ See the multidisciplinary research project "Att på ett etiskt godtagbart och effektivt sätt förvalta mänskligt vävnadsmaterial. – Etiska, sociala, näringspolitiska och legala aspekter kring utnyttjandet av svenska biobanker". (An ethically acceptable and efficient way of administering human biological material. – Ethical, social, industrial and legal aspects of the use of Swedish biobanks.)