chapter 5

Legal Considerations

"If 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 the winner."

—Thomas H. Murray
Congressional testimony, Oct. 19, 1985

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As the use of human tissues and cells becomes more prevalent in biotechnology-related research and development, increased attention will need to be focused on the legal considerations of such use. Are tissues and cells property? If so, what right does a patient or research subject have in such materials? Does the provision of tissues and cells constitute the sale of a product or service?

NO area of existing law definitely sets forth the rights held by an individual who provides tissues and cells to an academic or commercial researcher. No area of law clearly provides ownership rights with respect to human tissue and cell materials. Nor does any law prohibit the use or sale of human bodily substances by the living person who generates them or one who acquires them from such a person, except under certain circumstances. These circumstances relate to particular cell arrangements (e.g., organs, bodies) and uses (e.g., transplantation) that are not typically related to biotechnology research. Because neither judicial precedents nor statutes directly address the questions raised by the use of tissues and cells in research, the courts must do what common law judges have done for centuries; reason by analogy, using principles and precedents developed for other circumstances.

United States law has long protected people from those who would harm them physically or who would deprive them of full enjoyment of their property. Generally, this protection was afforded by the **common law,** the body of judge-made law built on judicial precedents. Common law has evolved "over centuries, as judges have been called on to resolve disputes that have not been addressed by statute. Congress and State legislatures have enacted a variety of **statutes** to codify, modify, and overrule the common law. Today, while statutes specify many of our legal rights and duties, common law remains the basis for our legal principles, and common law analysis and reasoning forms the basis for our techniques of statutory interpretation.

INJURIES TO PERSONS V. INJURIES TO PROPERTY

The common law classifies many injuries for which recovery is permitted as either injuries to **persons** (which are analyzed under tort law principles) or injuries to **property** (which generally are within the domain of property law). Contracts can be made with respect to both persons and property, although certain types of contracts and contractual remedies are permitted with respect to property but not human beings.

Personal Rights

The common law gives individuals various "personal" rights to exclude others from interfering with their physical and mental integrity. Many invasions of bodily integrity are subject to criminal penalties; in addition, the common law tort of battery allows for recovery for physical and mental damages resulting from harmful or offensive physical contacts.

Invasions of physical autonomy are permitted only in those few situations where either individual or public interests (particularly health) would be substantially and justifiably benefited by a modest encroachment on individual autonomy. Examples of legally permissible invasions of physical integrity include laws compelling vaccinations; blood tests for marriage licenses; and blood and urine sampling of suspected criminals, military service, and penal service.

Although the law clearly affords people substantial means of protecting themselves from harmful or offensive physical contacts, the extent to which people can use their bodies is less clear. State law generally prohibits disfigurement, prosti-

tution, and drug use. Federal law reflects similar policies and recently has added a new prohibition against organ sales (public Law 98-507). These restrictions rest on concerns about individual health, public health, and public moral sensibility.

Property Rights

Property is generally viewed not as a single indivisible concept but as a bundle of legally protected interests, including the right to possess and use, to transfer by sale or gift, and to exclude others from possession. Although the property concept can be invoked to protect various legal interests, one's right to use property is commonly limited to uses that do not offend public safety or sensibilities. For example, a person may own a car but not have a right to use it without first obtaining a driver's license.

Nevertheless, the term property introduces certain economic and market connotations and calling the body property may act to make the use of market incentives with respect to the body and its parts more acceptable. Alternatively, if human tissues and cells are not characterized as property but as a severed part of a person, then tort law principles would still provide certain rights with respect to one's tissues and cells (e.g., right to privacy, right to adequate disclosure to give an informed consent). However, a right to buy or sell would probably not be among the rights provided.

In the absence of clear legal restrictions, the sale of tissues and cells is generally permissible unless the circumstances surrounding the sale suggest a significant threat to individual or public health, or strong offense to public sensibility. But while the law permits the sale of such replenishing cells as blood and semen, it neither endorses such transactions nor does it often characterize such transactions as involving property. In this sense, either permitting or forbidding the sale of human specimens by patients and research subjects can be claimed to be consistent with existing law.

The broad array of legal principles that might have implications for the use of tissues and cells in biotechnology (table 10) are discussed in the following section.

Table 10.—Possible Sources of Rights Relating to Human Biological Materials

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SOURCE: Office of Technology Assessment, 1987.

POSSIBLE SOURCES OF RIGHTS

Law of Patents

Patent law has direct application to biotechnology research and development. The Constitution gives Congress the power "[T]o promote the Progress of Science and useful Arts" by securing to inventors exclusive right to their inventions (Article 1, Section 8, Clause 8). Because patents convey exclusive rights to their holders, they are personal property (35 U.S.C. 261).

Under U.S. law, inventions belong in the first instance to their inventors. An employed inventor is ordinarily obligated to assign his invention to his employer under the "hired to invent" doctrine and by express provision in his employment

agreement. Patents obtained by researchers thus generally are assigned to the institution funding the research.

A patent may be granted on any new, useful, and nonobvious composition of matter, or article of manufacture, machine, or process (35 U.S.C. 101-103). In 1980, the Supreme Court held in ***Diamond v. Chakrabarty*** that the mere fact that subject matter is "living" does not render it unpatentable (36). "Products of nature," however, are unpatentable because they lack novelty. The biological inventions being patented today are not crude, unaltered products of nature. A claim to the entire genetic material of a single cell would be rejected; but one may properly seek a patent on an isolated gene encoding a protein of interest.

The obviousness of a product is another bar to its protection by patent. Patent law creates a three-step test to determine whether an invention meets the non-obvious test for patentability (35 U.S.C. 103). This analysis consists of three factual inquiries concerning the prior art, that fund of information which is available or accessible to the public (81): 1) the scope and content of the prior art, 2) the difference between the prior art and the patent claims at issue, and 3) the level of ordinary skill in the pertinent art. If the claims in the patent would have been obvious, in view of the prior art, to a person having a level of ordinary skill in the pertinent art, then the patent is deemed obvious and does not meet the requisite criteria for patentability. For example, a patent on vitamin C (purified from lemon juice crystals) was denied because "lemon juice has been known for ages as a satisfactory specific for scurvy. " But a patent on adrenalin crystals was held valid in view of the dangerous side effects of dried gland extracts of lesser purity (71,102).

While it is clear that researchers may alter donated tissues and cells into a patentable invention, patients and research subjects who contribute cells to research will not be considered inventors. Typically, the person providing the material will not make any suggestion regarding the use of the cells, or of the means for using them. While the patient's cells may have some novel characteristic, it is unlikely that the characteristic was appreciated by the patient.

The case law on what constitutes an act of invention has developed through interpretation of various provisions of the patent law. Under a section of the patent statute relating to who of several claimants is the true inventor, the inventive process is divided into **conception** (an outwardly manifested mental act), **reduction to practice** (a physical demonstration of practicability, or the filing of a well-framed patent application) and **diligence** (efforts to reduce a conception to practice) (35 U.S.C. 102(g)).

Conception means that the person claiming to be the inventor thought of both the desired result and the means for achieving that result, that means being an operative form of the invention claimed. Conception must be manifested by exterior acts or declarations that disclose the conception in a form enabling a person of ordinary skill in the art to practice the invention without the exercise of the inventive faculty (80).

In ***Brenner v. Manson (14),*** the Supreme Court held that a patent cannot be obtained on a method of producing a novel composition unless the composition has a practical (nonresearch) utility. One patent law book states that, based on the context of the case, "a necessary implication of ***Brenner*** is that discovery of the utility is part of the act of inventing" (29). The Patent Office apparently agrees (34).

If contemplation of a nonresearch utility is a necessary part of conception, then the patient's or research subject's assertion that tissues have a value in research is not a conception unless there is recognition of a practical use for those tissues, or their derivatives, outside research. Besides appreciating the utility of the cells, the patient or research subject must also appreciate that the cells are novel. In a case involving a chemical invention, for example, a plaintiff who accidentally produced a particular catalyst but did not recognize that it differed in form from the prior art was held not to conceive the new catalyst (43). The rule that "there is no conception or reduction to practice where there has been no recognition or appreciation of the existence of the new form" was acknowledged in ***Silvestri v. Grant (86),*** but led to a different holding since Silvestri had recognized that ampicillin II was different from

ampicillin I, even though he had not recognized its superior stability.

Law of Cadavers and Autopsies

Property Rights in Corpses

The earliest Anglo-Saxon cases to consider ownership of human tissue-specifically, corpses—were decided almost 1,000 years ago by special ecclesiastical courts in England. Established by William the Conqueror, the church courts were completely independent of the civil courts and were eventually given complete jurisdiction over all matters concerning burials and disposition of corpses (49). With few exceptions, control of dead bodies remained within the exclusive jurisdiction of the church courts until the 19th century, when the growth of medical schools and their need for cadavers for dissection created a challenge to ecclesiastical dominion over bodies (85).

In colonial America, the absence of ecclesiastical courts resulted in civil jurisdiction over bodies and the application of common law principles. There were no commercial rights in cadavers, no right for a decedent to direct the manner of burial, and no burial rights enforceable by the next of kin. The refusal to create commercial rights was unquestionably based on religious and moral tradition. The absence of property rights led to the other rules, following the common law principle that courts should only be concerned with commercial considerations and not with sentimental concerns,

During the 1800s, it became apparent that the strict common law doctrine was inequitable and courts began assigning to the next of kin an enforceable right to possession of a body for burial. To preserve the continuity of common law principles, the right was sometimes characterized as a "property right" (49). This right became so well established that in 1891, a court suggested that the "fact that a person has exclusive rights over a body for the purposes of burial leads necessarily to the conclusion that it is his property in the broadest and most general sense of the term" (59).

Judicial references to property rights in corpses were misleading, however. While common law property rights generally include the right to possess and use, to transfer by sale or gift, and to exclude others from possession (15), few of these rights were applied to bodies: the theft of a cadaver was not larceny, the sale of a cadaver was a common law crime, the heirs had no right to repossess a body wrongfully taken from them, and a cadaver could not be the subject of a lien.

Recognizing the limited applicability of property law to corpses, 20th century American courts retreated from the broad pronouncement of bodies as property and began referring to more limited "quasi-property rights" vested in the next of kin and arising out of their legal duty to bury the dead. These rights include the right to possession and custody of the body for burial, the right to have it remain in its final resting place, and the right to recover damages for any outrage, indignity, or injury to the body of the deceased (1). The family's interest in the dead body was subject to various interests of the State government, including concern for public sensibility, promotion of public health, identifying cases of murder, and protecting the economic interests of undertakers and insurers.

Quasi-property analysis became the prevailing rule in both the United States and England during the early 20th century and continues to be applied to disputes over funeral arrangements (61).

Emotional Distress Caused by Wrongful Acts Toward Cadavers

In the 1930s, American jurists and legal scholars began questioning the applicability of property law concepts to cases involving wrongful conduct toward corpses. Gradually, the newly developing tort law framework of intentional infliction of emotional distress (also called "outrageous conduct") was viewed as a more appealing theoretical basis for a legal claim based on unauthorized retention of body parts and other forms of wrongful conduct. As William Presser stated in ***Law of Torts:***

> There are a great many cases involving the mishandling of dead bodies, whether by mutilation, disinterment, interference with proper burial, or other forms of intentional disturbance. In most of these cases the courts have talked of a somewhat dubious '(property right" to the body, usu-

> ally in the next of kin, which did not exist while the decedent was living, cannot be conveyed, can be used only for the one purpose of burial, and not only has no pecuniary value but is a source of liability for funeral expenses. It seems reasonably obvious that such "property" is something evolved out of thi„air to meet the occasion, and that it is in reality the personal feelings of the survivors which are being protected, under a fiction likely to deceive no one but a lawyer (77).

Today, cases concerning wrongful acts toward a dead body are generally treated as tort cases rather than property disputes. The American Law Institute's most recent Restatement ***of Torts,*** which describes the general principles of American tort law, states that one who intentionally, recklessly, or negligently removes, withholds, mutilates, or operates on the body of a dead person, or who prevents its proper interment or cremation, is subject to tort liability to a member of the family who is entitled to disposition of the body (4). The cause of action is a personal right of the survivor rather than a right of the decedent or his estate, since the courts are not primarily concerned with the extent of the physical mishandling or injury to the body per se, but rather with the effect of such improper activities on the emotions of the surviving kin (6).

It is important to note that to be actionable, the emotional distress must be genuine, not theoretical. If the plaintiff does not learn of the offensive conduct, or learns of it but is not distressed as a consequence, there is no basis for suit. Also, except in cases where the defendant has knowledge of the plaintiff's peculiar susceptibility and practices despite this knowledge, the distress must be of a nature that a reasonable person of "ordinary sensibilities" would also experience under the circumstances (7'7). A plaintiff must therefore show both subjective and objective elements of emotional distress.

Applicability to Cases Involving Human Tissues and Cells

Society's traditional refusal to allow commercial rights in cadavers or dead body parts suggests that a claim for property rights in living body parts could be judicially rejected as failing to state a cause of action. The burden would be on the party claiming such rights to demonstrate that the biological, economic, social, and ethical differences between dead and living specimens are more important than their similarities, and that living human specimens merit protection as a result of these differences.

As mentioned earlier, there are noncommercial quasi-property rights in a cadaver that arise out of the legal duty placed on survivors to bury their dead (1). The kin's duty to bury the dead appears to be irrelevant to research or commercial uses of biological materials from living sources, so any rights derived from such a duty would have little relevance.

The emotional distress theory provides a useful legal framework in cases where biological were obtained or used wrongfully, since the basis for the tort is the wrongfulness of the conduct and its effect on the living rather than property law concepts. To fulfill the legal requirements of the tort, the physician's conduct would probably have to demonstrate willful and wrongful disregard for the express or implied desires of the patient and that the conduct resulted in severe emotional distress. In one case, for example, a woman gave birth to a premature baby who died shortly thereafter. Several weeks later, through an unusual course of events, a hospital employee showed the mother a jar containing the infant's body. The mother suffered various physical and psychological injuries as a result and was awarded $175,000 in damages for the tort of "outrageous conduct" (41,52).

Variables Affecting Emotional Distress Claims

A plaintiff in an emotional distress case involving the use of human tissues or cells in research must prove two fundamental facts to prevail. First, the physician or researcher must have acted wrongfully. Acts that could be considered sufficiently wrongful in their disregard for the plaintiff's feelings include:

- using an individual's specimens in research without consent,
- misrepresenting the purpose of diagnostic or medical procedures when they are performed

solely for the purpose of obtaining specimens, and
- suggesting to a patient that refusal to donate specimens for research will affect the availability or quality of medical care.

All of these acts are related to the physician's or researcher's duty to disclose information to the patient or research subject and to obtain consent. The generally accepted standards of professional medical conduct are described in chapter 6.

Second, the plaintiff must also prove that substantial emotional distress-both objectively and subjectively—was suffered as a result of the wrongful act. While these factors will vary from case to case, a few generalizations can be made, particularly about the objective element that examines whether a "reasonable person" would be emotionally disturbed by the conduct.

Whether emotional distress can be shown is related to variables such as the **type** of biological material involved, the **use** to which the specimen is put, the **method** of procuring the specimen, and the **knowledge** of the attending physician or end-user, In addition, these variables may affect the size of consequential damage awards, which are based on the degree of the emotional stress and its effect on the patient's life, health, happiness, and pocketbook. These factors are also relevant in determining whether the wrongful conduct was so reprehensible that a court will permit the plaintiff to seek an additional (punitive damage) award, beyond actual damages, to punish the offender and create a strong deterrent for future wrongdoing.

It maybe especially upsetting to patients when certain **types** of biological materials are involved. For instance, most patients will probably have greater emotional sensitivity about research using their organs, limbs, or brain cells than research using their fingernail clippings, hair, blood, urine, or sweat. The enhanced sensitivity might be due to the fact that the former types of biological materials were especially important to the patient's well-being prior to removal, or because they are generally nonrenewable, or because they were removed using more invasive and traumatic techniques.

Similarly, the **use** to which a specimen is put may affect the patient's emotional reaction, particularly if the patient has religious or moral beliefs that conflict with the use. For instance, some people consider altruistic gifts of human tissues and cells to be less offensive than profitable exchanges. This is illustrated by the altruistic motivation that spurs most blood donations despite the legal permissibility of selling blood. For those who believe that altruism is the only proper motivation for transactions involving human biological, it would be less objectionable to them if their physician donated a specimen to biomedical researchers than if he sold it for a profit to those same researchers.

For other individuals, sales of biological materials might be permissible for some uses but not for others: one might agree to sell one's hair for use in a wig but not in a voodoo doll. Thus, selling placentas to shampoo manufacturers for use in formulating hair care products (which several hospitals allegedly did in the 1960s, causing substantial public outrage) is probably more egregious than selling them to scientists for research to reduce infant mortality. Similarly, some people may find some forms of research objectionable but not others.

The degree of emotional distress may also vary with the **method** of procurement. For example, a doctor who solicits and uses a urine sample for diagnostic purposes and who later uses the specimen in research may have acted wrongfully if he did not first obtain the patient's consent for research. However, any consequential emotional distress may not be actionable, unless it is shown that the physician acted outrageously, recklessly, wantonly, or willfully, or because a reasonable person of ordinary sensibilities would not experience serious emotional effects as a result.

A deception accompanied by an invasive or painful medical procedure is probably even more offensive. If the specimen obtained in the preceding example was not urine but bone marrow, the resulting emotional distress would probably be more severe. In addition, the plaintiff would be entitled to collect for his physical pain and suffering during and as a result of the extraction pro-

cedure if it was proven that the physician was also liable for battery due to invalidation of the patient's consent to the procedure.

The **knowledge** of those who procure the specimen would also have an effect on culpability since the tort generally requires an outrageous act and not merely a negligent one. As mentioned earlier, knowledge of the peculiar emotional susceptibilities of a patient can lead to liability where it otherwise would not exist. Early emotional distress cases dealing with dead bodies, for example, held that unauthorized embalming of a corpse was not actionable unless the mortician knew that the decedent's religious beliefs forbade embalming (7). Similarly, a patient who is distressed by an incident that would not distress a person of ordinary sensitivities would not be entitled to sue unless the physician knew that the patient was unusually squeamish and the doctor therefore should have foreseen the deleterious consequences of his act. Thus, a pyrophobic patient whose leg was amputated and cremated was not permitted to recover damages for the mental anguish he claimed he suffered as a result of the cremation because the hospital staff did not know of the patient phobia and had not acted unreasonably by disposing of the limb through the usual method (16).

Law of Organ Transplantation

Donation of Organs for Transplantation

In the mid-20th century, scientific advances led to an increasing need for transplantable tissue. From 1947 until 1968, 40 States enacted statutes permitting anatomical donations from cadavers for transplantation or scientific research (85). Variations among the statutes lead to the formation of a special committee of the Commissioners on Uniform State Laws to draft a uniform donation statute. The result of this effort is the Uniform Anatomical Gift Act (UAGA) which, after receiving final approval from the commissioners in 1968 (94), has been adopted throughout the 50 States and the District of Columbia (82). The UAGA supersedes only those areas of the common law of cadavers that are addressed by the act.

The UAGA permits any competent adult to make a gift—to take effect upon death-of all or any part of his body for purposes such as medical education, research, and transplantation. Donations for research purposes may only be made to hospitals, physicians, medical and dental schools, and tissue banks. Post mortem donations of human tissues and cells to noncommercial biomedical researchers are therefore permitted, although transfers from noncommercial researchers to commercial researchers are not addressed by the model law. Organs removed during surgery are not gifts, because the donative intent required for a legal gift generally is lacking (44).

Gifts may be made either by will or by a gift document such as a donor card. In the absence of contrary instructions by a decedent, the next of kin may authorize a gift. Recipients may accept or reject the gift, and a researcher who removes or accepts an organ in good faith in accordance with the terms of the UAGA is not liable for civil damages or subject to criminal prosecution.

It has been argued that the UAGA recognizes rights in the human body that may be classified as property rights (64). However, the UAGA does not discuss inter vivos (during life) gifts, nor does it say anything about the sale of organs or other body parts. The chairman of the committee that drafted the UAGA has written that it was intended neither to encourage nor prohibit sales (87).

As a result of ethical concerns raised by reports of impoverished Americans offering to sell a "spare" kidney or cornea (typically for $10,000 to $50,000) (57) and physicians offering rewards or finder's fees for acceptable organs (25), a few States have passed laws expressly prohibiting remuneration to living or dead organ donors (35). In the majority of States, however, a donor is apparently able to make a legal contract to sell a part of his body, unless the biological transfer is to take place after death and the common law provisions on cadaver disposition are held to forbid such a sale (69).

Sale of Organs for Transplantation

In 1984, Congress enacted the National Organ Transplant Act (NOTA; Public Law 98-507). ***NOTA*** prohibits the sale of a human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin. Although the act makes it a felony to

purchase specified human organs for transplantation, reasonable payments for a living donor's expenses (e.g., travel, housing, and lost wages) are permitted. NOTA's prohibition does not apply to sales of human tissues and cells for research, commercial, or other nontransplantation purposes.

The statute's organ sale prohibition was based primarily on congressional concern that permitting the sale of human organs might undermine the Nation's system of voluntary organ donation (102). It was also driven by concern that the poor would sell their organs to the rich, to the detriment both of poor people who might feel economically coerced to become organ suppliers and those who need but cannot afford transplantable organs. It may also reflect congressional distaste for sales of human body parts generally. The considerations that mitigate against the sale of organs for transplant may or may not apply to the sale of other human tissues and cells for research and development (37).

Law of Blood and Semen Sales

Sale of Blood and Semen

No State or Federal statute prohibits the sale of blood, plasma, semen, or other replenishing tissues if taken in nonvital amounts (69). Nevertheless, State laws usually characterize these paid transfers as the provision of services rather than the sale of a commodity, either in the State's version of the UAGA or in their version of the Uniform Commercial Code (UCC), which governs various commercial transactions including contracts for the sale of goods (95).

The primary legal reason for characterizing these transactions as involving services rather than goods is to avoid liability for contaminated blood products under either general product liability principles or the UCC's implied warranty provisions. In addition, services are not subject to the UCC's specific performance provisions.

Product Liability

Product liability is the name given to the area of law involving the liability of suppliers of goods or products for the use of others, and their responsibility for various kinds of losses resulting from defects in those products. Four possible theories of recovery are available under the complexities of modern product liability law:

- strict liability in contract for breach of an express or implied warranty,
- strict liability in tort largely for physical harm to persons and tangible things,
- negligence liability in contract for breach of an express or implied warranty that the product was designed and constructed in a workman-like manner, and
- negligence liability in tort largely for physical harm to persons and tangible things (78).

Generally, negligence liability may exist with respect to both products and services, but strict liability is applicable only to products. Thus, characterization of blood and semen sales as services enables blood and semen banks to avoid liability when a specimen was defective (e.g., contaminated or infected) if the bank was not negligent in its handling of the specimen (55).

Implied Warranties Under the UCC

If sales of tissues and cells were to be treated as sales of goods as opposed to sales of services, then UCC warranties would be applicable. The UCC provides that commodity contracts (but not service contracts) are subject to two implied warranties:

- the **implied warranty of merchantability** requires goods to be of "fair average quality" within the description provided by the seller and fit for the ordinary purposes for which such goods are used (97), and
- the **implied warranty of fitness** requires goods to be suitable for the buyer's particular purpose to the extent this purpose is known by the seller (98).

The merchantability warranty only applies to sales by "merchants," defined by the UCC as those who regularly supply the product (e.g., hospitals, tissue banks) but not occasional sellers (96). The fitness warranty applies equally to regular dealers and occasional sellers (98).

If transactions for blood or semen were treated as sales of commodities, these implied warranties could result in substantial liability for injuries re-

suiting from transfusion or insemination with a specimen infected with hepatitis, AIDS, or another contagious disease. Insemination with sperm containing a genetic defect could also result in substantial liability. Since liability would be based on strict liability for breach of warranty rather than negligence principles, careful examination of specimens for contamination or a genetic flaw would not entitle the providing entity to avoid liability if an injury occurred.

Alabama has added a subsection to its UCC as follows:

> Procuring, furnishing, donating, processing, distributing, or using human whole blood, plasma, blood products, blood derivatives, and other human tissues such as corneas, bones or organs for the purpose of injecting, transfusing, or transplanting any of them in the human body is declared for all purposes to be the rendition of a service by every person participating therein and whether any remuneration is paid is declared not to be a sale of such whole blood, plasma, blood products, blood derivatives, or other human tissues *(8).*

The amendment prevents recovery on a breach of warranty theory where a plaintiff contracts a disease such as hepatitis as a result of a blood transfusion (88). Other State courts have reached the same conclusion as Alabama by judicial interpretation (26), while other States have enacted statutes specifically exempting hospitals and blood banks from liability for disease transmitted by transfused blood without amending the official text of the UCC (9).

If exchanges involving human tissues and cells are treated like those involving blood and semen—i.e., if such exchanges are considered to be transactions for services rather than commodities—then certain types of liability may similarly be avoided by tissue and cell banks, research institutions, hospitals, and companies. While liability would continue to exist for negligence (e.g., failing to use an available and appropriate test to screen suppliers for viral infections) there would be no liability for imperfect specimens in the absence of negligence.

Specific Performance Under the UCC

The UCC and the common law of contracts provide that if a seller breaches or repudiates a contract, the buyer may recover monetary damages or, under appropriate circumstances, seek an injunction compelling **specific performance** (fulfillment of the contract according to its precise terms) (99). Generally, specific performance may be decreed if the goods are unique or in other circumstances where monetary damages are inadequate to make the buyer whole (100).

If a transaction in human tissues or cells is treated as **the sale of goods,** the UCC provides a possible remedy for the buyer, since it "seeks to further a more liberal attitude than some courts have shown in connection with the specific performance of contracts of sale" (102). However, a contract to **render personal services** will not be specifically enforced because it is undesirable to compel a continued personal association after disputes have arisen and confidence and loyalty are gone. In some instances, such imposed associations may seem like involuntary servitude, which is unconstitutional (2,48).

A 1978 case involved the forced donation of bone marrow to a man with a plastic anemia by his genetically compatible cousin (62). Initially, the healthy cousin agreed to undergo tests to determine his suitability as a donor. Early tests showed him to be a good match, but he failed to appear for additional confirmatory tests and refused to donate any bone marrow. The ill cousin sought an injunction that would have forced the healthy cousin to undergo the confirmatory tests and to donate bone marrow if found to be sufficiently genetically compatible. The court denied the injunction, saying "(forcible extraction of living body tissues causes revulsion to the judicial mind. Such would raise the specter of the swastika and the Inquisition, reminiscent of the horrors this portends (62). " While the case was argued on equitable rather than contractual grounds, the court abhorrence to coerced tissue donations might apply with equal force to a repudiated contract for human tissues and cells,

Blood as a Product for Tax Law Purposes

State laws usually characterize payment for blood as for the provision of services rather than the sale of a commodity. However, this characterization has not been applied consistently in the tax treatment of such transactions. The Tennessee Supreme Court has held that whole blood is an item of tangible personal property subject to a State sales tax (51,72). An Alabama court has indicated that it would have preferred to make a similar holding on the sales tax issue had it not felt constrained by the language in the Alabama version of the UCC to rule otherwise (88).

In an income tax case, a Federal appellate court considered whether the sale of blood is a service or a product (104). While the case was decided on due process grounds rather than on the basis of the property versus services distinction, the case suggests that "blood plasma . . . is tangible property which in this case commanded a selling price dependent on its value."

Law of Copyright

Copyright provides protection for "original works of authorship fixed in any tangible means of expression" (I7 U.S.C. 102). Works of authorship include literary, musical, dramatic, choreographic, pictorial, graphic, sculptural, and audiovisual works (17 U.S.C. 102(b)). Copyright protection, however, does not attach to any idea, procedure, process, system, method of operation, concept, principle, or discovery. Copyright provides an author with exclusive rights for the specific form of expression, but not for the underlying idea.

One writer on intellectual property law topics has suggested that DNA molecules are copyrightable as express "information, " albeit genetic information. To him, bases are letters; codons are words; and genes are sentences. Switching metaphors, he compares DNA molecules to computer programs; both are sets of instructions (53).

Others have challenged these views as based on false analogies (31). In any event, these arguments would not, even if fully accepted, confer copyright protection on human biological materials other than DNA. Even if DNA were copyrightable, a patient probably could not claim to be its author because the patient exercises no conscious control over the sequence of bases. Thus, to the extent that copyright protection is available, it would be applied solely to recombinant DNA as a composite work.

Law of Trade Secrets

The precise source of trade secret rights is a matter of dispute. Some consider trade secrets to be intangible property. Others regard trade secrets as merely information subject to restrictions on disclosure and use as a result of express contract provisions, or by operation of law in view of the trust and confidence reposed in the recipient by the discloser (so). Since a trade secret is rooted in secrecy, publication impairs the legal right to control disclosure and use. Unlike a patentee, a trade secret owner has no recourse against a later independent developer, or even one who discerns the secret by analysis of the products placed on the open market by the owner. Only the abuse of a confidential relationship creates liability.

Liability may flow from a statute or a contract (express or implied) between the parties. In making theft of a trade secret unlawful, a number of State criminal laws include cultures and microorganisms among the types of articles which may represent a trade secret (23,30)40,46). Recently, patent attorneys at one company published some suggested confidentiality agreements for use in disseminating biological materials, The most detailed of these agreements addressed the following issues:

- When the recipient is a university researcher, how should responsibilities be apportioned between the researcher and his or her university?
- What types of biological material are covered? In particular, what modification of the material might take it outside the agreement?
- To whom may the material be transferred?
- How may the material be used?
- Is the researcher free to publish his/her work?
- Does the recipient have an obligation to disclose his/her work to the supplier in advance of publication?
- If the work is patentable, what recognition will be given to the supplier's contribution?

- Is the transfer a sale or a license?
- Is the material warranted in any way?
- Who will bear liability for any harm arising from use of the material (54)?

A sample of human tissues and cells is not itself a trade secret (73), but may be characterized as a tangible article representing an intangible trade secret (65). Still, unless the patient contemplated, at the time of transfer, that the excised tissues or cells had commercial value, it would be difficult to argue that the biological material represented a "trade secret" of the patient. Because a trade secret is information used in one's business, a patient must be in the business of selling or using those tissues or cells in order to hold a trade secret. Under the more liberal Uniform Trade Secrets Act, use in business is not necessary, but reasonable efforts by the patient to maintain the secrecy of the tissue still would be required to retain trade secret status. permitting a researcher to publish a description of the tissue would seem antithetical to recognition of a trade secret therein.

Law of Conversion and Trespass to Chattel

Personal property is protected by both criminal and civil law. The theft of property is a crime known as larceny. Interference with another's property is the tort of trespass to chattel, or conversion, depending on the severity of the interference.

The tort of "trespass to chattel" occurs when one person intentionally interferes with someone else's personal property. However, to prevail in a trespass claim the owner must show he suffered some actual damages as a result. Establishing actual damages could be extremely difficult for an individual whose biological materials had been removed from the body for a diagnostic or therapeutic purpose. Furthermore, damages are limited —a plaintiff can only recover for the actual loss in value of the property caused by the interference.

For these reasons, a plaintiff seeking remuneration for use of biological substances would more likely claim that **conversion** has occurred. This tort has been defined as "an intentional exercise of dominion or control over a chattel which so seriously interferes with the right of another to control it that the actor may justly be required to pay the other the full value of the chattel (3)." Thus the potential recovery for a plaintiff in a conversion suit (full value of the property) can be much greater than in a claim only alleging trespass (actual damages to the property).

Hundreds of decisions involving the tort of conversion have been decided over the last several decades. Because tort law is determined primarily by individual States, and not by Federal law, significant variation in the conversion doctrine exists from State to State. Federal courts trying conversion cases usually apply the law of the relevant State. Because of a lack of uniformity in State conversion laws, the outcome of suits alleging conversion of biological substances would depend partly on the specific laws of the State whose law is being applied. Nevertheless, some general principles can be distilled from the different State and Federal cases. One analysis of tort law suggests that the following factors should be considered by a court in determining whether conversion has taken place:

- the extent and duration of the actor's exercise of dominion or control,
- the actor's intent to assert a right in fact inconsistent with the other's right of control,
- the actor's good faith,
- the extent and duration of the resulting interference with the other's right of control,
- the harm done to the chattel, and
- the inconvenience and expense caused to the other (3).

Property Interest

The essence of the tort of conversion is interference with the owner's right of possession or control. The plaintiff in a conversion suit must therefore show a right to possess the property or the suit will fail. Historically, establishing a property interest in a bodily part has been quite difficult. As discussed earlier, the sale or disposition of cadavers, cadaver tissues, or the cadaver organs has generally been restricted.

Perhaps the most direct support for a patient's property claim in tissue comes from State criminal statutes defining property. Listing the types of articles protected against larceny, a number of States have specifically included cultures and micro-organisms (23,30,40,46). A patient residing in such a State could cite the statute as evidence of a legislatively recognized property interest in cultures made from excised patient tissues and cells.

Possession

To successfully bring a claim of conversion, a plaintiff must be "entitled to immediate possession of the chattel" (l3,30). Without this clear right to possession, there is no tort of conversion. For example, an owner who leases equipment to another cannot bring an action against a third party for conversion during the lease period because the owner has no immediate right of possession (10). Similarly, a right that is contingent on future events will not support a claim for conversion (70,76). The individual's right to possession must therefore exist at the time the biological material is removed, and not arise months or years later when the substance has been shown to be commercially valuable.

Whether a person whose biological material is incorporated into a bioengineered product could be able to meet the test of possession is not altogether clear. Often, the material used by a researcher has been removed during some medical procedure. Neither State statutes nor the common law appear to have provided the patient with clear ownership rights in tissue removed during diagnosis or treatment.

For example, a California statute requires that:

> . . . recognizable anatomical parts, human waste, anatomical human remains, or infectious wastes following conclusion of scientific use shall be disposed of by treatment, incineration, or any other method determined by the State [Health] Department to protect the public health and safety (22).

While this statute does not foreclose the patient from having a limited property right in the anatomical parts that were amenable to use in scientific research, neither does it help a patient meet the burden of proving a clear property right in excised tissue (106). In a State where a statute or regulation forbids possession of tissue taken during treatment except for use in scientific research, a patient would probably have a difficult time in showing entitlement to immediate possession of the chattel.

If a right to possess tissue exists, this right could be argued to apply to all tissue removals, not just tissues that later prove to be of commercial value. If this were true, any bodily material disposed of by a physician could potentially present a claim for conversion. The broad scope of acts amenable to a conversion claim would have potentially large consequences because bodily tissues are routinely discarded by physicians. The interference with the patient's bodily material would not appear to be different whether tissue is thrown away after analysis or the researchers deny that the patient/plaintiff has an ownership interest in a bioengineered product. In both situations, the patient loses control over the tissue once it leaves the body. Thus it may be necessary for a patient/plaintiff to articulate criteria that would restrict the applicability of the conversion doctrine so that it would not apply to all human tissue that is tested by a researcher.

One such distinction may involve the type of tissue. Some substances, such as urine, feces, saliva, and sweat, are byproducts of life that are naturally exuded by the body. Because these substances are routinely discarded by all humans, an individual's claim of a property interest in such substances may be regarded as attenuated due to abandonment (103). perhaps a patient's claim would be strengthened if the tissue was one that was purposefully removed during a surgical procedure to which the patient had consented, and not simply as part of an ongoing, natural process of secretion or excretion. Some researchers have argued, however, that any deliberately excised diseased tissue is within the public domain once it has been examined by a surgical pathologist (103).

Whether a meaningful distinction can be drawn based on the mechanism by which the tissue is removed from the patient is not entirely clear. Neither case law nor statutes provide any definite answer. Nevertheless, it does appear that the strength of a "lack of possession" defense in a con-

version suit may be affected by whether the tissue used in the research is naturally and repeatedly discarded, or is surgically excised.

Injury to Plaintiff

In addition to demonstrating a property interest in the tissue, a successful suit for conversion must show that the plaintiff has suffered some injury through interference with the property. One form of injury is a diminution in the availability (and hence the value) of the property to the plaintiff. But "raw" tissues and cells have little pecuniary value in themselves, especially to the typical patient or research subject who is not trained to identify biological characteristics or develop cell lines or cloned gene probes. Arguably, tumor cells and other diseased tissue have a negative value, so a patient who is "deprived" of these biological may typically experience an increase in his physical, psychological, and financial well-being. In addition, a researcher's patent on a cell line, recombinant DNA clone, or hybridoma does not reduce the source's right to engage in research on his own (or to employ another scientist) using a similar cell. Since a patent is granted only to that which makes an invention new and unique, using raw material in a patented invention does not prohibit others from using the same raw material in a different way.

Frequently, researchers will create a subculture from an existing cell line (i.e., take a sample of an existing culture and grow this smaller sample separately) and will conduct tests on this subculture. In the meantime, the cells in the original sample may reproduce themselves so that total size of the original sample is unaffected. The period of time when the total amount of the cell population is "diminished" is dependent on the rate of cell division. The removal of a subculture of the cell line that is replaced by growing cells may not be regarded by a court as being inconsistent with the patient/plaintiff property rights in the original culture.

This argument may derive support from a case decided by a Federal appellate court, ***Pearson v. Dodd (74).*** In that case, reporters had obtained possession of photocopies of papers owned by a senator. The papers had been furtively "removed from the files at night, photocopied, and returned to the file undamaged before office operations resumed in the morning." The court found that these actions had not substantially deprived the senator of the utility of his records. Because the plaintiff was not significantly deprived of his property, or its value, the court found that conversion had not taken place.

In a situation where the amount of cultured tissue is limited by the physical environment, and not by time, a researcher possibly could draw on this photocopying case in defending against a claim of conversion (32). When an original manuscript is taken, copied by an outside agent, and replaced, there is no conversion; the same reasoning could apply when a portion of an original culture is taken but naturally replaced by the fecundity of the remaining original material, Either way, the value of the original substance does not appear to have diminished, and the ability of the person who provided the original material to exercise dominion and control over the property probably has not been substantially impaired.

This line of defense, however, probably would not rebut the plaintiff claim to ownership of the original culture. That is, while the researcher's use of the **subculture** may not have interfered with the patient's exercise of control over property, to exclude the patient from exercising control over the entire **culture** could constitute conversion.

Researchers might attempt to draw a different analogy from the photocopying case. Frequently, surgery is not successful in removing from the patient's body the entire tumor or all pathogenic cells. In this situation, additional cultures could be obtained by removing some of the cells remaining in the body. Accordingly, a researcher could argue that use of the initial culture did not deprive the patient of any property because the culture could readily be duplicated by using cells still within the patient's body. Items that are readily replaceable may be the basis for only a very limited financial recovery by the plaintiff in a conversion suit (107).

This argument, however, may not afford complete protection for the researcher. In some instances, the treatment might eradicate the sam-

pie, or make it very difficult to locate additional cells. Moreover, a new sample of the diseased tissue in vivo may not be easily accessible. Often, the tumor can only be reached through invasive treatment of the patient. A patient probably would not be barred from claiming conversion on the ground that a replacement culture can be established if the patient must undergo surgery for that new culture to be developed.

Abandonment

The courts have consistently ruled that abandonment of a person's property is a complete defense in any suit alleging conversion. This principle applies to all property, including organic material (28).

In a recent Louisiana case that may be analogous, the plaintiff owned a 130-year-old tree whose limbs extended over a neighbor's house. After a tree surgeon removed these overhanging limbs at the neighbor's request, the landowner sued the tree surgeon for conversion for not having chopped the limbs into firewood. The court ruled in favor of the tree surgeon, finding that he had given the landowner access to the branches. Since the landowner had not exercised any control over the excised limbs—even though she had the opportunity to do so—she could not assert a right to the limbs. The court further supported its conclusion by citing evidence that the landowner had given permission to the tree surgeon to prune the limbs without ever mentioning her desire to keep the excised limbs (11). Although arising in an entirely different factual setting, another case suggests that an individual who takes no affirmative steps to ensure a possessor interest in tissue removed during treatment will encounter difficulties in subsequently asserting any claim to that tissue (12).

Abandonment, if proven by the defendant, precludes a claim of conversion. Whether abandonment of biological materials has occurred, however, can only be decided by looking at the facts in each individual case. The defendant must show "an intention to abandon or relinquish accompanied by some actor omission to act by which such an intention is manifested" (83).

Res Nullius

Another defense that a researcher might assert is **res nullius,** which means things that are not owned (90). The res nullius category included islands newly risen from the sea and wild animals. Under common law, for instance, a distinction was drawn between domestic and wild animals. Domestic animals could be acquired and held as property just like inanimate articles, but wild animals could only be the subject of a qualified property right. Initially, wild animals were common property. The owner of land had the right to take wild animals found on his land, but this right was lost when the animals escaped from the land. The right was mainly of significance in disputes between landowners and poachers (17).

The main way of acquiring rights in wild animals was to lawfully domesticate or confine them. Mere pursuit of a hunted animal was insufficient. If the wild animal escaped, moreover, it could lawfully be seized by others unless they had perpetuated the escape or unless the animal had been domesticated to the point that it probably had an intention to return.

It could be argued the patient and his tissues stand in a relationship similar to that between a landowner and wild animals on his land. If tissues were removed without consent, the wrongful possessor would be like a poacher of wild animals, and would have rights inferior to those of the patient. If, however, the tissues were removed without the removal itself being wrongful, their status would be that of wild animals in a state of nature and the possessor could attempt to exercise dominion over them. Not having exercised dominion or control over the tissues, the patient's rights therein would be like those of a landowner who had made no attempt to capture wild animals passing over his land. The argument seems strongest in the case of tumors because these are not normal, healthy parts of the body. A defendant/researcher could contend that it was he, not the patient, who isolated and cultured the abnormal bodily constituents and thereby reduced them to "possession. "

This defense, however, is subject to the counterargument that the physician has a **fiduciary**

duty to the patient, that is, a duty to act in the patient's best interest. This common law duty is imposed because of a patient emotional vulnerability as well as his reliance on the physician's specialized knowledge. Since the physician's primary duty is to the patient, the exploitation of specimens without the patient knowledge or consent arguably constitutes a conflict of interest. Furthermore, since property entrusted to a fiduciary remains the property of the original owner, a patient could claim that any research performed without the patient consent is required to be for the patient's own benefit, Thus, a patient might claim that the transformation of the tumor from res nullius to a living substance now under control was achieved pursuant to a relationship from which the patient should derive the principle benefit. This argument probably could not be made by volunteer research subjects because their participation in providing cells is not for personal benefit.

Law of Accession

Although tissue is a valuable starting point, substantial modifications ordinarily must take place before a commercially valuable product is created. For example, the researcher might take the patient's cellular material, subject it to mutation-causing agents, and then select those mutated cells that show a desirable trait. The biological material may be combined with material obtained from an entirely independent source. The researcher might, for instance, develop a patient's cells into an immortal cell line and then fuse this cell line with the lymphocyte cell of another patient to yield an entirely new hybridoma cell line.

When a product combines biological material obtained from more than one source, or where the biological material has been significantly modified, the legal doctrine of **accession** maybe helpful in analyzing ownership issues. The doctrine of accession is derived from the civil law of continental Europe, not Anglo-American common law. It has, however, been invoked by American courts.

Accession is the principle by which the owner of property becomes entitled to all which it produces, and to all that is united or added to it, either naturally or artificially (i.e., by the labor or skill of another), even where such addition extends to a change of form or materials. Under this principle, the possessor of property becomes entitled to it, rather than the original owner, where the addition made by skill and labor is of greater value than the original property, or where the change is so great as to render it impossible to restore it to its original shape (92).

Accession may provide a useful analytical framework for property ownership disputes involving hybridomas and other substantially modified bioengineered products, If the labor of the researcher is regarded as of paramount importance, then title should vest with the researcher. However, if the efforts of the researcher are considered of lesser importance, then the major contributor to the finished product is the patient or research subject. This might be particularly true if the patient had supplied a very rare type of cell. The limited availability of the raw biological material might then be said to enhance the value of the patient contribution—even if involuntary—vis-a-vis the labors of the researcher.

Cases Involving Crops

A specialized subset of accession cases may have some relevance. Under Roman law, seeds, plants, and trees acceded to the land. Once in the soil, these botanic materials became the property of the owner of the land, regardless of how they were planted or who did the planting (90). As long as the crops remained in the ground, ownership resided with the landowner. For crops that had been removed from the soil, ownership depended on whether they were **fructus naturales** or **fructus industrials.** The former were generally perennials, such as trees, shrubs, and grasses; the latter were usually annuals, such as wheat, corn, rye, and potatoes. Severed fructus industrials crops were owned by the gardener, while severed fructus naturales crops belonged to the landowner. This distinction arose because of the relative amounts of human inputs: in fructus industrials) much effort was expended, while fructus naturales were much less labor-intensive (27)56).

This test would appear to favor the researcher over the patient. Cells taken from the individual can be analogized to a severed crop. To maintain

these cells requires considerable effort and energy; they would not thrive if left untended. Therefore, a researcher could plausibly assert that a cell culture is a fructus industrial, not a fructus naturales. Thus, the cells (the severed crop) should belong to the researcher (the cultivator).

Specification

Another variation on the Roman doctrine of accession provides a conceptually helpful tool. Known as **specification,** this doctrine governs situations in which a second person fashions an entirely new product out of materials belonging to another. If specification is applicable, the person who engineers the transformation, not the person whose materials are used, owns the final product. In determining whether specification has occurred, courts look to the uses, values, and common names of the starting material and finished product.

Specification might provide a basis for analyzing many of the factual situations that arise in biotechnology. For example, a researcher might take a blood sample of little commercial value and through mutation and careful selection develop a commercially valuable new cell line. In such a situation, the researcher could assert that specification has taken place because the original cell cannot be recovered from the genetically modified culture (103).

Judicial precedents will be of little help in applying the specification doctrine to modern circumstances. The case law is generally quite old and often inconsistent. While one court has held that grass that is cut and made into hay is not covered by specification (5), another court held that specification vested ownership in the person who had fired the bricks and not the person who had owned the clay (58).

REMEDIES

If the supplier of human tissues and cells prevailed in a lawsuit concerning ownership of a biological product by virtue of cell or tissue ownership, the court would then have to devise a remedy. Unless title has passed through the doctrine of accession, an original owner would be entitled to recover the original property (or its cash value) from the person who had converted the property.

Restoration of ownership, however, does not always occur when property has been disturbed. In a recent case, for example, the plaintiff bought a **$2,000** movable home, placed it on cement block, and then left the home for 2 years. In the intervening period, the defendant spent $18,000 to improve the house. The court refused to award the plaintiff the house, saying that this would result in "unjust enrichment," particularly since the plaintiff had virtually abandoned the building (89). This situation could be compared to a patient who asserts ownership of a bioengineered product that had acquired its substantial value only after several years of research and development efforts.

More commonly, a plaintiff alleging conversion will seek monetary damages. In a conversion suit, the plaintiff's damages will ordinarily be the fair market value of the property at the time of conversion (93,105). Usually, providing the owner with that sum should restore the owner to the financial position enjoyed before the conversion.

It may not be entirely clear, however, when the conversion of a biological substance actually occurred. The plaintiff would probably assert that value should be measured at the time when the cell line or gene probe was developed or even later. The researcher, in contrast, would assert that value should be determined earlier, either at the time the tissues or cells were still within the patient's body (when the patient still had physical possession), or after excision but before development. Neither time would be likely to yield a significant damage award for the patient. The tissues or cells would seem to have little value while still in the patient's body or immediately after removal.

Nor is it clear that the tissues or cells would have much value once developed. The great majority of cultures and cloned genes are of no commercial value-only a small fraction are ever patented and only a fraction of patents are licensed (103). Thus, even if the moment of culturing was the

appropriate time point, the patient would have to rely on the latent, potential value of the cells—not the immediate utility of the culture—to recover more than a nominal sum (108). However, there may be certain types of tissues or cells which, through rarity or immediately apparent special properties, would have some ascertainable market value once they were cultured (51).

Case law does not provide much direct authority concerning the point in time that should be used to compute damages. Nineteenth century British cases involving the conversion of coal by secretly removing it from a mine do tend to support choosing an earlier point. Cited with approval by the U.S. Supreme Court, these cases hold that the measure of damages is "the value of the coal as it was in the mine before it was distributed, and not its value when dug out and delivered at the mouth of the mine" (38). If this is analogized to a biological materials case, the appropriate point is when the cells are still in the patient. If so, the monetary harm to the patient probably would be trivial, In addition, not all patient tissue is unique or rare. If a bioengineered product is based on tissue with a relatively common trait, the market value of the tissue might be nil, because some biological materials are available at little or no cost from numerous sources.

Nevertheless, while the general rule is that damages are determined at the time of conversion, this rule has numerous exceptions. For example, courts have held that under certain circumstances the plaintiff could recover the highest value of a converted crop at any time between the date of conversion and the date of trial (42,47). Similarly, an individual ordered to leave the land on which he was growing crops was awarded the money that he would have received had the crops matured, not the value of the crops at the moment of his ejection (79). Because the plaintiff had introduced substantial evidence of what the yield of the crop would have been, the court rejected the defendant's argument that damages should be fixed at the moment of the conversion.

Well-established agricultural doctrine may strengthen the claim of the patient or subject to a larger recovery. Unless the parties agree otherwise, the progeny of animals belong to the mother's owner, in accordance with the maxim **partus sequitur ventrem** ("the birth comes from the womb"). And an owner who was wrongfully deprived of livestock can recover for lost output provided that this loss can be established with sufficient certainty, including eggs from converted chickens (39) and milk from converted heifers (63). These cases would seem to support a patient's claim for the value of the output of a cell line resulting from a wrongfully taken tissue or cell. Assuming that a patient did prevail on the conversion claim (68), the recovery might therefore include not only the value of the cells themselves, but also the value of any cell line and product derived from the cell line.

Variation Among States

State courts vary widely in the degree to which they depart from the strict test of market value at the time of conversion. Thus the amount that a plaintiff could recover for conversion of biological material could depend largely on which State's law applies to the claim.

The differences among the States in computing damage awards is illustrated by a California statute. (California is home to many biotechnology companies.) The basic rule in California is that "the owner of a thing owns also all its products and accessions" (18). Under this law,

> . . . [w]hen things belonging to different owners have been united so as to form a single thing, and cannot be separated without injury, the whole belongs to the owner of the thing which forms the principal part (19).

The legislature recognized the potential difficulty in determining which part was "principal ." To give guidance to the courts, the following statute was enacted:

> That part is deemed to be the principal to which the other has been united only for the use, ornament, or completion of the former, unless the latter is the more valuable, and has been united without the knowledge of its owner, who may, in the latter cases, require it to be separated and returned to him, though some injury shall result to the thing to which it has been united (20).

Once the owner of the "principal" part has been ascertained, that person can claim ownership to

the entire object. However, the owner must "reimburse the value of the residue to the other owner, or surrender the whole to him" (21). This is a substantial change from the common law approach followed in most jurisdictions.

It is clear that computing damages might be difficult in many biological tissue conversion cases. The problems could be further compounded by the need for the plaintiff to identify with specificity his or her property. It will not be enough for the patient to demonstrate that a cell culture or bioengineered product contains tissues or cells that originated with him or her. The patient also must identify specifically the cells which he or she claims to own (45). For example, if cows are converted and then mingled with another person's herd, the cows' owner must identify his particular cows in order to receive an award of damages (60). Simply showing commingling is not enough to justify a monetary recovery.

This need to establish ownership of discrete articles may not be difficult in some situations. Typically, considerable efforts are expended to maintain the purity of a cell line; biological material from another source is ordinarily excluded from a cell culture. Thus in many cases, it would not be difficult to trace to a single source the original material used to make a cell line. When this separate existence is not maintained, however, the plaintiff may have the difficult task of segregating the tissue or cells which he or she originated from those coming from another source.

Moreover, this need to identify specific property may be a barrier to recovery in cases involving anonymous or unidentifiable sources. Researchers frequently test tissues without knowing the source of the material (103). If a patient suspected that his or her tissue had been used to generate a bioengineered product, the individual would need to trace the product back to the tissue originally provided. This could be quite difficult where material has been pooled or where full documentation of tissue source has not been maintained by the research facility.

Third-Party Liability

Good faith of the defendant is generally irrelevant to the merits of the claim in a conversion suit and the person whose property has been converted can prevail, regardless of whether the defendant acted inadvertently (91). The intent of the defendant may, however, affect the damages. Some courts have held that where the acts are willful, the defendant must reimburse the lawful owner for the full value of the property even if the defendant had enhanced the value of the property through labor or materials (75).

Because good faith is not a defense, third parties who unknowingly participated in the conversion may be held liable to the plaintiff (84). Thus an auctioneer who unwittingly sold property that had been converted by a third party has been held liable to the true owner of the property (91). This principle could have important applications for the biotechnology industry. If good faith is not a defense to possession of a bioengineered product derived from a patient's tissue, then innocent purchasers of the product are potentially liable to the patient; similarly, licensees using the product might also be at risk of suit.

SUMMARY AND CONCLUSIONS

U.S. law has long protected people from those who would harm them physically or who would deprive them of full enjoyment of their property. The common law classifies many injuries to persons (which are analyzed under tort law principles) or injuries to property (which generally are within the domain of property law). Congress and State legislatures have enacted a variety of statutes to codify, modify, and overrule the common law.

No area of existing law definitely sets forth the rights held by an individual who provides tissues and cells to an academic or commercial researcher. Because neither judicial precedents nor statutes directly address the questions raised by the use

of tissues and cells in research, courts must handle emerging legal questions by using principles and precedents developed for other circumstances. In reasoning by analogy, courts can draw upon possible sources of rights that are outlined in this chapter.

Patent law has direct application to biotechnology research and development. Although patent law does provide inventors with a personal property right in the invention, it does not provide inventors or their sources with property rights in the original, unimproved tissues and cells.

The **law of cadavers and autopsies** provides a historical context for considering the property and quasi-property rights in human tissue. Although property law concepts have been useful in this area, the tort of intentional infliction of emotional distress has been developing as a more appealing theoretical basis for a legal claim based on unauthorized retention of body parts and other forms of wrongful conduct. Today, cases concerning wrongful acts toward a dead body are generally treated as tort cases rather than property disputes.

The **law of organ transplantation** is relevant because it shows congressional intent banning sales of certain human organs. The **law of blood and semen sales** is an area where regulation has been minimal. This area of law does open up the question of whether the sale of replenishing tissues and cells constitutes the sale of services rather than the sale of a commodity. If such sales are treated as the sale of commodities, then Uniform Commercial Code warranties would apply to the merchantability and fitness of such products. In addition, State sales taxes would apply. Although State law generally characterizes such transfers as the sale of commodities, such characterization has not been applied consistently.

The **law of copyright** will not provide a legal remedy for the provider of human biological material unless it can be shown that the source of such material is an author of such material. The **law of trade secrets** provides protection, either by contract or through statute, against the disclosure of certain information. A sample of human tissues and cells is not itself a trade secret but may be characterized as a tangible article representing an intangible trade secret. Still, unless the patient contemplated, at the time of transfer, that the excised tissues or cells had commercial value, it would be difficult to argue that the biological material represented a "trade secret" of the patient.

The **law of conversion and trespass to chattel** may provide tort protection for sources of human tissues and cells where it can be shown that there was intentional interference with personal property. Because tort law is determined primarily by State law, significant variation in the conversion doctrine exists from State to State. The **law of accession,** whereby the owner of property becomes entitled to all it produces, may be helpful in analyzing issues related to ownership of tissues and cells, particularly where the analysis hinges on the comparative value of the raw material provided by the source and the labor expended by the recipient of the material,

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