practicable enough so as to measure the vitamin-producing activity of raw extracts. [Id., 510]

The Supreme Court noted that "the particular species of microorganisms used by Pierrel belonged to the Schizomycetes class which had expressly been mentioned in the Merck patents. Further, it found that the specifications in those two patents were sufficient to enable a laboratory expert skilled in his art to choose . . . the strains which were most appropriate."[Id., 512.]

It seems fair to characterize this case as one expressing a very lenient standard of disclosure, as there was nothing to indicate *which* of "the 100,000 kinds of bacteria" suggested by the applicant should be tested first. The field of search suggested in *Tabuchi* was considerably narrower. Even if the LLD test were, as stated by the court, "a simple operation for any technical assistant," the search for a desirable strain might be quite time consuming.

CHAPTER 11

Other Forms of Protection for Biotechnology

§ 11.01 Trade Secret Protection of Cultures and "Knowhow"

Trade secret protection may be used (1) to protect a patentable invention while a patent application is still pending; (2) to protect peripheral, undisclosed knowhow surrounding a

the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operation of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

Secrecy. The subject matter of a trade secret must be secret. . . . Some factors to be considered in determining whether given information is one's trade secret are: (1) the extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and to his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

A more modern definition is given in the Uniform Trade Secrets Act:

"Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

(i) Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascer-

(*Text continued on page 11-3*)

tainable by proper means by, other persons who can obtain economic value from its disclosure or use, and

(ii) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.[1]

According to the Restatement,

One who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if

(a) He discovered the secret by improper means, or

(b) His disclosure or use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him, or

(c) He learned the secret from a third person with notice of the facts that it was a secret and that the third person discovered it by improper means or that the third person's disclosure of it was otherwise a breach of his duty to the other, or

(d) He learned the secret with notice of the facts that it was a secret and that its disclosure was made to him by mistake.

The "trade secret" concept is a peculiar hybrid of property, contract, trust, and agency law. A "trade secret" is "property," despite its evanescent nature (an "open" secret is not a "secret"), in the sense that its theft may by considered a form of larceny, and in the sense that its sale or exchange may have tax consequences. A trade secret may be established by contract, through an express agreement of party *A* to treat as confidential what is told to him by party *B*. Or it may be established by the courts, who, believing that it was natural for party *B* to repose his trust and confidence in party *A*, enjoin *A* from breaching that trust by unauthorized use or disclosure of *B*'s secrets. The extent to which the courts have emphasized one source of trade secrets law over the others has varied from decision to decision.

"Trade secret" protection does not arise from any Act of Congress; it is entirely a creature of state law. Consequently, there are *fifty* laws of trade secrets in this country, not one.

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[1] Milgrim, *Trade Secrets*, in Appendix A, Vol. 12A Business Organizations (1980).

[Kinter & Lahr, *An Intellectual Property Law Primer* 145-46 (1975), citing Gallowhur Chemical Corp. v. Schwerdle, 117 A.2d 426 (N.J. Super. Ct. 1955).]

Possible security measures include (a) briefing employees on the need for secrecy; (b) requiring employees to sign a confidentiality agreement and to agree to surrender documents and samples when employment is terminated; (c) inspecting speeches and articles before they are disseminated; (d) destroying lab samples and trash; (e) giving code numbers to ingredients; (f) numbering documents, stamping them "confidential" and controlling access to them on a "need-to-know" basis; (g) restricting visitors; (h) compartmentalizing the manufacturing operation; and (i) posting cautionary signs.

It will be difficult to ensure security. As Tom Kiley points out:

> Engineered microorganisms of immense value (e.g., those producing interferon in high yield) are invisible to the naked eye. A large batch capable of producing commercially important quantities of products can be grown from a single microorganism. The "missing microorganism" is never missed. No inventory can keep count, organism by organism, of microorganism stocks. The same is true of other substances important in biological research—gene fragments, messenger RNA from which DNA can be gotten by enzymatic "reverse engineering," one-of-a-kind cell lines that are the beginning point in the search for new research leads, etc.[6]

It is important that security measures be enforced, not merely announced. In *Wheelabrator Corp. v. Fogle,* even though Wheelabrator had issued notices purporting to limit admission to its steel shot plant, the court was more impressed by "the apparent routineness that customers, potential customers, independent contractors, and repairmen were allowed admission to the plant."[7]

Section 757(a) of the Restatement of Torts offers the trade secret owner an opportunity to recover damages for industrial

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[6] Speech by Tom Kiley, "Trade Secrets and Biotechnology" at 5.

[7] 317 F. Supp. 633, 638-39 (W.D. La. 1970).

The confluence of three forces led to the theft of valuable antibiotic-producing cultures from American Cyanamid in the late fifties and early sixties—the enormous commercial success of the first antibiotics; the absence of patent protection for pharmaceuticals in Italy; and the disaffection of several key technical employees. The description of the thefts, which appears below, is pieced together from a number of news accounts and the few reported opinions.

In *American Cyanamid v. Fox*,[10] defendant Fox and his accomplices were held to have appropriated American Cyanamid's trade secrets. In the winter of 1958, Nathan Sharff and Seymour Salb, of Bioorganic Laboratories in New Jersey, convinced Dr. Sidney Fox, a disgruntled research chemist at Cyanamid's Lederle Labs, to steal the organism and process data used to make triamcilone. Later Fox acquired the organisms and process data used to make Aureomycin, Tetracycline, and Declomycin. In September, 1959, Fox resigned from Lederle and devoted himself to selling the cultures through his alter ego, Kim Laboratories.

After making contact with European manufacturers through Elio Salvetti, Fox met with John Cancelarich, another Lederle chemist, who resented a management decision denying him participation in a profit-sharing plan, and induced him to supply Fox with Lederle's confidential documents and microorganisms. On one occasion, an innocent employee gave Cancelarich a sample of the residue of an antibiotic process from which the necessary organism could be recovered.

Later, Cancelarich, Fine, and Salvetti deserted Fox and negotiated a deal to supply Declomycin cultures and technology to Institute Biochemico Italiano for $50,000.

American Cyanamid successfully brought suit against Fox and his co-conspirators in New York and New Jersey, and also succeeded in obtaining their criminal prosecution.[11] Merck won a New Jersey case against Nathan Sharff and Seymour Salb, accused of stealing and selling Merck's vitamin B-12

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[10] 140 U.S.P.Q. 199 (N.Y. Sup. Ct. Spec. & Trial Term, N.Y. County, 1964). *See also* Michael Pearson, The Million Dollar Bugs (1969); Chemical Week, August 4, 1962 at 25-26.

[11] United States v. Bottone, 365 F.2d 389 (2nd Cir. 1966).

		Patents	*Trade Secrets*
1.	*Applicable Source of Law*	Federal Patent statute	State statutes and "common law"
2.	*Novelty and Nonobviousness*	Required	Not Required
3.	*Commercial Value*	Not Required, but invention must have "utility"	Required, but standard is modest
4.	*Effect of Actual Use*	Not Required for protection. Prolonged public use prior to filing of application forfeits right. Abandonment, suppression or concealment may also forfeit rights.	Possibly required for protection, though use may not need to be present or continuous. actual use risks disclosure through observation or "reverse engineering" by another.
5.	*Effect of Disclosure*	Right to patent protection lost if inventor delays too long after publishing his discovery before filing an application. Patent application must adequately disclose the invention.	Subject matter must not be publicly disclosed. All disclosures must be *sub rosa*, or trade secret is lost.
6.	*Period of Protection*	For seventeen years from the date the patent issues.	From the development of the subject matter until it becomes public knowledge
7.	*Rights of Others During Period of Protection*	Only if licensed	May use trade secret if it was discovered by independent invention, by "reverse engineering" the product (if product obtained by lawful means), by studying public literature or public use of an item embodying the secret, or if licensed.

lines to Gallo for his personal, noncommercial, and confidential use. They further allege that through Litton Bionetics, Gallo sent sample fluids containing cells of these lines to Dr. Sidney Pestka at the Roche Institute of Molecular Biology, at Petzka, and that through an agreement with HLR, Genentech acquired physical access to this cell sample and transferred the interferon-making genes from the KG-1 cells into a microorganism. Hoffman-La Roche, on the other hand, insisted that its behavior was proper, and charged defendants with defamation and slander of title.[20]

In a speech given by Genentech Vice President and General Counsel Thomas Kiley, he accused defendants of blurring the definition of a "trade secret" by regarding the KG-1 and KG-1A cell lines to be proprietary:

> 1. A trade secret must be *known* to its alleged owner. The counterclaim does not assert the "owner" to have known of the secret "embodied" in the cell line. See Bowser, Inc. v. Filter, Inc. 398 F.2d 7, 10 (9 Cir. 1968).
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> 2. A secret is an intangible value, not a thing. II Callman, Unfair Competition and Monopolies [3rd ed. 1968], Section 52.2 at pp. 381-82; Milgram, Trade Secrets, Section 1.02[1] at p. 1-14; Chappel v. United States, 270 F.2d 274, 278 (9 Cir. 1959); Oakes v. Suelynn Corp., 24 C.A.3d 271 (1972).
>
> 3. For reasons like those previously discussed, the genetic content of a cell line need be employed only once in the creation of a bacterial culture capable of producing a desired product. No actual part of the cell line enters the bacterium. At best, cell line components are used as templates from which other useful bits are struck off. But to qualify as a trade secret, *continued* use must be required to maintain a competitive advantage over others. *Cal Francisco Inv. Corp. v. Vrionis,* 14 C.A.2d 318, 322.
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> The separate question whether under any circumstance the cell line is protectible as *property* that can be converted or made the basis of a claim for unjust enrichment is outside the scope

[20] Answer to Amended Complaint and Counterclaim (June 16, 1981). In an unrelated case involving misappropriation of cell cultures, Dr. Hayflick was accused of selling government cultures of WI-38 and WI-26 cell strains for his private account. *See* Shriver letter of January 30, 1976, NIH Ref. No. P-75-211.

special item,[22] or the knowledge of the location of a rich ore body, is protectible under trade secrets law.

Both Merck and American Cyanamid won civil suits charging that theft of their antibiotic cultures constituted appropriation of their trade secrets, so the law appears clear in New York and New Jersey.

Further legal support for regarding cultures as trade secrets may be gleaned from the penal codes of twenty-one states. (*See* Table I at end of chapter.)

Thus, in California, Section 499c indicates that theft of a microorganism "representing" a "trade secret" constitutes misappropriation. Similar statutes have been enacted in Colorado, Florida, Georgia, Michigan, Minnesota, Nebraska, New Jersey (recently amended), New Mexico, Pennsylvania, Tennessee, and Texas. New York law indicates that theft of a "culture or microorganism" may be theft of "secret scientific material," punishable as grand larceny. Arkansas, Illinois, Maryland, Montana, North Carolina, and Wisconsin define a "microorganism" to be "property," thus bringing it within the larceny law. Protection is also afforded in Connecticut.

The discussion of the implication of these penal provisions leads naturally to consideration of the relevance of the National Stolen Property Act (18 U.S.C. §2314) to trade secret protection:

> Whoever transports in interstate or foreign commerce any goods, wares, merchandise, securities or money, of the value of $5,000 or more, knowing the same to have been stolen, converted or taken by fraud;
>
> Shall be fined not more than $10,000 or imprisoned not more than ten years, or both.

In *United States v. Bottone,*[23] the Second Circuit held that the stolen cultures "were stolen 'goods' on any view," and that

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[22] *Cf.* Waukies, Inc. v. Pincus, 86 U.S.P.Q. 182 (N.Y. Sup. Ct. Spec. Term N.Y. County 1950).

[23] 365 F.2d at 394.

case, the D.C. Circuit held that EPA may disclose the safety and efficacy data collected by one manufacturer to another.[25]

J. R. Norris has pointed out that the subjectiveness of bacterial taxonomy, the portability of bacterial cultures, and transnational differences in patent protection will make it difficult to police patents on microbial inventions. "It seems certain that many organizations will . . . rely on know-how and secrecy."[26]

The fermentation industry has a heritage of secrecy. In the Middle Ages, particular communities prospered because of the wine they produced or the cheese they manufactured, and they jealously guarded their trade secrets. During the industrial revolution, the brew-master was as secretive as his medieval forebears. According to H. B. Woodruff:

> As late as the 1930s, one seldom read accounts of citric acid production, of mushroom culture, [or] of protolytic-enzyme manufacture originating from laboratories of commercial producers. Such papers as appeared in the scientific literature originated largely from the research laboratories of agricultural colleges, and were deprecated in private by the industrial microbiologists for their naivete, and for the poor product yields reported. The patent system for fermentation processes . . . has led to the end of enforced secrecy. . . . The latest information in microbiological genetics or molecular biology is applied by the industrial microbiologist. Industrially important microorganisms . . . have become available for study of biochemical pathways and regulatory mechanisms . . . . The benefits from open research can be reaped only as long as the patent system provides an acceptable alternative to secrecy.[27]

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[25] *See* § 7.04.

[26] J. R. Norris, The Microbiologist and the First European Patent Convention, Process Biochemistry 29, 30 (June 1977).

[27] Woodruff, Importance of the Producing Organisms in Obtaining Patent Protection for Fermentation Processes, in Genetics of Industrial Microorganisms 403, 404 (1970).

such a practice may be underway already. . . .[28]

Two years later, Professor Kayton of George Washington University told a seminar audience that "(m)olecular biologists and genetic engineers may be surprised to learn (as may most everyone) that their expressions of intra-cellular genetic information, novel or otherwise, within living microorganisms or eukaryotic cells are also works of authorship protected from unauthorized reproduction by the terms of the new copyright law."[29] This author believes that "most everyone" includes the Copyright Bar, the Copyright Office, and the drafters of the new Copyright Act. The Copyright Office has unofficially indicated that it will refuse registration of gene sequences, DNA molecules, and organisms, but may register genetic maps. While genetic maps may be copyrightable, that would not prevent anyone from manufacturing the DNA molecule thus described.[29.1]

The proponents of gene copyright rely heavily on the analogy between genetic sequences and computer programs. Computer programs are, by the explicit provision of the legislators, protectible as "literary works," while the legislators never contemplated the copyright protection of genes. While the copyright statute is forward-looking, the legislative history of the

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[28] T. D. Kiley, Learning to Live With the Living Invention, 7 Amer. Pat. L. Ass'n Q.J. 220, 233-234 (1979). *Cf.* J. A. Taylor, Common Errors As Evidence of Copying, 22 Bull. Copyr. Soc'y Amer. 444 (1975).

[29] Kayton, Copyright in Living Genetically Engineered Works at 1, in Patent Resources Group, Genetically Engineered Microorganisms and Cells (1981).

[29.1] The Copyright Act provides that no action for infringment of the copyright in any work can be instituted until the copyright claim has been registered, or unless an application for registration, in proper form, was refused. In the latter case, the applicant may sue for infringement provided that notice of the suit is given to the Register of Copyrights. The Register may then enter an appearance in the action as a party with respect to the issue of registrability. That issue may, regardless of the actions of the Register, be determined by the Court. 17 U.S.C. §411(a). The significance of registration is that the certificate constitutes "prima facie evidence of the validity of the copyright and of the facts stated in the certificate." 17 U.S.C. §410(c). Thus, the current attitude of the Register of Copyrights towards applications for DNA molecules is of some import.

to protect but that future congresses may want to.[30]

Thus, while § 102 is not a straitjacket for expression, neither is it license to protect *via* copyright those forms of expression which are not analogous to the seven enumerated categories. Professor Nimmer suggests

> [I]f video tape and video discs had been developed after the effective date of the present Act, and were not included within the definition of "motion pictures" under Section 102(a)(6) [as, in fact, they are] they would, no doubt, be protected as works of authorship in that their respective functions are certainly analogous to motion picture film. . . . If, however, we were to imagine that sound recordings had not been invented until after the effective date of the present Act (and that Section 102(a)(7) were not included therein) it would be doubtful that sound recordings could be protected as works analogous to any of the other six categories of works listed under Section 102(a).[31]

Professor Kayton, in a more recent exposition of his position,[31.1] agreed that "a new form of expression should be regarded as within the congressional intent if it is sufficiently analogous to the seven categories of works enumerated in the statute," and, by implication, that subject matter which is not analogous is not protectible. Kayton urges, however, that "genetically engineered works are certainly analogous, if not nearly identical, to computer programs; the mode of expression is simply animate, rather than inanimate."

It is certainly true that a DNA sequence may be considered a set of instructions, like a computer program. The structural sequences may be thought of as print statements and the regulatory sequences as flow-of-control statements. But that is about as far as the analogy goes. Kayton makes frequent use of ambiguous terminology in order to conceal the imperfections in his reasoning. He speaks of the DNA and protein sequences

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[30] S. Rept. No. 94-473 (94th Cong. 1st Sess.) 50-51 (1975).

[31] Nimmer on Copyright, Vol. I, Section 2.03[A] at 2-27 (1981).

[31.1] Kayton, Copyright in Genetically Engineered Works, Geo. Wash. U.L. Rev., 191 (1982).

authorship, but is a particular kind of copy."[32]

Professor Kayton has made the ingenuous argument that a "scientist or engineer . . . authors a literary work when he applies the techniques of recombinant DNA to create original DNA sequences" because the various codons are "indicia."[33] Literary works are defined in the Act as those expressed in "words, numbers, or other verbal or numerical symbols or indicia, regardless of the nature of the material objects . . . in which they are embodied." Clearly, the adjectives "verbal" and "numerical" modify *both* of the synonymous nouns "symbols" and "indicia." The Kayton argument is equivalent to one classifying an igloo as a "stone or brick house or home" by relying solely on the term "home."

According to Dr. Jorge Goldstein, "the strongest reason for arguing, as Kayton does, that polynucleotide molecules are appropriate media of expression for genetic works is by analogy with the computer world."[33.1] *Apple Computer, Inc. v. Franklin Computer, Inc.* (1983), to which Dr. Goldstein points, held that "a computer program, whether in object code or source code, is a 'literary work' and is protected from unauthorized copying. . . ."[33.2] It also held that "the statutory requirement of 'fixation' . . . is satisfied through the embodiment of the expression in ROM devices."[33.3]

Dr. Goldstein, after discussing the Apple Computer case, remarks,

> Returning now to polynucleotides, it appears that while they are not "verbal or numerical indicia," neither are the electronic band levels of silicon. The genetic instruction coding for the amino acid leucine, for example, is TTG, which in a double helical DNA molecule occupies about 0.7 nm in length. The electronic program instruction, ADD BOTH NUMBERS AND SAVE THE RESULT is expressed in binary code as 01101001 on an Apple computer, and occupies about the same space on

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[32] S. Rept., *supra*, note 30 at 52.

[33] *Supra*, note 29 at 12.

[33.1] J. Goldstein, Copyrightability of Genetic Works, Bio/Technology 138, 139 (February 1984).

[33.2] 219 USPQ 113, 120-21 (3d Cir. 1983).

[33.3] Id., 121.

The DNA Telegram
Translated into the
Single Letter Amino Acid Code

T	h	e	M	e	d	i	u	m
Thr	His	Glu	Met	Glu	Asp	Ile	Umb	Met
ACT	CAT	GAA	ATG	GAA	GAT	ATT	TGA	ATG

I	s	N	o	t	T	h	e
Ile	Ser	Asn	Och	Thr	Thr	His	Glu
ATT	AGT	AAT	TAA	ACT	ACT	CAT	GAA

M	e	s	s	a	g	e
Met	Glu	Ser	Ser	Ala	Gly	Glu
ATG	GAA	AGT	AGT	GCT	GGT	GAA

The Copyright Act clearly differentiates literary works from the copies in which they are embodied. In the *Apple Computer* case, it was not the ROM chip that was the copyrighted subject matter, it was the set of instructions which had been encoded into that ROM chip. The DNA molecule is "copyrightable" only insofar as it constitutes a "copy"[33.6] of a "literary work," as in the case of my "DNA Telegram." It is not a literary work per se.

[2] A DNA Sequence Is Neither an "Original Work" Nor a "Compilation"

A second issue is whether the DNA sequences for which protection is sought are in fact "original" works. DNA sequences found in nature, per se, would not be claimed by anyone to be copyrightable. But some have argued that the ligation of preexisting DNA sequences into an original sequence is a copyrightable "compilation," *i.e.*, the composite plasmid is a "work formed by the collection and assemblying

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[33.6] "Copies" are "material objects, other than phonorecords, in which a work is fixed by any method now known or later developed, and from which the work may be perceived, reproduced or otherwise communicated, either directly or with the aid of a machine or device." 17 U.S.C. §101, 90 Stat. 2541 (1976).

which is fixed upon the tape in the form of a mosaic of magnetic dipoles.

Second, it expressly states, in 17 U.S.C. §102(b), that "in no case does copyright protection for an original work of authorship extend to any . . . discovery, regardless of the form in which it is described, explained, illustrated or embodied in such work." Thus, while liquid crystals might be a medium for the expression of a pictorial work, one could not copyright the discovery of the thermochromic characteristics of liquid crystals.

It is significant that the drafters of the Copyright Act chose to employ a constitutional term, "discovery," in 17 U.S.C. §102(b), while refraining from use of the constitutional term "writing" in 17 U.S.C. §102(a).

It is true that a patent can be obtained under 35 U.S.C. §171, for "any new, original and ornamental design for an article of manufacture," while "pictorial, graphic, and sculptural works" are the subject of copyright under 17 U.S.C. §102(a)(5).[34] But there is no contradiction here. The copyrightable subject matter is an abstract expression which may be fixed in a medium of expression which, in turn, is an inseparably identifiable part of an article of manufacture. The patentable subject matter is a specific design. The copyrightable expression, having its own identity, is something which may be embodied in different material objects, while the subject matter that is patentable as a design is the appearance of an object and is an inseparable part of the object. Thus, there is no direct conflict between 17 U.S.C. §102(b) and 35 U.S.C. §171.

The basic question under 17 U.S.C. §102(b) is whether the protection sought under the copyright laws is tantamount to protection of a "discovery." It is certain that a DNA molecule embodying a novel, useful, and nonobvious nucleotide sequence is patentable, its "inventor" having "discovered" that said molecular structure has a useful function by placing and "expressing" (in a scientific sense) that molecule in a host organism. But to allow one who has constructed an obvious DNA

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[34] Cases suggesting that an article of applied art might be the subject of both design patent and copyright include In re Yardley, 493 F.2d 1389 (CCPA 1974) and In re Penthouse Intern. Ltd., 565 F.2d 679 (CCPA 1977).

sented therein, then copying the forms to "use" the art, rather than to "explain" it, is not an infringement. Professor Nimmer would reject this justification of copying and limit *Baker* to a rule that copyright may not be claimed in a system or method per se.[36] The case law, on balance, seems to follow the broader rule that protection of a "writing" must be denied if enforcement of the rights granted under the Copyright Act would result in "a monopoly of use not only of the copyrighted work itself, but also of the system, function, process, or art (*i.e.*, the "idea") upon which the work is based or for which it is fitted."[37] Indeed, protection may be refused if there are merely a limited number of ways of expressing an idea.[38]

The statute itself does not make it clear whether 17 U.S.C. §102(b) is a bar to copyrightability or a defense to a suit for infringement. This is a familiar problem in copyright law.

As Alan Latman has remarked, "[I]n some areas, the validity of a copyright and its infringement are merely different dimensions of the same problem. . . ."[39] When is it difficult to distinguish between an idea and its expression, copyrightability and infringement questions merge. This "tendency . . . is perhaps most evident as the possible permulations of expression become fewer."[40]

The "idea" here is a method of causing an organism to manufacture a particular protein under a particular circumstance. The "expression" is the sequence of nucleotides in a

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[36] Nimmer, *supra* note 31.

[37] Id.

[38] *See* American Institute of Architects v. Fenichel, 41 F. Supp. 46 (E.D.N.Y. 1941)(legal forms); Morrissey v. Proctor & Gamble Co., 379 F.2d 675 (1st Cir. 1967)(game rules), Freedman v. Grolier Enterprises, Inc., 179 U.S.P.Q. 476 (S.D.N.Y. 1973) (point count system of bridge bidding when printed on playing cards—"the idea and its expression are functionally inseparable, to permit the copying of the expression would be to grant the copyright owner a monopoly of the ides"—"plaintiff was denied a United States patent for his cards"); Herbert Rosenthal Jewelry Corp. v. Kalpakian, 446 F.2d 738 (9th Cir. 1971) (jeweled bee pin—"the 'idea' and its 'expression' appear to be indistinguishable"—"copyright would effectively prevent others from engaging in the business of manufacturing and selling jeweled bees").

[39] A. Latman, The Copyright Law 29-33 (5th Ed. 1979).

[40] Id.

bases) would subtly affect the structure of the protein manufactured or mechanisms of induction and repression.[41.1]

Thus, it is conceivable that the use of sequence *A*, in preference to sequence *B* (albeit that they encode the same polypeptide) might be an "idea" in its own right, and the protection of sequence *A*, even if not excluding use of sequence *B*, would then be tantamount to appropriation of an "idea."

What, then, is the "idea" underlying a DNA molecule expression? The expression of a particular protein by a particular structural DNA sequence, or by any DNA sequence encoding that polypeptide? The use of a particular combination of regulatory DNA, structural DNA, replicon, and host, or of any combination yielding a protein having the desired biological activity.

Goldstein suggests that if the idea is something as broad as linking any heterologous promoter to the human alpha interferon gene and placing it on a suitable plasmid vector, and the expression is considered to be the particular promoter-structural gene-vector combination chosen, there is no preemption of the underlying idea so long as there are many promoters and vectors to choose from. He admits, however, that as the "idea" is more narrowly defined, and as the scope of copyright protection is widened, a point is reached where the idea is in danger of merging with the protected expression.[41.2]

Without resolving these questions, we cannot determine whether copyright protection for DNA molecules is curbed by the Baker doctrine, as codified by the Copyright Act. However, one thing is certain: if the copyrightable expression is defined narrowly so as not to preempt the idea, the commercial value of asserting a copyright in the DNA molecule will be reduced.

The computer program analogy—a set of instructions for constructing a protein is like a set of instructions for operating a digital computer—is not the only analogy available. A DNA base sequence may be compared to a rule book (a set of in-

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[41.1] This speculation has now been confirmed. SeeTable I, in Itakura, U.S. 4,356,270 (1982), identifying the codons preferred for expression of microbial genomes.

[41.2] Goldstein, *supra* at 141.

Clause as "writings."[43]

Copyright protection of the DNA molecule is also akin to the protection of instructions for games. There is an absolute prohibition, of course, on the protection of a method of playing the game per se. While some early decisions permitted the copyright protection (narrowly circumscribed) of game instructions, the more recent cases have rejected it. In *Morrissey v. Procter and Gamble Co.*,[44] the First Circuit refused to protect the rules for a sweepstakes contest:

> Nonetheless, we must hold for the defendant. When the uncopyrightable subject matter is very narrow, so that "the topic necessarily requires," Sampson & Murdock Co. v. Seaver-Radford Co., 1 Cir. 1905, 140 F. 539, 541; cf. Kaplan, An Unhurried View of Copyright, 64-65 (1967), if not only one form of expression, at best only a limited number, to permit copyrighting would mean that a party or parties, by copyrighting a mere handful of forms, could exhaust all possibilities of future use of

(*Text continued on page 11-27*)

[43] Nimmer, Section 2.18[T].

[44] 379 F.2d 675 (1st Cir. 1967). Similar doctrines limit the application of trademark rights. *See* In re Deister Concentrator Co., 289 F.2d 496 (CCPA 1961); and *compare* Diamond Match Co. v. Saginaw Match Co., 147 Fed. 727 (6th Cir. 1906) and Campbell Soup Co. v. Armour & Co., 175 F.2d 795, 798 (3d Cir. 1949) *with* Marian Labs., Inc. v. Michigan Pharmarcal Corp., 338 F. Supp. 762 (E.D. Mich. 1972), aff'd without opin., 473 F.2d 910 (6th Cir. 1972).

the substance. In such circumstances it does not seem accurate to say that any particular form of expression comes from the subject matter. However, it is necessary to say that the subject matter would be appropriated by permitting the copyrighting of its expression. We cannot recognize copyright as a game of chess in which the public can be checkmated. Cf. Baker v. Selden, supra.

[5] Copyright Protection Does Not Extend to the Utilization of the Functional Aspects of an Article

While copyrights, trademark, and design patent rights may, as some courts state, co-exist in the nonfunctional features of a tangible object, they cannot reside in its functional features, which are the domain of the utility patent law.

A DNA molecule, the "material object" fixing the sequence, is purely functional, indeed, it is the most efficient, accurate machine ever created. It is clear from the legislative history that the functional features of a tangible object cannot be said to embody an original work of authorship, since those features are dictated by other considerations. A design of a useful article is "considered a pictorial, graphic, or sculptural work only if, and only to the extent that, such design incorporates pictorial, graphic or sculptural features that can be identified separately from, and are capable of existing independently of, the utilitarian aspects of the article" (17 U.S.C. §101).

Thus, the Committee suggested that unless the shape of an automobile . . . contains some element that physically or conceptually, can be identified as separable from the utilitarian aspects of that article, the design would not be copyrighted under the bill.[45] The Committee also noted that "where the only elements of shape in an architectural design are conceptually inseparable from the utilitarian aspects of the structure, copyright protection for the design would not be availabe.[46]

It might be argued that a DNA sequence is not comparable to a "pictoral, graphic or sculptural work." DNA molecules are, however, three dimensional structures, and this is the only

[45] H. Rept. at 55.
[46] Id., 55, 105.

models.[48]

An ordinary structure is normally deemed "a useful article," and an architectural plan is therefore a "work that portrays a useful article," under 17 U.S.C. §113(b). Note that the § 113 exclusion of articles which "convey information" from the special limitations on copyright protection of useful articles and the like evidently does not cover articles whose information content is, like an architectural plan, the *portrayal* of a useful article. Clearly, a base sequence, set forth on paper, is a "work portraying a useful article," a DNA molecule. A DNA sequence would in turn, is a "useful article."

Just as the construction of an architectural structure would not, taken alone, infringe on architectural plan depicting that structure, construction of a protein according to the instructions conveyed in a DNA sequence would not infringe a copyright on the sequence.

[6] The Courts Will Be Reluctant to Confer the Rights of a Copyright Owner Upon the Originator of a New Nucleotide Combination Without a Clear Signal from Congress

The proponents of gene copyright note that the copyright term is of very long duration, and that the penalties for copyright infringement may be draconic—imprisonment for up to one year, a $10,000 fine, destruction of equipment used in the manufacture of the infringing copies, statutory damages of $50,000, recovery of lost profits and reasonable attorneys' fees, and injunctions against further reproduction. They stress that copyright might subsist in even an obvious gene sequence unsuitable for patent protection. If it were certain that gene sequences were copyrightable, these would be weighty arguments in favor of asserting copyright.

However, the case for claiming copyright in gene sequences is flimsy, and a court is unlikely to venture out on a long, nar-

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[48] *See* DeSilva Constr. Corp. v. Herrald, 213 F. Supp. 184 (M.D. Fla. 1962); Ga-On Homes, Inc. v. Spitzer Homes, Inc., 178 U.S.P.Q. 183 (M.D. Fla. 1973).

§ 11.02A Copyright Protection for Plant and Animal Phenotypes

Peter Trzyna has advanced the thesis that ornamental features of new plants, developed by such techniques as mutagenesis and viral infection, are copyrightable expressions.[50.1] Precedent for such protection exists in that artificial plants and flowers have been deemed registrable.[50.2] One who cloned the gene encoding a maize enzyme for production of red pigment into a petunia could thereby obtain protection of the expression — a petunia with brick-red blossoms — but the underlying gene would not be copyrighted.

It should be evident that animal coats could also be the subject of copyright. There is no doubt that if an artist took the hide from an animal and stained it with colored patterns, that the work would be registrable. Arguably, it should make no difference that the work was obtained by genetic modification of the animal and expression of the new genotype.

(*Text continued on page 11-31*)

[50.1] Peter K. Trzyna, "Are Plants Copyrightable Under the Copyright Act?" (unpublished manuscript).

[50.2] Prestige Floral S.A. v. California Co., 201 F. Supp. 287 (S.D.N.Y. 1962).

TABLE I: *State Laws Relating to Theft of Cultures*

State Code	*Section*	*Imprisonment/Fine*
Ark. Crim. Code	§41-2201,2203	1 yr/$1,000 2-10 yrs/$10,000 3-20 yrs/$15,000
Calif. Penal Code	§499c	1 yr/$5,000
Col. Rev. Stat.	18 §4-408	6 months/$500 24 months/$5,000 2-4 yrs.
Conn. Gen. Stat. Ann.	§53a-124	6 months
Fla. Stat. Ann.	§812.081	1 yr/$1,000
Ga. Code Ann.	26 §1809	1-5 yrs 1 yr/$1,000
Ill. Ann. Stat.	38 §16-1, 15-1	1 yr/$1,000 1-3 yrs/$10,000 2-5 yrs/$10,000
Md. Ann. Code	27 §342	15 yrs/$1,000 1½ yrs/$500
Mich. Stat. Ann.	§28.643 (52)	1 yr/$1,000
Minn. Stat. Ann	§609.52	90 days/$500 5 yrs/$5,000 10 yrs/$10,000
Mont. Code Ann.	45 §6-301,2-201	6 months/$500 10 yrs
Neb. Rev. Stat.	§28-548.02	1-7 yrs/$1,000-$5,000
N.J. Stat. Ann.	2 C:20-2,20-1	1½yrs/$7,500 3-5 yrs/$7,500 5-10 yrs/$100,000
N.M. Stat. Ann	30-16-24	1-5 yrs/$5,000
N.Y. Penal Code	§165.07	4 yrs
N.C. Gen. Stat.	§14-75.1	4 yrs./$5,000
Okla. Stat. Ann.	21 §1732	30 days /$10-$100 5 yrs

is defined to include "samples, cultures, microorgamisms, specimens. . . ."[51] Maryland, which has a thriving biotechnology industry, likewise considers "samples, cultures, microorganisms, specimens" to be property.[52]

Human biological materials are, however, a different matter. Here, the law requires numerous distinctions: between donation and sale; vital and nonvital organs; regenerative and nonregenerative tissues; and inter vivos or post mortem transfers. The attempted inter vivos sale or donation of a vital organ would of course run afoul of state criminal prohibitions of suicide, and the recipient would probably be criminally liable for soliciting the supplier to commit suicide.[53] The inter vivos "sale" or donation of a regenerative bodily substance, such as blood, sperm, urine, sweat or skin, in nonvital amounts, is not prohibited by any state statute.[54] On the other hand, I am not aware of any case in which an intended recipient was allowed to enforce an executory contract for the supply of a bodily substance against the wishes of a personal supplier. The inter vivos sale or donation of a nonvital but nonregenerative organ, such as the kidney, the spleen, a parathyroid gland, an adrenal gland, or a gonad, is not unlawful per se, but in some cases may be considered "battery," a criminal offense and a civil tort.[55] In Italy, inter vivos sales and donations of most such organs are prohibited by law. According to Dukeminier, the pertinent provision was enacted in the 1930's "after a rich man bought a testis from a young Neapolitan and had it transplanted by a

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[51] 38 Ill. Ann. Stat. 15-1 (1979).

[52] 3A Maryland Code Anno., Art. 27, sec. 340(h)(10).

[53] Note, The Sale of Human Body Parts, 72 Mich. L. Rev. 1182, 1237 (1974), citing State v. Willis, 121 S.E.2d 854 (1961).

[54] Id.; Dukeminier, Supplying Organs for Transplantation, 68 Mich. L. Rev. 811, 850 (1970).

[55] The ALI Model Penal Code, Sec. 211(2)(a), makes consent to bodily harm a defense only when the harm consented to "is not serious." Section 3.08(4)(a) exempts acts intended "for the purpose of administering a recognized form of treatment which the actor believes to be adapted to promoting the physical or mental health of the patient." It has been argued that the donation of a kidney, particularly to a family member, is a physical loss but a spiritual (mental) gain. *See* Human Body Parts, 72 Mich. L. Rev. at 1237-40.

and the rights and duties of the donee and physician at death (Sec. 7). The "body parts" to which the act applies are "organs, tissues, eyes, bones, arteries, blood, other fluids and any other portions of a human body" (Sec. 1).[61] An AMA form provides for the donation of a body part for "any purpose authorized by law or transplantation or therapy or research or medical education."[62]

The UAGA itself says nothing about the sale of cadaver parts. The State of Delaware, however, expressly prohibits remuneration to UAGA donors.[63] Several other states had pre-UAGA prohibitions on payments for body parts, and the legal effect on such sales of the replacement of these provisions by those of the UAGA is unclear.[64] Brams warns against the "erroneous" impression that "because the Uniform Anatomical Gift Act authorizes gifts of organs, but is silent concerning sales of organs," such sales are unlawful in a UAGA state.[65]

Many states provide, either in their version of the UAGA, or in the implied warranty provisions of their version of the UCC, that the provision of blood (and sometimes other bodily fluids and tissues) is a service, rather than a sale, regardless of remuneration. Thus, Tennessee law provides that "human tissues [such as corneas, bones, or organs], whole blood, plasma, blood products, or blood derivatives shall not be considered commodities subject to sale or barter."[66] Some would suggest that the definition of the transfer of blood for pay as a "service" rather than as a "sale" speaks against the recognition of contractual or property rights in blood; others argue that such a provision implies that a transfer for pay (though characterized as a service) is at least lawful.

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[61] 8 U.L.A. 22 (Nat. Conf. Comr. Unif. Laws, 1968).

[62] 15 Am. Jur. Legal Forms 2d 202.104.

[63] Del. Code Ann., tit. 24, sec. 1783(f) (Supp. 1970).

[64] *See* Dukeminier, *supra* at 861-64 and Human Body Parts, *supra* at 1248 n. 446.

[65] Brams, Transplantable Human Organs: Should Their Sale Be Authorized by State Statutes, 3 Am. J. Law & Med. 187, 189 (1977). This view is perhaps reinforced by the comment of E. Blythe Stason, chairman of the UAGA drafting committee: "every payment is not necessarily unethical," quoted in Human Body Parts, *supra* at 1248.

[66] Tenn. Code Sec. 47-2-316 ("Exclusion of Modification of Warranty") (U.C.C).

conversion may arise from the use of the chattel of another.[69] Section 228 is of particular interest, because it states that "one who is authorized to make a particular use of a chattel, and uses it in a manner exceeding the authorization, is subject to liability for conversion to another whose right to control the use of the chattel is thereby seriously violated." In a Comment, we are told that

> the test is frequently whether a reasonable man, in the light of all the circumstances, would regard the use of such character that it would have been included within the agreement had the parties anticipated the occasion for such a use. The character of the chattel, its adaptability to the use made of it, and the purposes for which it is customarily used, are factors to be considered.

Suppose that the alleged conversion-by-use was the taking of a subculture from an existing culture. Suppose also that the rate of mitosis of the cells in question is such that the cells abstracted are quickly replaced by the reproductive activities of their fellows. Finally, suppose that the number of cells in the culture was limited, not by time for reproduction, but by the richness of the nutrient medium or the growing room provided. On these facts, I would suggest that under *Pearson v. Dodd* (1969), there is no conversion of the original culture.

In *Pearson v. Dodd*, newspaper columnists had come into possession of copies of certain embarrassing senatorial papers. These copies were covertly "removed from the files at night, photocopied, and returned to the files undamaged before office operations resumed in the morning." The D.C. Circuit held that insofar as the value of the documents to the senator resided in their usefulness as records of the business of his office, the senator was clearly not substantially deprived of his use of them. Moreover, since none of the papers amounted "to literary property, to scientific invention, or to secret plans

[69] Use of another's desk daily for six months, use of the desk with an assertion that the user owns it, and use of the desk in a manner which seriously damages it would all be considered conversion, though using another's desk on one occasion, without consent, to write a short letter would not be a conversion of the desk. Restatement, Sec. 227, "Illustrations."

carrying it across the property line.[71]

Presumably, reputable microbiologists do not sneak onto private property to carry off soil and water specimens. However, one may envision a few cases in which the landowner's interest is uncertain. First, suppose that the microbiologist comes onto private property, collects specimens, and departs, all without knowing that he has trespassed, albeit innocently. Second, suppose that the landlord consents to the entry of a biologist on the land to study its lifeforms, but does not expressly consent to the taking of specimens.

Where the landowner has consented to the taking of specimens, but without appreciation of their potential value, it is unlikely that any remedy is available to him.

The second situation to which I alluded is that of the transfer of biological material from a patient to a researcher. Ordinarily, this will arise in the context of a therapeutic and diagnostic procedure, and the removal of the material from the patient's body will have been necessitated by the procedure.

Conlin suggests that medical researchers who may wish to make commercial use of biological materials abstracted from patients should obtain the patient's consent to this use prior to the operation, lest there be a lack of "informed consent."[72] While this advice may be prudent to avoid an action for conversion, it is doubtful that the patient's consent to a remote commercial use of biological materials withdrawn from him must be obtained in order to avoid an action for battery.

A medical operation is an intentional touching of the person of another; such touchings, unless consented to, constitute

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[71] *See, e.g.*, State v. Mallory, 83 S.W. 955 (Ark 1904).

[72] Conlin, *supra* note 67, at B-13 through B-15.

David Conlin, regaling a seminar audience with the KG-1 cell line story, asked, "What about Homer Cohen?" Homer Cohen, as the reader may have guessed, was the unsung patient from whose tissues the KG-1 cell line was derived. Conlin was of the view that conventional "informed consent" forms were inadequate because they did not provide for an absolute transfer of property rights in excised tissues. Homer Cohen, he thought, might be the true equitable owner of the KG-1 cell line, absent such consent. 1 Biotechnology Law Report 6 (January 1982). For commentary on the industry reaction to the settlement of the KG-1 suit, *see* 1 Biotechnology Law Report 186 (December 1982).

turn give reproducing material to a third party not working under his direct supervision, who owns any materials derived from the transferred materials, who owns the patent rights in any patentable biological materials derived from the transferred materials, and so on. And these questions in turn invite others: What is direct supervision? What is a "derivative?" A number of these issues have been addressed by Kelly and Jaworski in their article, "Agreements Concerning Exchanges of Biological Materials."

Supposing that a former patient brought an action for conversion against a researcher, what defenses might be interposed? One defense might be that the abstracted biological material is not the property of the patient. Conlin argued that case and statutory law permitting the sale of blood, hair and sperm and the testamentary donation of body tissues and organs to be precedent in favor of holding that such biological materials are, in the first instance, the property of their progenitor.

I have toyed with the idea of drawing a distinction between these normal and desirable bodily constituents, and abnormal and undesirable residents of the body such as pathogenic organisms and malignant tumors. One might argue that the latter are res nullius[76]—things not owned—until they are withdrawn from the body. Just as one must exercise dominion over a wild animal by confining it in some manner in order to enjoy a protectible property interest in the animal, one should be required to exercise dominion over the pathogen or tumor in order to claim it as property. One way to exercise such dominion, of course, is to destroy the pathogen or tumor, but this course of action does not permit of much cause for future litigation over property rights. Another way is to isolate the pathogen or tumor from the body.

One problem with the res nullius defense is that a patient could argue that, in authorizing a physician to excise a tumor or take a culture of a pathogen, he is exercising dominion over this unruly biological material through the agency of the physi-

[76] Thomas, Textbook of Roman Law 166 (1976). The concept of a thing as res nullius is not limited to wild animals in a state of nature, but applies also to islands newly risen from the sea.

"slander of goods," and "trade libel." It most often arises when one party asserts that the other is guilty of patent or copyright infringement, but it clearly could arise from an injurious aspersion on a party's right to use a biological material. This cause of action is closely related to the torts of interference with a prospective commercial advantage and interference with present contractual relations.

While the discussion above focused on defenses that could be raised against a conversion action brought by a patient, it should be understood that some of these defenses, or defenses analogous to them, are applicable to conversion actions brought by landowners or researchers.

Hopefullly, the foregoing discussion should make it clear there may be many a slip twist cup and lip when a suit is brought for conversion of a patient's biological materials.

Suppose now that *B* does not merely maintain the biological material supplied by *A*, but improves it in some manner. For example, *B* may take the yeast strain isolated by *A* and subject it to a course of mutation and selection yielding an improved yeast strain. Or suppose *B* takes *A*'s biological material and combines it in some manner with his own biological material to yield some more desirable biological entity. For example, *B* may have fused *A*'s immortal cell line with *B*'s lymphocyte cell line to produce a new hybridoma cell line. Or *B* might have taken a gene from a genomic library provided by *A*, linked it to a heterologous promoter, placed it on a suitable vector, and used it to transform a suitable host. Under these circumstances, the doctrine of accession applies. Black's Law Dictionary describes "accession" as

> A principle derived from the civil law, by which the owner of property becomes entitled to all which it produces, and to all that is added or united to it, either naturally or artificially, (that is, by the labor or skill of another) even where such addition extends to a change of form or materials; and by which, on the other hand, the possessor of property becomes entitled to it, as against the original owner, where the addition made to it by his skill and labor is of greater value than the property itself, or where the change effected in its form is so great as to render it impossible to restore to its original shape.

a line of cases which have held that one who in good faith makes another's grass into hay acquires title in the hay under the doctrine of accession. The cases allude to the fact that "the value of the grass before it was cut was small," and make the observation that "the labour of defendant . . . gave to the hay substantially all its value." While the court did not say so in *Hamilton v. Rock* (1948), there is the clear implication of accession to the hay based on the labor of cutting.[81]

These cases on "accession" are significant in the biological materials context. There is little doubt that a tumor in the body of a patient is worthless. It acquires commercial value only after it is cultured, and maintained stably in culture for a period of time. Thus, it may be argued that the researcher who cultivates the tumor cells, and not the patient who contributes them, has made the principal contribution to the resultant cell culture and thereby acquires title in the culture under the doctrine of accession.

If, on the other hand, the labor of the researcher is discounted, then the only material contribution is that of the patient and the patient might retain a property interest in the propagated cell culture.

Another wrinkle on accession to cell cultures is offered by an analogy with the accession of seeds, plants or trees to land. This was considered in Roman law to be a particular case of accession. Once implanted in the soil, whatever the manner of planting, or whoever the planter, they became the property of the owner of the land.[82] It does not seem to be too fearsome a simile to say that a petri dish is to a microbe like a plot of land to a seed.

Consider the possibility of a patient arguing that his body is analogous to privately held land, and his tissues, to the crops grown on that land. Would this analogy be beneficial or harmful to his case? When crops are harvested by one wrongfully in possession of the land on which they grew, the rule as to their disposition is dependent on whether they may be characterized as fructus naturales or fructus industriales. Anciently, the former were perennials such as trees, shrubs, and grasses,

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[81] 191 P.2d 663, 668 (Mont. 1948).

[82] Thomas, *supra* at 173.

In an action to recover possession of livestock, one may recover damages for the loss of use of the livestock while they were wrongfully out of the owner's possession.[88] However, recovery for the loss of the output of an animal during a period in which it is misappropriated may be denied as speculative.[89] Recovery of the value of the loss of output will also be denied when the owner eschews recovery of the property itself and asks for its value as damages, since the value of the property can be expected to reflect its potential for generating offspring and salable metabolites.[90]

However, in a proper case, recovery for the damages stemming from the loss of the output of a converted animal can be obtained, and the same should hold true when it is merely an animal cell culture, and not a whole animal, which is converted.[91]

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[88] Drinkhouse v. Van Ness, 260 P. 869 (Cal. 1927); Maslof v. Christian, 208 N.W. 135 (Minn. 1926); Seran v. Parker, 58 P.2d 581 (Okla. 1936). A trespasser in good faith may setoff the cost of caring for the livestock. *See generally* Annotation: Livestock—Loss or Injury—Damages, 79 ALR2d 77.

Similarly, one may recover for the loss of productivity of an animal due to an injury. Bradford v. Moore Bros. Feed & Grocery, 105 So. 2d 825 (Ala. 1958) (cattle fed moldy feed); Miller v. Economy Hog and Cattle Powder Co., 293 N.W. 4 (Ia. 1940) (sheep); Ellis v. Lindmark, 225 N.W. 395 (Minn. 1929) (eggs); Jorritsma v. Farmers' Feed & Supply Co., 538 P.2d 61 (Ore. 1975) (en banc).

[89] In Daugherty v. Lady, 73 S.W. 837 (Tex. Civ. App. 1903), the court held that the value of milk and butter produced by cattle while misappropriated is too remote to be considered in determining the damages for the conversion of the cattle, following Lackey v. Campbell, 54 S.W. 46 (Tex. Civ. App. 1899). *See also* Dennen v. Charles, 12 Pa. Super. 476 (1900) (milk). *Cf.* S.A. Gerrard Co. v. Fricker, 27 P.2d 678 (Ariz. 1933) (loss of bees' honey too speculative).

[90] Madsen v. Madsen, 269 P. 132 (Utah 1928) (sheep); Martinez v. Vigil, 142 P. 920 (N.M. 1914). The special qualities of living property are pertinent to their valuation. *See* Covey v. Western Tank Lines, 218 P.2d 322 (Wash. Sup. Ct. 1950) (breeding quality of mink).

[91] In Eizen v. Hilbert, 131 N.W. 449 (Sup. Ct. Mich. 1911), the plaintiff was allowed to submit to the jury evidence that he might have made $.25 a day in eggs and chickens from the the unlawfully detained hens. In McGrath v. Wilder, 60 A. 801 (Vt. 1905), it was held that the value of the use of a heifer during a period of unlawful detention was the value of the heifer's milk less the cost of her care and keeping. *See also* Cook v. Waldrop, 133 So. 894 (milk).

> 79. Where the nature of the article is changed recourse to natural law is also required. Hence, if you make wine, oil, or grain, out of my grapes, olives, or heads of wheat, the question arises whether the said wine, oil, or grain is mine or yours. Likewise, if you manufacture a vase out of my gold or silver, or build a ship, a chest, or a bench with my lumber, or you make a garment out of my wool, or mead out of my wine and honey, or a plaster or eye-wash out of drugs belonging to me, the question arises whether what you have made out of my property is yours or mine. Certain authorities hold that the material or substance should be taken into consideration, that is to say, that the article manufactured should be deemed to be the property of him to whom the material belongs, and this opinion was adopted by Sabinus and Cassius. Others [the Proculians], however, hold that the article belongs to him who manufactured it.[95]

In determining whether the doctrine of specification is applicable, the respective uses, value, and common name of the starting material and finished product will be considered.

Taking this advice into account, specification might be applicable to the drastic improvement of a yeast strain as an antibiotic producer by mutation and selection, since one cannot recover the original strain by manipulation of the new strain. Specification might also be applicable to the conversion of an unruly tumor into a stable suspension or plate culture.

American case law on accession by specification is confusing, at best. "It has been held that there is no such change of identity as to effect a change of title, where timber has been converted into boards, charcoal, cordwood, cross ties, rails and posts, saw logs, shingles, or staves, or where grass is cut and made into hay, or cucumbers into pickles, or canvas into sails for a boat."[96]

The most learned American opinion on accession by specification appears in *Lampton's Executors v. Preston's Executor's* (1828). *Preston* had fired *Lampton's* clay into bricks. Counsel

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[95] Scott, *supra* note 78, at 120. See Bozeman Mortuary Ass'n v. Fairchild, 68 S.W.2d 756 (Ky. Ct. App. 1934), 92 ALR 419.

[96] 1 C.J.S. Accession, Sec. 5 at 418.

posed, and reduced to their elements; so of the block." Mills held that title to the bricks had passed under the doctrine of specification.

It is generally held that one who knowingly and wilfully converts a chattel cannot take any right in the property, even under the doctrine of specification, no matter how great the labor invested.[100]

Where the trespass was innocent, the trespasser may be permitted to keep the property. The courts will consider whether a change of identity has occurred (Roman specificatio)[101] or whether the trespasser made by far the greater contribution of labor or materials (Roman accessio).[102]

In the case of the intermingling of goods of different owners by mistake or accident, there is no forfeiture of interest, and each owner shares in the intermingled property as a tenant in common of the whole.[103]

We come now to the important question of remedies.[104] Unless title has passed from him under the principles of accession discussed above, the original owner has the right to recover possession of his property, however enhanced by the wrongdoer. If he exercises this right, he need not compensate the wrongdoer for the value added to the property, or even for the value of the wrongdoer's labor and materials.

The owner may also waive his right to retake the property and instead sue for damages. When title has passed to the wrongdoer by accession, of course, this is the original owner's only remedy for the wrong.

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[100] *Cf.* Baisch v. Publishers' Typographic Service, Inc., 175 A.2d 485, 486 (N.J. Super. Ct. Chancery 1961): "If a person having charge of property of another so confounds it with its own that it cannot be distinguished, he must bear all the inconvenience of the confusion."

[101] The change of identity standard is a difficult one to apply. *Compare* Lampton's Executors v. Preston's Executors, 1 J.J. Marsh (Ky.) 454 and Strubbee v. Cincinnati R. Co., 78 Ky. 481 (Ky. Ct. App. 1880) *with* Eaton v. Langley, 47 S.W. 123 (Ark. 1898) and Baker v. Wheeler, 8 Wend. 505 (N.Y. 1832).

[102] Thus, in Polks County v. Parker, 160 N.W. 320 (Ia. 1916), maps and plats owed far more to the assessor who made them than to the county which owned the blank plat book.

[103] *See, e.g.,* Intermingled Cotton Cases, 92 U.S. 651 (1876).

[104] *See generally* C.J.S., Accessions, Sec. 6.

mine."[106] I would suggest that there is an analogy between tissues in the body and coal in the mine. If this analogy is accepted, then the damages for conversion of a patient's tissues will be monetarily insignificant.

The discussion up to now has been limited to the case of "innocent trespass," *e.g.*, use of property in the mistaken belief that one has a right to its use. Where the trespass is wilful, the trespasser will be mulcted for the value of the property as enhanced, without any compensation for his own labor or materials.[107] The burden is on the wrongdoer to establish that his tortious conduct was not wilful.[108]

Yet another concern is the status of a bona fide purchaser from one who has converted biological material. If a bona fide purchaser may have better rights than his vendor, then there is some motivation for companies to deliberately make some payment for the biological materials which they receive.

When the original owner of the property elects to sue for damages, a bona fide purchaser from a wilful trespasser may setoff the labor and expense which in good faith was expended in enhancing the property. Otherwise, the purchaser stands in the shoes of the trespasser.[109]

In some jurisdictions, the doctrine of accession has been codified, not necessarily in full accordance with the rules of the common law. One such jurisdiction is California. Because California is one of the centers for research in molecular biology and kindred disciplines, it may be helpful to dissect its personal property law.

The basic statutory rule is that "the owner of a thing owns also all its products and accessions."[110] Accession may occur under California law by uniting several things:

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[106] Cited in E.E. Bolles Wooden-ware Co. v. United States, 106 U.S. 432, 433 (1883).

[107] Pine River Logging Co. v. United States, 186 U.S. 279 (1902); E.E. Bolles Wooden-ware Co. v. United States, *supra*. But even in this situation, lesser measures of damage have been employed. Moode v. Whitney, 38 Me. 174 (1856); Clay v. Palmer, 177 N.W. 840 (Neb. 1920).

[108] Powers v. Tilley, 32 A. 714 (Me. 1894).

[109] Am. Jur. 2d, Accession and Confusion, Sec. 31. Note that the enhancements made by the purchaser may be such as to pass title to the latter.

[110] Cal. Civ. Code, Sec. 732.

> Where one has made use of materials which in part belong to him and in part to another, in order to form a thing of a new description, without having destroyed any of the materials, but in such way that they cannot be separated without inconvenience, the thing form is common to both proprietors, in proportion, as respects the one, of the materials belonging to him, and as respects the other, of the materials belonging to him and the price of his workmanship.
>
> When a thing has been formed by the admixture of several materials of different owners, and neither can be considered the principal substance, an owner without whose consent the admixture was made may require a separation, if the materials can be separated without inconvenience. It they cannot be thus separated, the owners acquire the thing in common, in proportion to the quantity, quality and value of their materials, but if the materials of one were far superior to those of the others, both in quantity and value, he may claim the thing on reimbursing to the others the value of their materials.[114]

California follows the general rule that an intentional trespasser cannot accede to property.[115] It also has codified the rule that the owner of property has the option of suing either for restitution of his material (or, if he is entitled to it, the product made from his material) or for damages for the value of his property.[116]

It may be helpful now to put some flesh on the bones of our theoretical discussion by examining some actual cases. Unfortunately, none of the cases which follow have reached the stage of trial and formal decision, still, they give a flavor of the kind of disputes which can arise.

In *Hoffman La-Roche v. Golde, Golde* asserted a counterclaim for conversion. *Golde* alleged that he and his fellow counterclaimants were owners of the cell lines KG-1 and KG-1A, and had conveyed cultures of the cell lines, under an understanding that they were to be used solely for cancer research in collaboration with counterclaimants, to Dr. Robert Gallo of NCI. These cell lines came into the hands of a Hoffman

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[114] Cal.. Civ. Code, Secs. 1029, 1030.
[115] Cal. Civ. Code, Sec. 1031.
[116] Cal. Civ. Code, Secs. 1032, 1033.

cancer cells. Learning of Royston's project, Hagiwara suggested the use of lymph cells from his mother, who was suffering from cervical cancer. On January 19, 1981, the Hagiwara cells were fused to a stable, immortal, lymphoblastoid cell line developed by Royston and known as UC 729-6. By February 24, UCSD scientists had confirmed that the resulting hybridomas, CLNH11 and CLNH5, were in fact secreting anti-tumor antibodies. In June, Hagiwara, without permission, took subcultures of the hybridoma cell lines with him to Japan and gave them to the Hagiwara Institute of Health, directed by his father. UCSD sent the Hagiwaras a letter agreement, which they executed on July 7, 1982, which read as follows:

> I will be pleased to permit your use of these materials within your nonprofit research institution laboratory for cooperative scientific research. However, before forwarding them to you, I would like your agreement that the materials will be received by you only for use in scientific research, that you will bear all risk resulting from your use, and that you will not pass on these materials, their progeny or derivatives, on to any other party or use them for commercial purposes without the express written consent of The Regents of the University of California. You understand that no other right or license to these materials, their progeny or derivatives, is granted or implied as a result of our transmission of these materials to you.

On November 16, 1982, counsel for the Hagiwaras asserted rights to the human hybridoma cell line and antibody. Apparently, their legal position was that they had tangible personal property rights in the lymphatic tissue they had provided and were therefore entitled to an interest in the derivative cell line. By April, 1983, an agreement with UCSD was reached, under which UCSD retained all patent rights and the Hagiwaras received an exclusive license for Japan and Asia.[121]

More recently, a leukemia patient, John Moore, filed a lawsuit alleging that his "blood and bodily substances" had been converted when Drs. Golde and Quan withdrew them, allegedly in order to provide guidance for his medical treatment, and retained them, supposedly in the name of scientific

[121] 2 Biotechnology Law Report 43 (March-April 1983).

material. In a licensing situation, it may well be appropriate for the licensor to ask the licensee for a "hold harmless" clause to immunize it from an action for conversion.

Corporate counsel and officers should also check on the protection afforded by the company's insurance coverage. If the claim is sizeable, and outside the scope of the company's policies, the financial consequences could be quite serious.

Requests by company scientists for biological materials must also be monitored. Requests of the kind appearing below would help insulate the company from liability to university researchers:

> Dear Dr. X: We much admired your article on Y. We wondered if we might obtain a small sample of Y for our use. We will be happy to acknowledge your contribution in any publication discussing the use of your material. We will respect any patent rights that you may lawfully assert in the material, and we trust that you will give us the opportunity to take a license under such patent rights. We accept this material, however, under the understanding that your rights to control our use of this material are limited to those provided by the patent laws.

The foregoing provision owes its inspiration to the "unsolicited idea submission agreements" that are used in many industries. Note, however, that since your company wants the biological material in question, it may find that it needs to offer less one-sided terms.

Every coin has two sides. Sometimes, your company researchers will be asked to provide biological materials to others. This outflow of potentially valuable property cannot be stemmed entirely, lest outside researchers become unwilling to provide biological materials to your researchers. It must, however, be monitored and controlled.

Recognizing that the increased commercial value of biological materials was fraying many an unwritten understanding, Patrick Kelly and Ernest Jaworski of Monsanto's Biological Science Group prepared a set of three agreements for use in connection with the release of biological materials. The first was a mere letter of transmittal, for use when the supplier did not wish to maintain a proprietary interest. The purpose of this

a viability problem crops up after that employee has left the company.

The notion that there may be separately transferrable tangible and intangible property rights in biological materials may still create a feeling of uneasiness of some. Think, however, of a painting. The copyright act specifically recognizes that one may sell the painted canvas without relinquishing ones copyright in the depiction, or convey the right to copy the painted image without yielding custody of the canvas itself.[125] If consideration is given to the tangible property rights in biological materials before such materials are accepted, utilized or disseminated, biotechnology companies will have little to fear. Moreover, it should be apparent that patients cannot ask for the moon and expect to get it; the doctrine of accession, the prevailing measure of damages in innocent conversion cases, and the res nullius and *Pearson v. Dodd* defenses all can be used to the advantage of a defendant recipient.

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[125] 17 U.S.C. §202.

APPENDIX 1

U.S Utility Patent Materials

App.1.01 Excerpts from the Manual of Patent Examining Procedure

[1] MPEP § 608.01(p) [Deposit of Microorganisms]

Some inventions which are the subject of patent applications depend on the use of microorganisms which must be described in the specification in accordance with 35 U.S.C. 112. No problem exists when the microorganisms used are known and readily available to the public. When the invention depends on the use of a microorganism which is not so known and readily available, applicants must take additional steps to comply with the requirements of § 112.

In re Argoudelis, et al., 168 U.S.P.Q. 99 (CCPA 1970), accepted a procedure for meeting the requirements of 35 U.S.C. 112. Accord-

13bis.3 References: Contents; Failure To Include Reference or Indication

(a) A reference to a deposited microorganism shall indicate,

(i) The name and address of the depositary institution with which the deposit was made;
(ii) The date of deposit of the microorganism with that institution;
(iii) The accession number given to the deposit by that institution; and
(iv) Any additional matter of which the International Bureau has been notified pursuant to Rule 13*bis*.7(a)(1), provided that the requirement to indicate that matter was published in the Gazette in accordance with Rule 13*bis*.7(c) at least two months before the filing of the International application.

(b) Failure to include a reference to a deposited microorganism or failure to include, in a reference to a deposited microorganism, an indication in accordance with paragraph (a), shall have no consequence in any designated State whose national law does not require such reference or such indication in a national application.

13bis.4 References: Time of Furnishing Indications

If any of the indications referred to in Rule 13*bis*.3(a) is not included in a reference to a deposited microorganism in the international application as filed but is furnished by the applicant to the International Bureau within sixteen months after the priority date, the indication shall be considered by any designated Office to have been furnished in time unless its national law requires the indication to be furnished at an earlier time in the case of a national application and the International Bureau has been notified of such requirement pursuant to Rule 13*bis*.7(ii), provided that the International Bureau has published such requirement in the Gazette in accordance with Rule 13*bis*.7(c) at least two months before the filing of the international application. In the event that the applicant makes a request for early publication under Article 21(2)(b), however, any designated Office may consider any indication not furnished by the time such request is made as not having been furnished in time. Irrespective of whether the applicable time limit under the preceding sentences has been observed, the International Bureau shall notify the applicant and the designated Offices of the date on which it has received any indication not included in the international application as filed. The Interna-

national law applicable for any designated Office as soon as, under that law, the international publication has the effects of the compulsory national publication of an unexamined national application.

13bis.7 National Requirements: Notification and Publication

(a) Any national Office may notify the International Bureau of any requirement of the national law,

(i) That any matter specified in the notification, in addition to those referred to in Rule 13*bis*.3(a)(i), (ii) and (iii), is required to be included in a reference to a deposited microorganism in a national application;

(ii) That one or more of the indications referred to in Rule 13*bis*. 3(a) are required to be included in a national application as filed or are required to be furnished at a time specified in the notification which is earlier than sixteen months after the priority date.

(b) Each national Office shall notify the International Bureau a first time before entry into force of this Rule and then each time a change occurs of the depositary institutions with which the national law permits deposits of microorganisms to be made for the purposes of patent procedure before that Office or, if the national law does not provide for or permit such deposits, of that fact.

(c) The International Bureau shall promptly publish in the Gazette requirements notified to it under paragraph (a) and information notified to it under paragraph (b).

(PCT Rule 13*bis* became effective on January 1, 1981.)

[3] MPEP § 2105 [Patentable Subject Matter—Microorganisms][R-3]

The decision of the Supreme Court in *Diamond v. Chakrabarty*, 206 U.S.P.Q. 193 (1980) held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. § 101. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

iwork, but his own; accordingly it is patentable subject matter under § 101."

A review of the Court statements above as well as the whole Chakrabarty opinion reveals:

(1) That the Court did not limit its decision to genetically engineered living organisms,
(2) The Court enunciated a very broad interpretation of "manufacture" and "composition of matter" in Section 101 (Note esp. quotes 1, 2, and 3 above),
(3) The Court set forth several tests for weighing whether patentable subject matter under Section 101 is present stating (in Quote 7 above) that: "The relevant distinction was not between living and inanimate things but between products of nature, whether living or not, and human-made inventions."

The tests set forth by the court are (note especially the italicized portions):

(1) The laws of nature, physical phenomena and abstract ideas are not patentable subject matter
(2) A nonnaturally occurring manufacture or composition of matter—a product of human ingenuity—*having a distinctive name, character, [and] use,"* is patentable subject matter
(3) A new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."
(4) However, the production of articles for use from raw materials prepared by giving to these materials *new forms, qualities, properties or combinations whether by hand, labor or machinery* (emphasis added) is a manufacture under Section 101.

In analyzing the history of the Plant Patent Act of 1930, the Court stated: "In enacting the Plant Patent Act, Congress addressed both of these concerns [the belief that plants, even those artificially bred, were products of nature for purposes of the patent law . . . were thought not amendable to the written description]. It explained at length its belief that the work of the plant breeder 'in aid of nature' was patentable invention. S. Rep. No. 315, 71st Cong. 2d Sess. 6-8 (1930); H.R. Rep. No. 1129, 71st Cong. 2d Sess. 7-9 (1930)."

14 . Involving glucose or galactose
15 . Involving transferase
16 . . Involving transaminase
17 . . Involving creatine phosphokinase
18 . Involving hydrolase
19 . . Involving esterase
20 . . . Involving cholinesterase
21 . . . Involving phosphatase
22 . . Involving amylase
23 . . Involving proteinase
24 . . Involving peptidase
25 . Involving oxidoreductase
26 . . Involving dehydrogenase
27 . . Involving catalase
28 . . Involving peroxidase
29 . Involving viable microorganism
30 . . Methods of sampling, or innoculating or spreading a sample; methods of physically isolating an intact microorganism
31 . . Testing for sterility condition
32 . . Testing for antimicrobial activity of a material
33 . . . Using multifield media
34 . . Determining presence or kind of microorganism; use of selective media
35 . . . Using radioactive material
36 . . . Streptococcus; Staphylococcus
37 . . . Nitrate to nitrite reducing bacteria
38 . . . Enteriobacteria
39 . . . Quantitative determination
40 . . . . Using multifield media
41 MICROORGANISM, TISSUE CELL CULTURE OR ENZYME USING PROCESS TO SYNTHESIZE A DESIRED CHEMICAL COMPOUND OR COMPOSITION
42 . Process involving microorganisms of different genera in the same process, simultaneously
43 . Preparing compound having a 1-thia-4-aza-bicyclo (3.2.0) heptane ring system, *e.g.*, penicillin, etc.
44 . . By desacylation of the substituent in 6-position
45 . . By acylation of the substituent in 6-position
46 . . In presence of phenyl acetic acid or phenyl acetamide or their derivatives
47 . Preparing compound having a 1-thia-5-aza-bicyclo (4.2.0) octane ring system, e.g., cephalosporin, etc.

through only acyclic carbon atoms to a nonsaccharide heterocyclic ring, *e.g.*, bleomycin, phleomycin, etc.

78 . . . Oxygen atom of the saccharide radical is directly bonded to a condensed ring system having three or more carboxyclic rings, *e.g.*, dauomycin, adriamycin, etc.

79 . . . Oxygen atom of the saccharide radical is bonded to a cyclohexyl radical, e.g., kasugamycin, etc.

80 . . . . Cyclohexyl radical is substituted by two or more nitrogen atoms, *e.g.*, destomycin, neamin, etc.

MICROORGANISM, TISSUE CELL CULTURE OR ENZYME USING PROCESS TO SYNTHESIZE A DESIRED CHEMICAL COMPOUND OR COMPOSITION

. Preparing compound containing saccharide radical

. . Preparing O-glycoside, *e.g.*, glucosides, etc.

. . . Oxygen atom of the saccharide radical is bonded to a cyclohexyl radical, *e.g.*, kasugamycin, etc.

. . . . Cyclohexyl radical is substituted by two or more nitrogen atoms, *e.g.*, destomycin, neamin, etc.

81 . . . . . Cyclohexyl radical is attached directly to a nitrogen atom of two or more N-C(=N)-N radicals, *e.g.*, streptomycin, etc.

82 . . . . . Having two saccharide radicals bonded through only oxygen to adjacent ring carbons of the cyclohexyl radical, *e.g.*, ambutyrosin, ribostamycin, etc.

83 . . . . . Containing three or more saccharide radicals, *e.g.*, liquidomycin, neomycin, lividomycin, etc.

84 . . Preparing nitrogen-containing saccharide

85 . . . N-glycoside

86 . . . . Cobalamin, *i.e.*, vitamin B12, LLD factor

87 . . . . Nucleoside

88 . . . . . Having a fused ring containing a six-membered ring having two N-atoms in the same ring, *e.g.*, purine nucleosides, etc.

89 . . . . Nucleotide

90 . . . . . Dinucleotide, *e.g.*, NAD, etc.

91 . . . . . Polynucleotide, *e.g.*, nucleic acid oligoribonucleotides, etc.

92 . . . . . Having a fused ring containing a six-membered ring having two N-atoms in the same ring, *e.g.*, purine based mononucleotides, etc.

93 . . Mashing or wort making

94 . . Produced by the action of an isomerase, *e.g.*, fructose by the action of xylose isomerase on glucose, etc.

123 . . Oxygen as only ring hetero atom
124 . . . Containing a hetero ring of at least seven ring members, *e.g.*, zearalenone, macrocyclic lactones, etc.
125 . . . Containing six-membered hetero ring, *e.g.*, fluorescein, etc.
126 . . . Containing five-membered hetero ring, *e.g.*, griseofulvin, etc.
127 . Preparing compound containing at least three carbocyclic rings
128 . Preparing nitrogen-containing organic compound
129 . . Amide, *e.g.*, chloramphenicol, etc.
130 . Preparing sulfur-containing organic compound
131 . Preparing organic compound containing a metal or atom other than H, N, C, O, or halogen
132 . Preparing oxygen-containing organic compound
133 . . Containing quinone nucleus, *i.e.*, quinoid structure
134 . . Fat; fatty oil; ester-type wax; higher fatty acid, *i.e.*, having at least seven carbon atoms in an unbroken chain bound to a carboxyl group; oxidized oil or fat
135 . . Carboxylic acid ester
136 . . Containing a carboxyl group
137 . . . Sugar acid having five or more carbon atoms, *i.e.*, aldonic, keto-aldonic, or saccharic acid
138 . . . . Alpha-ketogulonic acid, *i.e.*, 2-ketogulonic acid
139 . . . Lactic acid
140 . . . Acetic acid
141 . . . Propionic or butyric acid
142 . . . Polycarboxylic acid
143 . . . . Having keto group, *e.g.*, alpha-ketoglutaric acid, etc.

MICROORGANISM, TISSUE CELL CULTURE OR ENZYME USING PROCESS TO SYNTHESIZE A DESIRED CHEMICAL COMPOUND OR COMPOSITION

. Preparing oxygen-containing organic compound
. . Containing a carboxyl group
. . . Polycarboxylic acid
144 . . . . Tricarboxylic acid, *e.g.*, citric acid, etc.
145 . . . . Dicarboxylic acid having four or less carbon atoms, *e.g.*, fumaric, maleic, etc.
146 . . . Hydroxy carboxylic acid
147 . . Containing carbonyl group
148 . . . Ketone
149 . . . . Cyclopentanone or cyclopentadione containing compound

180 . . Carrier is synthetic polymer
181 . . . Attached to the carrier via a bridging agent
182 . . . Enzyme or microbial cell is entrapped within the carrier, *e.g.*, gel, hollow fibre
183 ENZYME, *E.G.*, LIGASES (6.), ETC., PROENZYME; COMPOSITIONS THEREOF; PROCESS FOR PREPARING, ACTIVATING, INHIBITING, SEPARATING, OR PURIFYING ENZYMES
184 . Enzyme inactivation by chemical treatment
185 . Malt
186 . Pancreatin
187 . Preparing granular- or free-flowing enzyme composition
188 . Stabilizing an enzyme by forming a mixture, an adduct or a composition or formation of an adduct or enzyme conjugate
189 . Oxidoreductase (1.), *e.g.*, luciferase
190 . . Acting on CHOH group as donor, *e.g.*, glucose oxidase, lactate dehydrogenase (1.1)
191 . . Acting on nitrogen-containing compound as donor (1.2, 1.5, 1.7)
192 . . Acting on hydrogen peroxide as acceptor (1.11)
193 . Transferase other than ribonuclease (2.)
194 . . Transferring phosphorus containing group, *e.g.*, kineases, etc. (2.7)
195 . Hydrolase (3.)
196 . . Acting on ester bond (3.1)
197 . . . Carboxylic ester hydrolase (3.1.1)
198 . . . . Triglyceride splitting, *e.g.*, lipase, etc. (3.1.1.3)
199 . . . Ribonuclease (3.1.4)
200 . . Acting on glycosyl compound (3.2)
201 . . . Acting on alpha-1, 4-glucosidic bond, *e.g.*, hyaluronidase, invertase, amylase, etc. (some 3.2.1)
202 . . . . Alpha-amylase, microbial source
203 . . . . . Fungal source
204 . . . . Alpha-amylase, plant source (3.2.1.1)
205 . . . . Glucoamylase (3.2.1.3)
206 . . . Acting on beta-1, 4 link between N-acetylmuramic acid and 2-acetylamino 2-deoxy-D-glucose, *e.g.*, lysozyme, etc.
207 . . . Acting on beta-galatose-glycoside bond, *e.g.*, beta-galactosidase, etc.
208 . . . Acting on alpha-galatose-glycoside bond, *e.g.*, alpha-galactosidase, etc.

240.1 ANIMAL OR PLANT CELL, *E.G.*, CELL LINES, TISSUES; CULTIVATION OR MAINTENANCE THEREOF; MEDIA THEREFORE
240.2 . Animal cells, per se, culture techniques and media
240.21 . . Techniques of establishing a primary culture
240.22 . . Culture of encapsulated cells
240.23 . . Culture of cells on solid support, *e.g.*, anchorage dependent cells
240.24 . . . Support is suspendable particle
240.241 . . . Culture of cells on membrane
240.242 . . . . Hollow fibre membrane
240.243 . . . Solid support treated or coated to enhance attachment or growth
240.25 . . Culture in suspension
240.26 . . Fused or hybrid cells
240.27 . . . Ab or Ig fragments producing cells
240.3 . . Culture medium, per se
240.31 . . . Defined medium
240.4 . Plant cells, per se, culture techniques and media
240.45 . . Culture techniques, *e.g.*, meristem culture, etc.
240.46 . . . Culture in suspension
240.47 . . . . Protoplasts
240.48 . . . Callus culture
240.49 . . . . Regeneration (includes nonflowering ornamentals)
240.5 . . . . . Agronomic crops, *e.g.*, tobacco, grains, etc.
240.51 . . . . . Fruit and vegetable crops, *e.g.*, tomato, etc.
240.54 . . Culture medium, per se, or regeneration medium, per se
242 SPORE FORMING OR ISOLATING PROCESS
243 MICROORGANISM PER SE, *E.G.*, PROTOZOA, ETC.; COMPOSITIONS THEREOF; PROCESS OF PROPAGATING, MAINTAINING OR PRESERVING MICROORGANISMS OR COMPOSITIONS THEREOF; PROCESS OF PREPARING OR ISOLATING A COMPOSITION CONTAINING A MICROORGANISM; CULTURE MEDIA THEREFOR
244 . Chemical stimulation of growth or activity by addition of chemical compound which is not an essential growth factor; stimulation of growth by removal of a chemical compound
245 . Adaptation or attenuation of cells
246 . Foam culture
247 . Utilizing media containing lower alkanol, *i.e.*, having one to six carbon atoms
248 . Utilizing media containing hydrocarbon

284 TISSUE, ANIMAL OR PLANT CELL, OR VIRUS CULTURE APPARATUS
285 . With means providing thin layers
286 . With means providing suspensions
287 APPARATUS
288 . For use of free or immobilized enzyme
289 . Including condition or time responsive control
290 . . Temperature responsive control
291 . Including measuring or testing with condition sensing or measuring means
292 . Innoculator streaker or sampler
293 . . Multifield or continuous
294 . . Sampler or innoculator is part of container
295 . . . Sampler or innoculator is swab
296 . Tube or bottle
297 . Petri dish
298 . . Including cover seal
299 . Containing or adapted to contain solid media
300 . . Multiple field or compartment
301 . . . Horizontal, planar field
302 . Malting or mashing apparatus
303 . . Rotary drum
304 . . Cascade or vertically spaced stages
305 . . With agitator or mash turner
306 . . . With horizontal axis of rotation
307 . . . With vertical axis of rotation
308 . . . . Rakes
309 . . With multilevel gas introduction means
310 . With means providing thin layer or with multilevel trays
311 . With sterilizer or filtration means
312 . Rotatably mounted
313 . With gas introduction means
314 . . With draft tube
315 . . With agitator
316 . With agitator or heat exchanger
317.1 MISCELLANEOUS

CROSS-REFERENCE ART COLLECTIONS

800 ELIMINATION OR REDUCTION OF CONTAMINATION BY UNDESIRED FERMENTS, *E.G.*, ASEPTIC CULTIVATION
801 ANEROBIC CULTIVATION

840 . . Brevibacterium
841 . . Chainia
842 . . Clostridium
843 . . Corynebacterium
844 . . . Corynebacterium diphtheriae
845 . . . Corynebacterium poinsettiae
846 . . . Corynebacterium pyogenes
847 . . Erwinia
848 . . Escherichia
849 . . . Escherichia coli
850 . . Flavobacterium
851 . . Haemophilus
852 . . Klebsiella
853 . . Lactobacillus
854 . . . Lactobacillus acidophilus
855 . . . Lactobacillus brevis
856 . . . Lactobacillus casei
857 . . . Lactobacillus plantarum
858 . . Methylomonas
859 . . Micrococcus
860 . . . Micrococcus flavus
861 . . . Micrococcus glutamicus
862 . . . Micrococcus lysodeikticus
863 . . . Mycobacterium
864 . . . Mycobacterium avium
865 . . . Mycobacterium fortuitum
866 . . . Mycobacterium smegmatis
867 . . Micromonospora
868 . . . Micromonospora chalcea
869 . . . Micromonospora purpurea
870 . . Mycoplasma
871 . . Neisseria
872 . . Nocardia
873 . . Proteus
874 . . Pseudomonas
875 . . . Pseudomonas aeruginosa
876 . . . Pseudomonas fluorescens
877 . . . Pseudomonas putida
878 . . Rhizobium
879 . . Salmonella
880 . . Serratia
881 . . . Serratia marcescens
882 . . Staphylococcus

923 . . . Candida lipolytica
924 . . . Candida tropicalis
925 . . Cephalosporium
926 . . . Cephalosporium acremonium
927 . . . Cephalosporium caerulens
928 . . . Cephalosporium crotocinigenium
929 . . Fusarium
930 . . Hansenula
931 . . Mucor
932 . . Paecilomyces
933 . . Penicillium
934 . . . Penicillium brevi
935 . . . Penicillium chrysogenum
936 . . . Penicillium notatium
937 . . . Penicillium patulum
938 . . Pichia
939 . . Rhizopus
940 . . Saccharomyces
941 . . . Saccharomyces carlsbergensis
942 . . . Saccharomyces cerevisiae
943 . . . Saccharomyces lactis
944 . . Torulopsis
945 . . Trichoderma
946 . Using algae
947 . Using protozoa
948 . Using viruses or cell lines

[2] Classification Definitions for Class 435*

I. Statement of Class Subject Matter

This class provides for the following subject matter when *not provided for elsewhere:*

A. A process of using a microorganism or enzyme to synthesize a chemical product.

B. A process of treating a material with a microorganism or enzyme to separate, liberate, or purify a preexisting substance.

C. An in vitro process of measuring and testing in which:
(1) A microorganism or enzyme is used to determine

* U.S. Patent & Trademark Office, Documentation Organizations, July 1979.

(3) An enzyme is identified by its catalytic activity.
(4) The presence of microorganisms is detected.
(5) A live microorganism is used in an antigen antibody test as an antigen.

D. A process of propagating a microorganism.

E. A process in which the genetic structure of a microorganism or extrachromosomal genetic structure is altered.

F. A process of organ or tissue maintenance.

G. A process of mashing or malting.

H. Apparatus claimed or solely disclosed as for A-G.

I. Microorganisms per se or the subcellular parts thereof.

J. Enzymes, immobilized enzymes or enzyme containing compositions not otherwise provided for and the processes for purifying enzymes or forming immobilized enzymes.

K. Compositions claimed or solely disclosed as for the propagation of microorganisms or for measuring and testing processes in C above.

II. Classification Lines With Other Classes

A. Lines with classes providing for the use of a microorganism, an enzyme and the apparatus therefor and the composition classes providing for the products of a microorganism or enzyme.

Class 8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, provides for processes of (a) dyeing employing a microorganism or enzyme (b) treating hides or skins by use of a microorganism or enzyme with subsequent tanning of the hides or skins or subsequent operations that are preliminary and peculiar to tanning of hides or skins or peculiar to making leather.

Class 435 provides for a process of using an enzyme or microorganism to treat a hide or skin particularly depilating or bating as well as treating feathers or animal tissue with a microorganism or enzyme not otherwise provided for.

Class 23, Chemistry, Analytical and Physical Processes,

Class 48, Gas, Heating and Illuminating, for fuel gas compositions when the processes of making such compositions involve a microorganism; processes of producing fuel gas compositions that include a microorganism; articles, compositions, or apparatus, for uses in such processes; or processes of making such articles or compositions for such uses.

Class 435 provides for the production or purification of a gas by the use of microorganisms or enzymes if such process is not ancillary to the production of fertilizer or a Class 210 liquid purification by living organisms or directed to the production of a fuel gas by living organisms.

Class 62, Refrigeration, for processes or apparatus for preserving an organ, microorganism, or enzyme by the removal of heat and the cooled or frozen product resulting. The process may involve the use of a composition to eliminate or minimize cooling or freezing damage, *e.g.*, sperm preservation, etc.

Class 435 provides for methods and apparatus of maintaining the viability of an animal organ tissue including blood and sperm or cell as well as the process and apparatus for the treatment of propagation of animal cells or tissue.

Class 71, Chemistry, Fertilizers, provides for processes of producing a composition or article having utility as a fertilizer; plant stimulating or eradicating by use of a microorganism or enzyme as well as the composition containing a microorganism or enzyme and the apparatus used to carry out the process.

Class 435 provides for the production of microorganisms having utility for fertilizer production and microorganism containing starter compositions useful in a Class 71 process.

Class 75, Metallurgy, provides for processes and compositions containing a microorganism or enzyme for use in

diseases of the bodies of men and animals which apparatus is provided with means for connection to the living body.

Class 435 provides for the maintenance of blood or sperm and viable tissue and virus cultures and the media for such processes.

Class 131, Tobacco, for tobacco-containing articles, or compositions, or articles or compositions when tobacco is used in the making thereof, when the processes of making such articles or compositions involve the use of a microorganism or enzyme; processes of making such articles or compositions, or treating tobacco, that include the use of a microorganism or enzyme; or articles, compositions, or apparatus, for uses in such processes, or processes of making the latter articles or compositions for uses in the above noted processes.

Class 435 provides for processes of growing a microorganism or using an enzyme the media for which may comprise plant material.

Class 162, Paper Making and Fiber Liberation, provides for processes and apparatus which includes use of a microorganism or enzyme when combined with a step peculiar to Class 162 as well as the use of a microorganism or enzyme as a component of a paper or fiber pulp.

Class 435 provides for fiber paper pulping and textile treatment by a microorganism or enzyme per se. For an exhaustive listing of fiber treatment classes, see the notes immediately following the class definition of Class 162.

Class 166, Wells, provides for processes and apparatus for treating oil or an oil bearing mineral with a microorganism or enzyme while in the ground.

Class 204, Chemistry, Electrical and Wave Energy, provides for processes and apparatus involving electrical or wave energy. Class 204 provides for processes of measuring and testing in which the activity of a microorganism

enzyme are controlling for classification over other processes of making chemical compounds.

Class 435 provides for a process of synthesis or liberation, separation, or purification of a compound utilizing a microorganism or enzyme per se.

Class 435 provides for an enzyme per se and the process of recovering the enzyme from a natural source or immobilizing or insolubilizing an enzyme.

Class 435 provides for a process utilizing a microorganism or enzyme combined with a physical separation or purification.

Class 435 will provide for preliminary chemical treatment to produce a starting material which is subjected to the action of a microorganism or enzyme or a chemical reaction simultaneously with or subsequent to the action of a microorganism or enzyme which perfects or improves the action of the microorganism or enzyme.

Class 424, Drug, Bio-Affecting and Body Treating Compositions, for a process of treating the living body with a microorganism or enzyme and the compositions therefor which may contain a live microorganism, co-enzyme, or enzyme. Class 424 provides for antigen-antibody diagnostic tests of a live microorganism is not involved in the process as well as for antigen antibody compositions. Class 424 provides for the products of microorganism and enzymes which are drug or bio-affecting compositions under section I A and C. of the Class 424 definition and methods of purification of such products. See especially subclass 3 for a composition useful for animal tissue histology; subclasses 85+ for an antibody or interferon composition; subclasses 88+ for an antigen composition; subclasses 86 and 87 for a method of inducing immunity using virus or bacteria; subclass 93 for a composition including whole live microorganism or virus; and subclass 94 for a composition containing an enzyme or co-enzyme.

Class 435 provides for a process of propagating a mi-

elaboration of the line regarding the placement of yeast patents, see (1) Note in subclass 255 of this class.

Class 429, Chemistry, Electrical Current Producing Apparatus, Product and Process, provides for a current producing device having a microorganism as an integral part and the process of operating the device and a process involving the device.

Class 435 provides for processes of producing microorganisms in bulk, i.e., propagation of microorganisms.

Class 435, Chemistry: Molecular Biology and Microbiology, provides for a photo imaging process in which an enzyme whose activity is altered upon exposure to light is used and the material therefor.

B. Lines With Related Classes

Class 8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, provides for compositions for dyeing materials of any kind which may contain a microorganism or enzyme.

Class 15, Brushing, Scrubbing and General Cleaning, provides for dust cloths, mops, or other cleaning devices which include detergents which may contain enzymes.

Class 23, Chemistry, Analytical and Physical Processes, provides for testing compositions.

(a) which contain an enzyme if the enzyme participates in a chemical reaction in a noncatalytic manner,

(b) which are of use in an antigen-antibody test and do not involve a microorganism or enzyme and are not diagnostic.

(1) **Note.** The burden of showing an enzyme is functioning noncatalytically is on Class 23, *i.e.*, the presumption, as between Class 435 and Class 23, is that

Class 435 provides for apparatus claimed or solely disclosed as used for propagating a microorganism or for use of an enzyme.

Class 137, Fluid Handling, is the residual place for processes, systems, combinations, and subcombinations for fluid material handling. Part III of the headnotes of Class 137 provide a guide to the automatic control provided for therein.

Class 435 will provide for condition responsive control of a process with a step of microbial growth or enzymology and for condition responsive control apparatus when claimed or solely disclosed as involving a microorganism or enzyme.

Class 159, Concentrating Evaporators, provides for the concentration of solids held in solution or suspension by evaporation of liquid and the recovery of a concentrate or a dry solid which includes the treatment of a feed stream to or the treatment of a product of a microorganism or enzyme.

Class 435 is superior to Class 159 and will provide for the concentration of a solid by the evaporation of liquid when combined with process or apparatus involving a microorganism or enzyme.

Class 241, Solid Material Comminution or Disintegration, provides for processes and apparatus for the comminution or disintegration of solids which includes the comminution of the feed material to or the product of a microorganism or enzyme.

Class 435 provides for the combination of comminution or disintegration with a process or apparatus for microorganism use or enzymology.

Class 250, Radiant Energy, provides for all methods and apparatus for using, generating, controlling, or detecting radiant energy including radioactivity not elsewhere provided for. Class 250 provides a comprehensive guide

Class	Section	Subclass
3		1, 284
8	II A, B	29, 263, 264, 265, 270, 277
15	II B	
19		263, 279
23	II A, B	4, 289
34	II B	1, 262
47	II A	254, 257, 287
48	II A, B	167
53		287
55		262, 266
62	II A	1, 2, 262, 283
65		174
71	II A	167, 243, 265, 270, 287
73	II B	4, 13, 262, 287, 289, 291
75	II A	168, 282
99	II B	287
106	II A	68, 174
127	II A	72, 262, 275
128	II A	2, 4, 283, 287
131	II A	
134		264, 270
137	II B	4, 266, 289, 291
156		174
159	II B	262
162	II A	226, 263, 277
166		281
196		281, 289, 291
201		262
203		262, 266
204	II A	4, 262, 281, 289, 291
206		287, 294, 298
208		4, 262, 281
210	II A	167, 174, 262,

Derivative—For purposes of this class derivatives included with the production of a named compound are *only* the inorganic anion or inorganic cation salts thereof, *e.g.*, metal, ammonium, halogen, carbonate, etc.

Diastace—For purposes of this class classified as an amylase.

Fermentation—The use of a microorganism or enzyme to carry a molecular transformation.

Hetero—Containing only O, N, S, Se, or Te in addition to carbon in a ring.

Media—Material which supports or sustains growth of microorganisms which material may contain substances which will not support or may inhibit the growth of selected microorganisms.

Microorganism—For purposes of this class, bacteria, actinomycetales, cyanobacteria (unicellular algae), fungi, protozoa, animal cells or plant cell or virus.

Nucleic Acid—A polynucleotide or more than two nucleotides.

Test Media—Distinguished from (propagation) media by the presence of an indicator, *e.g.*, chromophore, etc.

VI. Classification Guidelines for This Class

Apparatus—This class takes only apparatus claimed or solely disclosed as for fermentation or enzymology, organ, and tissue maintenance or genetic engineering not otherwise provided for. Apparatus by name only which is claimed as a collection of compounds or compositions in a kit without structure is classified on the basis of the compositions into the subclasses 4+ area.

Compositions—In general, this class will not provide for compositions other than an immobilized or insolubilized enzyme or a test or culture media.

Compounds—In general, this class does not provide for com-

(4) **Note.** Processes of continuously perfusing a functioning excised cell, tissue, or organ with a fluid, *e.g.*, blood, blood components, or blood substitutes to extract and subsequently isolate desired constituents from said perfusing fluid are included herein.

Search This Class, Subclass:

235, for virus culture and treatment.

240, for tissue or animal cell culture processes.

283, for organ perfusion apparatus.

284, for tissue or virus culture apparatus.

Search Class:

3, Artifical Body Members, subclass 1 for an implantable living gland encased in a porous membrane.

34, Drying and Gas or Vapor Contact with Solids, for methods of preserving tissue by freeze drying.

62, Refrigeration, for methods of maintaining the viability of living tissue and cells under refrigeration or in the frozen state.

2. Maintaining Blood or Sperm in a Physiologically Active State or Compositions Thereof or Therefor or Methods of In Vitro Blood Cell Separation or Treatment:
Processes or compositions under the class definition for the maintenance of blood or sperm in a physiologically active state or for the in vitro separation or treatment of blood cells.

(1) **Note.** This subclass includes methods for preserving the viability of sperm by chemical means.

means, i.e., mere observation by an operator is not sufficient to constitute measurement for purposes of this subclass.

Search This Class, Subclass:

289 and 290, for condition or time responsive control apparatus.

Search Class:

364, Electrical Computers and Data Processing Systems, subclass 496 for data processing systems or calculating computer designed for use in chemistry, chemical engineering or other areas of engineering or for the solution of problems in these areas.

4. Measuring or Testing Process Involving Enzymes or Microorganisms; Composition or Test Strip Therefore; Processes of Forming Such Compositions or Test Strip:
Processes under the class definition in which there is a direct or indirect qualitative or quantitative measurement or test of a material which contains an enzyme or microorganism or processes in which a material containing an enzyme or microorganism is used to perform a qualitative or quantitative measurement or test and compositions therefor and the processes of making such compositions.

(1) **Note.** "Involving" in this and the indented subclasses includes (a) the use of a known microorganism or enzyme to detect or identify a chemical compound or composition, (b) the use of a chemical compound or composition to detect or identify a microorganism or enzyme, (c) a composition containing a microorganism or enzyme for use as in (a), and (d) a composition distinguished by the presence of an indicator for use as in (b). Thus, "involving" in this and the indented subclasses means that the steps in the measurement or test either use the designated chemical compound, microorganism, or individual plant or animal cells or enzyme or the steps in the measurement or test indicate the

73, Measuring and Testing, for processes and apparatus for making a test or measurement of any kind not provided for in other classes. In general, the classes superior to 73 are 435, 422, 424, 204, 350, and 356.

128, Surgery, for methods of treatment of the living body or a test which involves contact with a body and apparatus used in the inspection and treatment of diseases of the bodies of men and animals which apparatus is provided with means for connection to the living body.

137, Fluid Handling, subclasses 2+ for processes of controlling the flow of a fluid in response to the sensing of a condition or characteristic of a fluid.

204, Chemistry, Electrical and Wave Energy, subclass 195 for electrolytic or electrophoretic testing of biological materials which may include the use of an enzyme.

208, Minerals Oils: Processes and Products, for chemical tests claimed in association with processes for recovery or treatment of naturally occurring mineral oil.

235, Registers, subclass 92 for sizing or counting of discrete particles such as bacteria colonies one at a time by numerical counting apparatus which registers the counts.

252, Compositions, subclass 408 for testing compositions.

260, Chemistry, Carbon Compounds, for chemical tests claimed in association with processes for the treatment or modification of carbon compounds.

324, Electricity, Measuring and Testing, appropriate subclasses for methods and apparatus for testing and electrical property or condition of a material by electrical means, even though the result of the test may be used as an indication of some other physical or chemical property or condition.

cleic acid or the agent used for the measurement or test contains nucleic acid.

(1) **Note.** The tests provided for in this subclass may involve the determination of the mutagenic effect of drugs on nucleic acid containing genetic materials such as genes and chromosomes.

(2) **Note.** Nucleic acids for the purpose of this subclass are defined as polynucleotides of three or more nucleotides.

7. Involving Antibody Binding Assay, e.g., Antigen-Antibody Reaction, etc:
Subject matter under subclass 4 where the measurement or test utilizes an enzyme or microorganism or individual plant or animal cell to indicate the extent or presence of an antibody-antigen type reaction or utilizes an enzyme as an antigen or a living antigen, i.e., a microorganism, individual plant or animal cell, in an in vitro antibody-antigen type reaction.

(1) **Note.** An antibody-antigen type reaction denotes the formation of a complex which is an insoluble molecular aggregate that is formed by the specific interaction of antigens and antibodies.

(2) **Note.** Similar antigen-antibody and immunino-diffusion tests and the materials therefore are to be found in Class 23, subclass 230; and Class 424, subclasses 89+; and Class 252, subclass 408, as well as Class 260, various subclasses.

(3) **Note.** In the absence of a clearly claimed step of killing or inactivating a microorganism in an antigen-antibody test, the microorganism should be treated as a living antigen.

Search This Class, Subclass:

5, for processes in which a virus is involved, as for example, as an antigen.

73, Measuring and Testing, subclass 64.1 for apparatus used for testing the ability of blood to clot.

14. Involving Glucose or Galactose:
Subject matter under subclass 4 where the material to be measured or tested contains glucose or galactose or the agent used for the measurement or test contains glucose or galactose.

15. Involving Transferase:
Subject matter under subclass 4 where the material to be measured or tested contains a transferase or the agent used for the measurement or test contains a transferase.

16. Involving Transaminase:
Subject matter under subclass 15 subclass where the material to be measured or tested contains a transaminase or the agent used for the measurement or test contains a transaminase.

17. Involving Creatine Phosphokinase:
Subject matter under subclass 15 where the material to be measured or tested contains creatine phosphokinase or the agent used for the measurement or test contains creatine phosphokinase.

(1) Note. Creatine phosphokinase is also known as creatine kinase.

18. Involving Hydrolase:
Subject matter under subclass 4 where the material to be measured or tested contains a hydrolase or the agent used for the measurement or test contains a hydrolase.

19. Involving Esterase:
Subject matter under subclass 18 where the material to be measured or tested contains an esterase or the agent used for the measurement or test contains an esterase.

20. Involving Cholinesterase:
Subject matter under subclass 19 where the material to be mea-

sured or tested contains an oxidoreductase or the agent used for the measurement or test contains an oxidoreductase.

26. Involving Dehydrogenase:
Subject matter under subclass 25 where the material to be measured or tested contains a dehydrogenase or the agent used for the measurement or test contains a dehydrogenase.

27. Involving Catalase:
Subject matter under subclass 25 where the material to be measured or tested contains catalase or the agent used for the measurement or test contains catalase.

28. Involving Peroxidase:
Subject matter under subclass 25 where the material to be measured or tested contains peroxidase or the agent used for the measurement or test contains peroxidase.

29. Involving Viable Microorganism:
Subject matter under subclass 4 where the material to be tested contains a microorganism or the agent used for the measurement or test contains a microorganism.

(1) **Note.** A microorganism for the purposes of this subclass includes antinomycetates, unicellular algae, bacteria, fungi (including yeast), plant cells, and animal cells.

Search Class:

8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, subclass 94.11 for reactive treatment of biological specimens as by a bleach or dye.

250, Radiant Energy, for methods and apparatus for detecting radiant energy.

424, Drug, Bio-Affecting and Body Treating Compositions,

31. Testing for Sterility Conditions:
Subject matter under subclass 29 wherein the efficacy of a prior step intended to destroy living organisms is assessed by attempting to culture a microorganism which has been exposed to such treatment and determining subsequent growth or by exposing an enzyme to such treatment and subsequently testing for enzymatic activity.

(1) **Note.** Included in this subclass is the use of a living microorganism as the test agent or the use of enzymes which simulate the living microorganism's ability to survive as a test agent.

32. Testing for Antimicrobial Activity of a Material:
Subject matter under subclass 29 where the in vitro ability of a material to kill or inhibit the growth of microorganisms is determined.

(1) **Note.** This subclass provides for (a) a determination of the sensitivity of a microorganism to known antibiotics, and (b) determining the presence or amount of an antibiotic or toxicant in a sample.

33. Using Multifield Media:
Subject matter under subclass 32 where the test field contains more than one zone or area.

(2) **Note.** Zones or areas can contain different concentrations of the same antibiotic or different antibiotics and are generally separated by an identifiable boundary.

(2) **Note.** Media as used in this subclass includes culture media which sustains growth and medias which kill or inhibit certain microorganisms.

34. Determining Presence or Kind of Microorganism; Use of Selective Media:
Subject matter under subclass 29 where the presence of or identity of a microorganism is determined.

(2) **Note.** Included here are detection of nitrite in materials, such as an indication of bacteriuria.

38. Enteriobacteria:
Subject matter under subclass 34 where the microorganism involved is an enteriobacteria or the agent is specific for indicating the presence or absence of enteriobacteria.

39. Quantitative Determination:
Subject matter under subclass 34 where the number or concentration of living microorganisms in the material is found.

(1) **Note.** The identity of the microorganism is not necessarily known.

(2) **Note,** Included herein are tests for the purity of water.

Search Class:

350, Optics, Systems and Elements, for the use of an optical element such as a lens of a microscope for magnification for counting particles such as bacteria colonies one by one.

40. Using Multifield Media:
Subject matter under subclass 39 which uses a test substrate that has more than one test zone or area.

41. Microorganism, Tissue, Cell Culture or Enzyme Using Process to Synthesize a Desired Chemical Compound or Composition:
Processes under the class definition wherein the product is synthesized by a biochemical transformation of matter, i.e., a transformation wherein the transforming agent is a microorganism, or an enzyme or an immobilized enzyme or an animal or plant cell culture or organelles.

(1) **Note.** Microorganism for the purpose of this subclass includes bacteria, fungi (including yeast), virus, ac-

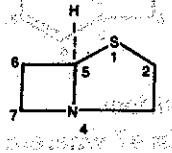
260, Chemistry, Carbon Compounds, for the synthesis of carbon compounds by means not including a microorganism or enzyme.

423, Chemistry, Inorganic, for the synthesis of inorganic compounds or elements other than metals by means not including the use of a microorganism or enzyme.

426, Food or Edible Material: Processes, Compositions and Products, for fermentation processes that are solely disclosed or claimed in preparing an edible, and for mixtures of enzymes or ferments solely disclosed or claimed as edible or used in preparation of an edible. Class 426 provides for compositions and processes of preparation relating to compositions which have the capacity to ferment and produce an edible, but which are claimed as being in an inactive state, and also provides for compositions which are undergoing a fermentation to produce an edible product.

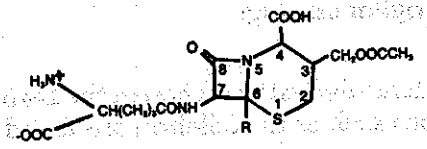
42. Process Involving Microorganisms of Different Genera in the Same Process, Simultaneously:
Processes under subclass 41 wherein microorganisms of different genera are simultaneously propagated on the same culture media.

43. Preparing Compound Having a 1-thia-4-aza-bicyclo (3.2.0) Heptane Ring System, e.g., Penicillin, etc.:
Processes under subclass 41 wherein the product synthesized contains a 1-thia-4-aza-bicyclo (3.2.0) heptane polycyclic ring system, i.e.,



(1) **Note.** The media of the processes included in subclass 45

49. Cephalosporin C:
Processes under subclass 47 wherein the product contains 7-(D-5-amino-5-carboxy valeramido)-3-(hydroxy methyl)-8-oxo-1-thia-5-aza-bicyclo (4.2.0)-oct-3-ene-3-carboxylic acid acetate, i.e.,

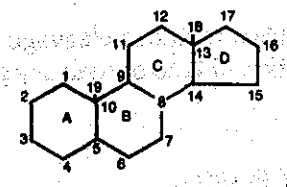


(1) **Note.** For purposes of this subclass, derivatives include only metal and ammonium salts.

50. By Acylation of the Substituent in the 7-Position:
Processes under subclass 47 wherein the product synthesized is prepared by amide bond formation with the nitrogen present at the 7-position.

51. By Desacylation of the Substituent in the 7-Position:
Processes under subclass 47 wherein the product synthesized is prepared by cleaving the amide bond with the nitrogen attached to the 7-position.

52. Preparing Compound Containing a Cyclopentenohydrophenanthrene Nucleus; Nor-, Homo- or D-Ring Lactone Derivatives Thereof:
Processes under subclass 41 wherein the product synthesized contains a cyclopentenophenanthrene ring system, i.e.,



or the nor or homo or D-ring lactone derivatives.

Processes under subclass 54 wherein the product synthesized has a hydroxyl group at the 16-position and is formed by the addition of oxygen to the ring pendant hydrogen atom.

58. Hydroxylating:
Processes under subclass 52 wherein a carbon atom on the substrate nucleus is hydroxylated by the addition of oxygen to the ring pendant hydrogen atom.

59. At 11-Position:
Processes under subclass 58 wherein the product synthesized has a hydroxyl group formed at the 11-position.

60. At 11 Alpha Position:
Processes under subclass 59 wherein the product synthesized has a hydroxyl group formed at the 11 Alpha position.

61. Dehydrogenating; Dehydroxylating:
Processes under subclass 52 wherein the product synthesized is produced by the removal from the nucleus of a pair of hydrogen atoms creating an unsaturated bond or the product is synthesized by formation or addition of a hydroxyl group.

(1) **Note.** The mere shifting of unsaturated bonds from adjacent positions such as from the 5, 6 position to the 4, 5 position is not a dehydrogenation.

62. Forming an Aryl Ring From "A" Ring:
Processes under subclass 61 wherein the product synthesized contains an aromatic "A" ring which is formed by dehydrogenation.

63. Preparing Compound Containing a Prostaglandin Nucleus:
Processes under subclass 41 wherein the product synthesized contains a five-membered ring having two side-chains in ortho position to each other, and having at least one oxygen atom directly bound to the ring in ortho position to one of the side-chains, one side-chain containing, not directly bound to the ring, a carbon atom having three bonds to hetero atoms with at the

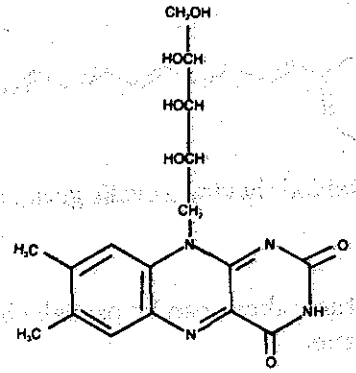
(1) **Note.** Gibberellic acid and gibberellins are properly classified here.

(2) **Note.** Saccharide derivatives are excluded herefrom.

Search This Class, Subclass:

78, for saccharide derivatives.

66. Preparing Compound Other than Saccharide Containing Alloxazine or Isoalloxazine Nucleus:
Processes under subclass 41 wherein the product synthesized contains an alloxazine or isoalloxazine ring system, e.g.,



and is not a saccharide.

(1) **Note.** Riboflavin is not considered a saccharide derivative for the purposes of this subclass and is therefore provided for here.

(1) **Note.** This subclass provides for peptones which are the result of partial protein hydrolysis.

(2) **Note.** A peptide bond is defined as an amide linkage between two amino acid residues.

Search Class:

106, Compositions, Coating or Plastic, for protein containing coating or plastic compositions, particularly subclasses 4, 24, 79, 91, 112, 113, 124 and indented subclasses.

260, Chemistry, Carbon Compounds, subclasses 6+ for a synthetic resin containing protein; subclass 112 for proteins and their reaction products; and subclass 529 for amino acids produced from protein.

424, Drug, Bio-Affecting and Body Treating Compositions, especially subclasses 36+ for a composition of that class in protein ingestible capsule, and subclasses 177+ for a composition containing protein.

426, Food or Edible Material: Processes, Compositions and Products, appropriate subclasses, especially subclasses 63, 92, 105, 211, and 212 for edible protein compositions or products and related process involving the same.

428, Stock Material or Miscellaneous Articles, subclasses 474+ for a nonstructural stock material product in the form of a composite web or sheet including a layer comprising protein, and other appropriately titled subclasses (e.g., subclasses 435 and 458).

536, Organic Compounds for nucleic acids and processes of chemical synthesis thereof.

69. Produced by the Hydrolysis of a Peptide Bond:
Processes under subclass 68 wherein the product synthesized is

atoms are not provided for in this subclass but are provided for in an appropriate subclass below.

Search This Class, Subclass:

137, for sugar acids.

158+, for sugar alcohols.

262, for processes of liberation or purification of carbohydrates using a biochemical reaction.

Search Class:

127, Sugar, Starch and Carbohydrates, for the hydrolysis of carbohydrates including their conversion to sugar by means other than a microorganism or enzyme. Class 127 will provide for such processes using an enzyme or microorganism only where the hydrolysis by microorganism or enzyme is followed by steps of concentration, purification, or treatment (such as crystallization) to make a sugar or syrup.

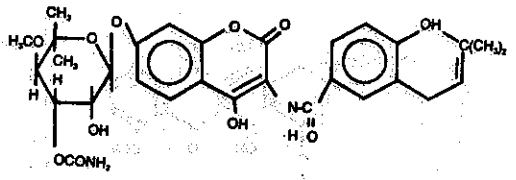
536, Organic Compounds, for the chemical manufacture or synthesis of sugar or carbohydrates by a process other than hydrolysis and the rearrangement of one carbohydrate to form another carbohydrate by means other than a microorganism or enzyme.

73. Preparing S-Glycoside, e.g., Lincomycin, etc.:
Processes under subclass 72 wherein the product synthesized is a thioacetal derivative of a cyclic form of sugar in which the hydrogen atom of the hemithioacetal sulfhydryl group has been replaced by an alkyl, aralkyl, or aryl group.

(1) **Note.** An S-glycoside is a compound having a sugar moiety connected to an aglycone moiety via a sulfur.

Contains a Nonsaccharide Heterocyclic Ring, e.g., Coumermycin, Novobiocin, etc.:

Processes under subclass 74 wherein a nonsaccharide heterocyclic ring or a fused- or bridged-ring system which contains a nonsaccharide heterocyclic ring is attached to an oxygen of the saccharide radical, e.g.,

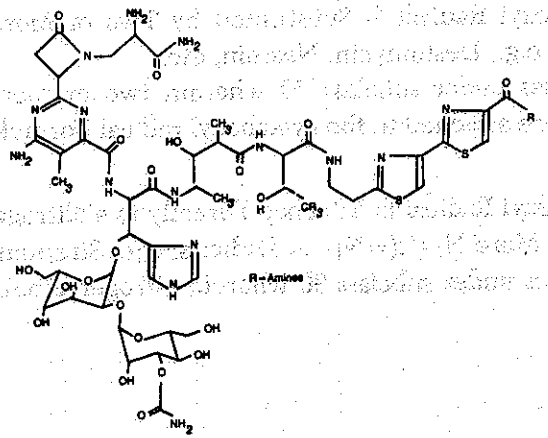


76. The Hetero Ring Has Eight or More Ring Members and Only Oxygen as Ring Hetero Atoms, e.g., Erythromycin, Spiramycin, Nystatin, etc.:

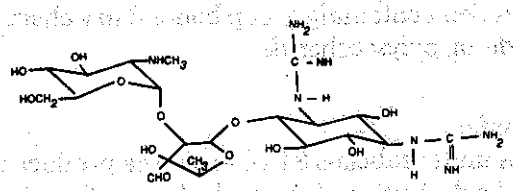
Processes under subclass 75 wherein the nonsaccharide heterocyclic ring has eight or more ring members and only oxygen as the ring heteroatom [formula omitted].

77. Oxygen Atom of the Saccharide Radical Is Directly Linked Through only Acyclic Carbon Atoms to a Nonsaccharide Heterocyclic Ring, e.g., Bleomycin, Phleomycin, etc.:

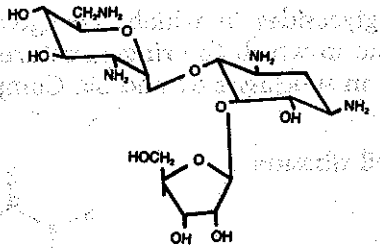
Processes under subclass 74 wherein the Heterocyclic ring is directly linked to an oxygen atom of the saccharide radical directly through only acyclic carbon atoms, e.g.,



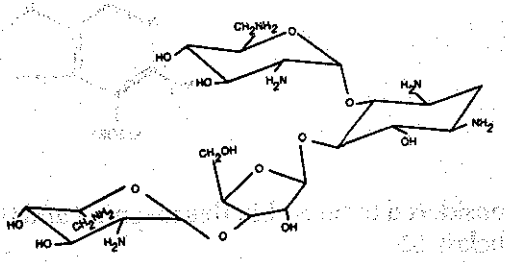
more N—C(=N)—N radicals are bonded to the cyclohexyl radical, e.g.,

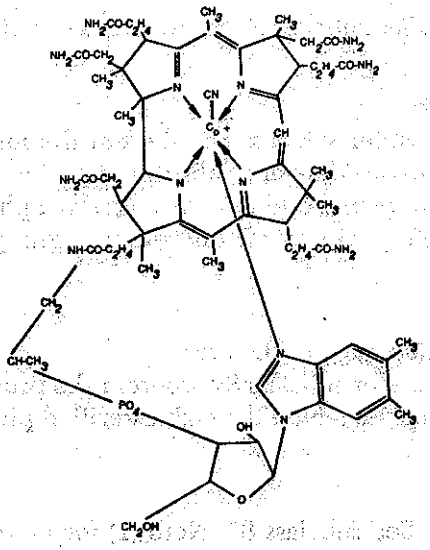


82. Having Two Saccharide Radicals Bonded Through Only Oxygen to Adjacent Ring Carbons of the Cyclohexyl Radical, e.g., Ambutyrosin, Ribostamycin, etc.:
Processes under subclass 80 wherein the cyclohexyl radical is separately, independently bonded to two or more oxygen atoms of saccharide radicals at adjacent ring carbons, e.g.,



83. Containing Three or More Saccharide Radicals, e.g., Liquidomycin, Neomycin, Lividomycin, etc.:
Processes under subclass 82 wherein the cyclohexyl radical is bonded directly or indirectly to three or more saccharide radicals, e.g.,

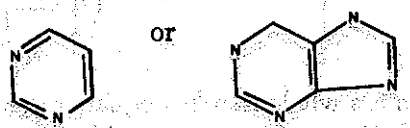




87. Nucleoside:

Processes under subclass 85 wherein the nitrogen is part of a purine or pyrimidine or a substituted purine or pyrimidine ring and the product synthesized does not contain phosphorus.

(1) **Note.** Substituted purine or pyrimidine includes only those derivatives which are substituted on rather than in the respective ring positions, i.e.,



is present in the structure. The internal ring bonding may be altered by tautomerism or by the addition of substituents without excluding a compound from this subclass.

88. Having a Fused Ring Containing a Six-Membered Ring Having Two N-Atoms in the Same Ring, e.g., Purine Nucleosides, etc.: Processes under subclass 87 wherein the nitrogen is part of a purine or substituted purine ring.

Processes under subclass 89 wherein the nitrogen atoms are part of a purine or substituted purine ring.

(1) **Note.** See subclass 87, Note (1) for a definition of the term substituted.

93. Mashing or Wort Making:
Processes under subclass 72 wherein the product is mashed grain or wort which has been prepared by a biochemical reaction utilizing malt, or malt diastase, or a malt extract.

(1) **Note.** Malt, malt diastase, and malt extract are considered to include a mixture of alpha- and beta-amylases.

(2) **Note.** Diastase (as distinguished from malt diastase) is considered to be alpha-amylase.

Search This Class, Subclass:

95+, for products other than mash or wort produced by malt, malt diastase, or malt extract.

99, for producing compounds containing saccharide radials by diastase.

201, for the production of maltase.

202, for the production of diastase from microorganisms.

203, for the production of diastase from a fungal source.

204, for the production of diastase from a plant source such as barley malt.

Search Class:

produced by the hydrolysis of alpha-1, 4-glucan bonds of saccharides or polysaccharides.

Search This Class, Subclass:

105, for the production of dextrose by other methods.

174, for immobilized glucoamylase preparations.

205, for glucoamylase enzymes.

97. Produced by the Action of a Glycosyl Transferase, e.g., Alpha, Beta, or Gamma-cyclodextrins by the Action of Glycosyl Transferase on Starch, etc.:
Processes under subclass 72 wherein the product synthesized is produced by the direct transfer of a glycosyl moiety from one saccharide or polysaccharide to another, e.g., cyclodextrins, etc.

Search This Class, Subclass:

174+, for immobilized transferase preparations.

193+, for transferases.

98. Produced by the Action of an Alpha-1, 6-glucosidase, e.g., Amylose, Debranched Amylopectin by Action of Pullulanase, etc.:
Processes under subclass 72 wherein the product is produced by the hydrolysis of alpha-1, 6-glucan bonds in polysaccharides.

Search This Class, Subclass:

174+, for immobilized enzyme preparations which may be used in this process.

210+, for the enzyme which may catalyze this process.

Processes under subclass 101 wherein the polysaccharide is prepared through the cultivation of a species of Xanthomonas.

105. Monosaccharide:
Processes under subclass 72 wherein the product synthesized is a monosaccharide.

106. Preparing Alpha or Beta Amino Acid or Substituted Amino Acid or Salts Thereof:
Processes under subclass 41 wherein the product synthesized is an organic compound that contains both a basic amino group and an acidic carboxyl group where a primary or secondary amino group is directly bonded to the alpha or beta carbon.

(1) **Note.** This subclass takes compounds such as pantothenic acid and amino acids that additionally contain heterocyclic groups.

(2) **Note.** This subclass provides for the salt form as well as the acid form.

107. Proline; Hydroxyproline; Histidine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of alpha-2-pyrrolidine carboxylic acid or 4-hydroxy-2-pyrrolidine carboxylic acid or alpha-amino-4-imidazole propionic acid.

108. Tryptophan; Tyrosine; Phenylalanine; 3, 4, Dihydroxyphenylalanine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of alpha-amino-beta-phenyl-propionic acid or p-hydroxyphenylaminoacetic acid or 2-amino-3-(3, 4-dihydroxyphenyl) propanoic acid or 1-alpha-aminoindole-3-propionic acid.

109. Aspartic Acid (Asparaginic Acid); Asparagine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of amino succinic acid or alpha-amino succinamic acid.

no-1,5-pentane dicarboxylic acid or 2-amino-3-hydroxy butanoic acid or 2-amino-3-methyl butanoic acid.

116. Alanine; Leucine; Isoleucine; Serine; Homoserine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of 2-aminopropanoic acid or 2-amino-4-methyl pentanoic acid or 2-amino-3-methyl pentanoic acid or 2-amino-3-hydroxypropionic acid or 2-amino-4-hydroxy butanoic acid.

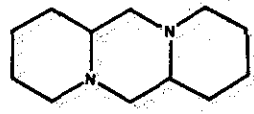
117. Preparing Heterocyclic Carbon Compound Having Only O, N, S, Se, or Te as Ring Hetero Atoms:
Processes under subclass 41 wherein the product synthesized is a carbon compound which contains a ring composed of carbon and at least one element from the group consisting of nitrogen, sulfur, seleniun, tellurium, or oxygen and no other atoms.

(1) **Note.** Processes wherein the product synthesized is an acid anhydride or lactone, or lactam are properly classified herein.

118. Containing Two or More Hetero Rings:
Processes under subclass 117 wherein the product synthesized contains at least two hetero rings.

119. Containing at Least Two Hetero Rings Bridged or Fused Among Themselves or Bridged or Fused with a Common Carboxylic Ring System, e.g., Rifamycin, etc.:
Processes under subclass 118 wherein the product synthesized contains at least two hetero rings which are bridged or fused among themselves or bridged or fused with a common carbocyclic ring system.

(1) **Note.** Ring systems containing two carbocyclic rings fused to a common heterocyclic ring where each of the carboxyclic rings share a hetero ring are included herein, e.g.,



, etc.

contains an O-containing hetero ring of seven or more ring members.

125. Containing Six-Membered Hetero Ring, e.g., Fluorescein, etc.:
Processes under subclass 123 wherein the O-containing hetero ring has only six members.

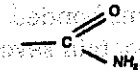
126. Containing Five-Membered Hetero Ring, e.g., Griseofulvin, etc.:
Processes under subclass 123 wherein the O-containing hetero ring has five members.

127. Preparing Compounds Containing at Least Three Carbocyclic Rings:
Subject matter under subclass 41 in which the product contains three carbocyclic rings.

(1) **Note.** The rings need not be fused or contiguous.

128. Preparing Nitrogen-Containing Organic Compound:
Processes under subclass 41 wherein the product is an organic compound which contains nitrogen.

129. Amide, e.g., Chloramphenicol, etc.:
Subject matter under subclass 128 wherein the product has the following structural group,



130. Preparing Sulfur-Containing Organic Compound:
Processes under subclass 41 wherein the product synthesized contains sulfur.

131. Preparing-Organic Compound Containing a Metal or Atom Other Than H, N, C, O, or Halogen:
Processes under subclass 41 wherein the product contains an atom other than H, N, C, O, or halogen.

135. Carboxylic Acid Ester:
Processes under subclass 132 wherein the product synthesized contains an ester group,

i.e.,  wherein R=alkyl, aryl, alkenyl, alkynyl.

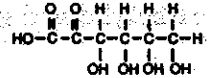
136. Containing a Carboxyl Group:
Processes under subclass 132 wherein the product synthesized contains a carboxylic acid

functional group, i.e.,  which is either in the acid or salt form.

137. Sugar Acid Having Five or More Carbon Atoms, i.e., Aldonic, Keto-Aldonic or Saccharic Acids:
Processes under subclass 136 wherein the product synthesized is a polyhydroxy acid having five or more carbon atoms.

(1) **Note.** The processes of this subclass typically involve the oxidation of a carbohydrate and include the production of aldonic, keto-aldonic and saccharic acids.

138. Alpha-Ketogulonic Acid, i.e., 2-Ketogulonic Acid:
Processes under subclass 137 wherein the product synthesized is an acid or salt form of



139. Lactic Acid:
Processes under subclass 136 wherein the product synthesized is an acid or salt form of alpha-hydroxy propanoic acid.

145. Dicarboxylic Acid Having Four or Less Carbon Atoms, e.g., Fumeric, Maleic, etc.:
Processes under subclass 142 wherein the product synthesized contains two carboxylic acid groups and four or less carbon atoms.

146. Hydroxy Carboxylic Acid:
Processes under subclass 136 wherein the product synthesized contains one or more hydroxy groups.

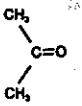
147. Containing Carbonyl Group:
Processes under subclass 132 wherein the product synthesized contains a carbonyl group, i.e.,

(1) Note. This subclass provides for linear carbocyclic acid anhydrides such as acetic acid anhydride.

148. Ketone:
Processes under subclass 147 wherein the product synthesized contains a keto group, i.e.,

149. Cyclopentanone or Cyclopentadione Containing Compound:
Processes under subclass 148 wherein the product synthesized is cyclopentanone or cyclopentadione or a substituted cyclopentanone or cyclopentadione.

150. Acetone Containing Product:
Processes under subclass 148 wherein the product synthesized contains acetone, i.e.,



260, Chemistry, Carbon Compounds, subclasses 97.5 and 124 for the treatment of source materials such as sulfite waste liquor or black liquor to derive a specific carbon compound, subclass 527 for the production of oxalic acids from waste sulfite liquor.

426, Food or Edible Material: Processes, Compositions and Products, for fermentation to produce beverage alcohol. Class 426 also provides for methods of clarifying alcoholic beverages by fermentation.

156. Aromatic:
Processes under subclass 155 wherein the product synthesized contains at least one aryl ring.

157. Acyclic:
Processes under subclass 155 wherein the product synthesized is acyclic.

158. Polyhydric:
Processes under subclass 157 wherein the product synthesized contains two or more hydroxyl groups.

159. Glycerol:
Processes under subclass 158 wherein the product is 1, 2, 3, propanetriol.

(1) **Note.** Glycerine is another name for glycerol.

160. Butanol:
Processes under subclass 157 wherein the product synthesized is 2-methyl-2-propanol or 1-butanol or 2-methyl-1-propanol or 2-butanol.

(1) **Note.** Butanol is typically produced as a product in fermentation process for producing acetone.

167. Only Acyclic:
Processes under subclass 166 wherein the only hydrocarbon product is acyclic.

(1) **Note.** This subclass is largely devoted to production of methane.

Search Class:

48, Gas, Heating and Illuminating, especially subclass 197 for processes of producing a fuel gas by anerobic fermentation of sewage.

71, Chemistry, Fertilizers, for processes whose primary intent is to make a product of that class which may incidentally produce a methane containing gas by-product.

210, Liquid Purification or Separation, subclasses 2+ for fermentative processing of liquid which may result in the production of a methane containing gas. The following criteria are determinative of placement in Class 210.

(1) Where water is the only disclosed liquid purified, the patent will be classified in Class 210.

(2) Where the disclosure includes water, mineral oils and/or other liquids, the patent will be classified:

(a) In Class 210 if all the claims are broad as to the liquid.

(b) In Class 210 if several species of liquid are claimed and one species includes waters.

(c) In the appropriate art class if some liquid other than water is the only liquid claimed (e.g., mineral oils in Class 208; organic compounds in Class 260). When the treatment of mineral oils

(3) **Note.** This subclass provides for methods of modifying plasmids by chemical or biochemical processes, e.g., use of restriction enzymes, etc.

Search This Class, Subclass:

317, for subcellular parts, such as plasmids or organelles, e.g., mitochondria, ribosomes, as products or materials for genetic engineering.

Search Class:

536, Organic Compounds, for the chemical modification of nucleic acids.

173. Treatment of Microorganism or Enzyme with Electrical or Wave Energy, e.g., Magnetism, Sonic Waves, etc.:
Processes under the class definition wherein a microorganism is subjected to a magnetic field, soundwaves, or electromagnetic radiation either prior to or during propagation or enzymes are subjected to a magnetic field or soundwaves or electromagnetic radiation.

(1) **Note.** This subclass does not include the treatment of plant cells, tissues thereof, or algae with light for propagation thereof. Such subject matter is provided for in Class 47 or in subclasses 243+ of this class.

174. Carrier-Bound or Immobilized Enzyme or Microbial Cell; Carrier-Bound or Immobilized Cell; Preparation Thereof:
Subject matter under the class definition which is an artificially produced composition or complex or compound under the class definition containing microbial cell or enzyme or individual plant or animal cell which imparts to the enzyme or the microorganism or the individual plant or animal cell the property of physical confinement or localization during a continuous biochemical process or the property of enhanced recoverability in a batch process for repeated future use and processes for preparing the same.

(9) **Note.** An enzyme conjugate, enzyme ligand, enzyme adduct for the purpose of this subclass are deemed to enhance enzyme stability.

(10) **Note.** In documents where it is unclear whether an enzyme joined to a chemical moiety is an immobilized enzyme or is an enzyme conjugate or adduct, the following factors should be considered.

A. If the document states that the product is an enzyme conjugate, adduct or ligand bound enzyme placement is proper in subclass 188.

B. If the ratio of nonenzyme moiety to enzyme is in the range of 0.01-100:1 placement would be indicated in subclass 188. A ratio of 1-40 nonenzyme moieties per enzyme indicates placement in subclass 188.

C. If the molecular weight of the nonenzyme moiety is less than about 100,000 placement would be indicated in subclass 188.

D. If the intended use of the enzyme containing product is a reagent in competitive assay placement is indicated in subclass 188. If the use of the product is as a catalyst in the preparation of chemical compounds with recoverability (i.e., insolubility) an important consideration, placement as an immobilized enzyme is indicated in subclasses 174+.

Search Class:

65, Glass Manufacturing, for processes of making glass articles, particularly subclass 3 for making a resin coated glass fiber; and subclass 22 for making a porous glass article which may find utility as an immobilization agent.

106, Compositions, Coating or Plastic, for protein containing coating or plastic compositions, particularly subclasses 4, 24, 79, 91, 112, 113, 124 and indented subclasses.

156, Adhesive Bonding and Miscellaneous Chemical Manufacture, subclasses 77+ for pore forming in combination with a laminating step.

210, Liquid Purification or Separation, subclasses 41+ and 263+ for processes and apparatus for ion exchange or sorption of components from a liquid; and subclass 17 for a process of use of an immobilized enzyme or microorganism to purify sewage.

260, Chemistry; Carbon Compounds, various subclasses for coenzymes or immobilized coenzymes; subclasses 6+ for resinous products and the processes of preparing them wherein a protein is incorporated into the resinous structure; subclasses 112+ for resins incorporating proteins with utilities intended for use as dyestuffs or pharmaceuticals or otherwise excluded from Class 260, subclasses 2.01+ by Note (1) of subclass 2.01.

264, Plastic and Nonmetallic Article Shaping or Treating: Processes, subclasses 41+ for significant molding processes which include the step of pore forming in situ.

362, Illumination, for cells which are propagated fixed to a surface.

424, Drug, Bio-Affecting and Body Treating Compositions, especially subclasses 19 and 31 for coated products which may contain a protein; subclass 94 for a composition containing an enzyme or coenzyme including immobilized forms; and subclasses 177+ for a composition containing a protein.

426, Food or Edible Material: Processes, Compositions and Products, appropriate subclasses, for edible protein compositions or products and related process involving the same.

428, Stock Material or Miscellaneous Articles, subclasses 474+

(1) **Note.** Immobilization results from covalent bonding between an enzyme or microorganism and the carrier or an ionic bonding between an enzyme or microorganism and a carrier or sorption of an enzyme or microorganism within a carrier, or entrapment of an enzyme or microorganism within a carrier.

(2) **Note.** A carrier material may be either water soluble or water insoluble.

(3) **Note.** Reaction or ultra filtration cells, vials, or beakers which contain enzymes or microorganisms are not considered to be immobilized complexes or compositions.

(4) **Note.** Enzymes chemically or physically bonded to a water-insoluble matrix, enzymes contained within a polymer or gel, enzymes absorbed on a resin are examples of immobilized enzymes.

(5) **Note.** Proenzymes are considered to be enzymes for the purpose of this subclass.

(6) **Note.** When a carrier is composed of more than one material, the patent is placed in the subclass which corresponds to the material to which the enzyme is bound, e.g., a carrier which is a synthetic polymer coated metal is placed in subclass 177.

(7) **Note.** The carrier material or the carrier material and a covalent bond forming agent impart to the enzyme or the microbial or plant or animal cell the property of physical confinement or localization during a continuous process or the property of enhanced recoverability in a batch process which it did not possess prior to treatment with the carrier material or carrier material and a covalent bonding agent.

(8) **Note.** A microbial cell for purposes of this subclass includes bacteria, fungi (including yeast), actinomycetales, animal or plant cells, unicellular algae or protozoa.

and the treatment of other materials (other than water) are claimed the patent will be classified in Class 208.

168. Preparing Element or Inorganic Compound Except Carbon Dioxide:
Processes under subclass 41 wherein the product is an element or inorganic compound.

(1) **Note.** The exclusion of carbon dioxide is intended to exclude carbon dioxide as a normal respiration product of microorganisms.

169. Using Actinomycetales:
Processes under subclass 41 wherein the product synthesized is prepared by actinomycetales.

170. Using Bacteria:
Processes under subclass 41 wherein the product synthesized is prepared by bacteria.

171. Using Fungi:
Processes under subclass 41 wherein the product synthesized is prepared by fungi.

172. Mutation or Genetic Engineering:
Processes under the class definition for producing a stable inheritable change in the genotype of an animal or plant cell or a microorganism by artificially inducing a structural change in a gene or by the incorporation of genetic material from an outside source.

(1) **Note.** An outside source may include chemically synthesized or modified genes.

(2) **Note.** This subclass includes fused cells of the same or different species, such as the fusion of animal and plant cells.

Search This Class, Subclass:

150+, for processes for producing acetone which also produces a butanol by-product.

161. Ethanol:
Processes under subclass 157 wherein the product synthesized is ethanol which is not directly suitable for food or beverage use.

162. Multiple Stages of Fermentation; Multiple Types of Microorganisms or Reuse of Microorganisms:
Processes under subclass 161 wherein ethanol is prepared by (a) two or more distinct fermentation steps, or (b) by using microorganisms of different species sequentially, or (c) by a process wherein the microorganism is recycled and reused.

163. Produced as By-Product or from Waste or from Cellulosic Material Substrate:
Processes under subclass 161 wherein ethanol produced as a by-product in a process for the production of another chemical species or is prepared by the biochemical conversion of materials containing cellulose or unrefined waste materials of another process.

164. Substrate Contains Sulphite Waste Liquid or Citrus Waste:
Processes under subclass 163 wherein ethanol is prepared by the biochemical conversion of waste sulfite liquor or citrus waste.

(1) **Note.** Waste sulfite liquor is the residual material obtained after the sulfurous acid treatment of paper pulp.

165. Substrate Contains Cellulosic Material:
Processes under subclass 163 wherein ethanol is prepared by the biochemical treatment of a cellulose containing material.

166. Preparing Hydrocarbon:
Processes under subclass 41 wherein the product synthesized is a hydrocarbon.

(1) **Note.** Molasses is not considered a grain or cereal material for purposes of this subclass.

(2) **Note.** Care should be taken with the word "mash" to determine if sugar, or grain or cereal material is intended.

(3) **Note.** This subclass does not include dihydroxy acetone.

151. Substrate Contains Grain or Cereal Material:
Processes under subclass 150 wherein acetone is prepared by biochemical transformation of farinaceous material.

(1) **Note.** Molasses is not considered a cereal or grain substrate.

(2) **Note.** Care should be taken with the word "mash" to determine if sugar or grain-cereal is intended.

152. Substrate Contains Protein as Nitrogen Source:
Processes under subclass 150 wherein the product media contains a protein as the nitrogen source.

153. Substrate Contains Inorganic Nitrogen Course:
Processes under subclass 150 wherein the production media contains an inorganic nitrogen source.

154. Substrate Contains Inorganic Compound, Other Than Water:
Processes under subclass 150 wherein the production media contains an added inorganic compound other than water.

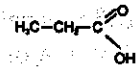
155. Containing Hydroxy Group:
Processes under subclass 132 wherein the product contains a hydroxyl group, i.e., R-OH.

140. Acetic Acid:
Processes under subclass 136 wherein the product synthesized is ethanoic acid which by the nature of the process cannot be readily used as a food product.

Search Class:

426. Food or Edible Material: Processes Compositions and Products, subclass 17 for fermentation of alcohol to produce vinegar. The oxidizing of alcohol to produce acetic acid as a chemical compound is subject matter for Class 435.

141. Propionic or Butyric Acid:
Processes under subclass 136 wherein the product synthesized is an acid with the structure:



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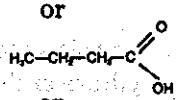

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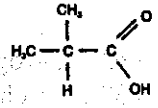


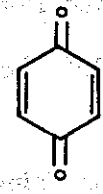
142. Polycarboxylic Acid:
Processes under subclass 136 wherein the product synthesized contains two or more carboxylic acid groups.

143. Having Keto Group, e.g., Alpha Ketoglutaric Acid, etc.:
Processes under subclass 142 wherein the polycarboxylic acid synthesized contains a keto group.

144. Tricarboxylic Acid, e.g., Citric Acid, etc.:
Processes under subclass 142 wherein the product synthesized contains three carboxylic acid groups.

132. Preparing Oxygen-Containing Organic Compound:
Processes under subclass 41 wherein the product is an organic compound containing oxygen.

133. Containing Quinone Nucleus, i.e., Quinoid Structure:
Processes under subclass 132 wherein the product contains the following structure, i.e.,



134. Fat; Fatty Oil; Ester-Type Waxes; Higher Fatty Acid, i.e., Having at Least Seven Carbon Atoms in an Unbroken Chain Bound to a Carboxyl Group; Oxidized Oil or Fat:
Processes under subclass 132 wherein the product synthesized is a fat or fatty oil or ester-type wax or fatty acid, oxidized oil or fat.

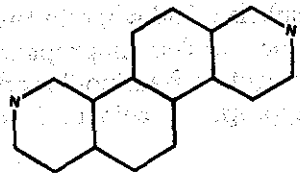
(1) **Note.** "Fats" and "fatty oils" are the glycerides of higher fatty acids having seven or more carbon atoms.

(2) **Note.** "Higher fatty acid" is a monocarboxylic acid containing seven or more carbon atoms bonded to a carboxyl group, e.g., lauric, palmitic stearic, oleic, ricinoleic, linoleic, and behonolic acids. Where there are several unbroken chains of carbon atoms bonded to the carboxyl group, one of the chains must contain seven or more carbon atoms.

(3) **Note.** Ester-type waxes and esters of a higher fatty acid having seven or more carbon atoms and a monohydric alcohol.

(4) **Note.** The conversion of fats, proteins, and carbohydrates to fatty acids is a step in the anaerobic digestion of sewage provided for in Class 210, subclasses 2+.

(2) **Note.** A common carbocyclic ring system may contain three or more carbon atoms and may be bridged or fused, e.g.,



(3) **Note.** This subclass provides for compounds generally referred to as alkaloids.

120. Nitrogen or Oxygen Hetero Atom and at Least one Other Diverse Hetero Ring Atom in the Same Ring:
Subject matter under subclass 117 wherein the product synthesized contains a hetero ring which contains at least two different hetero atoms, one of which is either nitrogen or oxygen.

121. Nitrogen as Only Ring Hetero Atom:
Processes under subclass 117 wherein the product synthesized contains a hetero ring having nitrogen as the only hetero atom.

122. Containing Six-Membered Hetero Ring:
Processes under subclass 117 wherein the N-containing hetero ring contains six-members.

123. Oxygen as Only Ring Hetero Atom:
Processes under subclass 117 wherein the product synthesized contains a hetero ring wherein oxygen is the only hetero atom.

124. Containing a Hetero Ring of at Least Seven Ring Members, e.g., Zearalenone, Macrocyclic Lactones, etc.:
Processes under subclass 123 wherein the product synthesized

110. Glutamic Acid; Glutamine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of 2-amino pentanedioic acid or alpha-amino-glutaric acid or 1-amino propane-1, 3-dicarboxylic acid or 2-amino glutaramic acid or glutamic acid 5-amide.

111. Utilizing Biotin or Its Derivatives:
Processes under subclass 110 wherein biotin or biotin derivative is present in the production media.

(1) **Note.** Biotin derivatives include desthio-biotin, biotin-d-sulfoxide, biocytin.

(2) **Note.** Molasses and various carbohydrate and protein hydrolyzates provide biotin.

112. Utilizing Surfactant, Fatty Acids or Fatty Acid Esters, i.e., Having Seven or More Carbon Atoms:
Processes under subclass 110 wherein a surfactant or a fatty acid or a fatty acid ester is present in the production media.

(1) **Note.** A fatty acid or its ester is defined as containing seven or more carbon atoms in a single chain.

113. Methionine; Cysteine; Cystine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of 2-amino-4-(methyl thio) butyric acid or 2-amino-3-mercaptopropanoic acid or 3,3'-dithiobis (2-amino-propanoic acid).

114. Citrulline; Arginine; Ornithine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of alpha-amino-6-ureidovaleric acid or 1-amino-4-guanidovalenic acid or 2,5 diaminopentaneic acid.

115. Lysine; Diaminopimelic Acid; Threonine; Valine:
Processes under subclass 106 wherein the product synthesized is an acid or salt form of 2,6-diaminohexanoic acid or 2,4 diami-

99. Produced by the Action of a Carbohydrase, e.g., Maltose by the Action of Alpha Amylase on Starch, etc.:
Processes under subclass 72 wherein the product synthesized is a saccharide or polysaccharide produced by the enzymatic hydrolysis of a polysaccharide.

Search This Class, Subclass:

174, for immobilized enzyme preparations which may catalyze this process.

200, for the enzyme which may catalyze this reaction.

100. Disaccharide:
Processes under subclass 72 wherein the product synthesized is a glycoside composed of only two glucan moieties.

101. Polysaccharide of More than Five Saccharide Radicals Attached to Each Other by Glycosidic Bonds:
Processes under subclass 72 wherein the product synthesized contains five or more saccharide moieties bonded together.

102. Pullulan:
Processes under subclass 101 wherein the polysaccharide is composed of glucose units which are joined predominantly by 1, 6-glucosidic bonds.

103. Dextran:
Processes under subclass 101 wherein the polysaccharide is composed of maltotriose units which are linked by 1, 6-glucosidic bonds.

(1) **Note.** Dextrin and Dextrine are not variant spellings of "Dextran," instead they are respectively a starch hydrolysis product and a variant spelling of dextrin.

104. Xanthan, i.e., Xanthomonas-Type Heteropolysaccharides:

426, Food or Edible Material: Processes, Compositions and Products, particularly subclasses 16, 28+, and 64 for processes of producing mash or wort when combined with steps for producing an edible, e.g., a beverage and the product of such processes.

94. Produced by the Action of an Isomerase, e.g., Frutose by the Action of Xylose Isomerase on Glucose, etc.:
Processes under subclass 17 wherein the product synthesized is an enzymatically isomerized polysaccharide or saccharide containing compound.

Search This Class, Subclass:

174, for immobilized isomerase preparation.

233 and 234, for isomerase.

95. Produced by the Action of a Beta-Amylase, e.g., Maltose by Action of Beta-Amylase on Amylose, etc.:
Processes under subclass 72 wherein the product is produced by the successive hydrolysis of alpha-1, 4-glucan bonds in a polysaccharide from a terminal end.

(1) **Note.** Malt and malt diastase are considered to include a mixture of alpha- and beta-amylases. Products containing saccharide radicals (other than mash or wort) produced by malt, malt diastase, or malt extract are provided for here.

Search This Class, Subclass:

174+, for immobilized beta-amylase preparations.

201, for beta-amylase type enzymes.

96. Produced by the Action of an Exo-1.4 Alpha Glucosidase, e.g., Dextrose by the Action of Glucoamylase on Starch, etc.:
Processes under subclass 72 wherein the product synthesized is

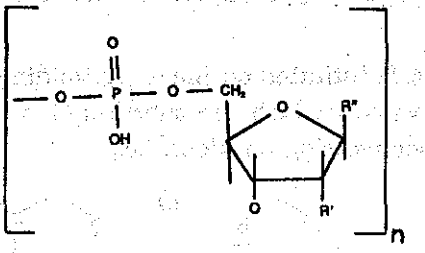
(1) **Note.** See subclass 87 Note (1) for a definition of substituted.

89. Nucleotide:
Processes under subclass 85 wherein the nitrogen is part of a purine or pyrimidine or a substituted purine or pyrimidine ring and the compound additionally contains a phosphoric acid residue esterified to one of the hydroxyl groups of a saccharide moiety.

90. Dinucleotide, e.g., NAD, etc.:
Processes under subclass 89 wherein the product contains only two nucleotides joined through esterified phosphoric acid residues.

(1) **Note.** See subclass 87, Note (1) for definition of the term substituted.

91. Polynucleotide, e.g., Nucleic Acid Oligoribonucleotides, etc.:
Processes under subclass 89 wherein the product synthesized is



where n is a whole number equal or greater than two, R′ = H, OH and R″ = purine or pyrimidine or a substituted purine or pyrimidine.

(1) **Note.** See subclass 87, Note (1) for a definition of substituted.

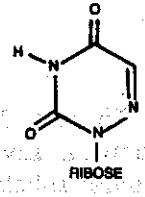
92. Having a Fused Ring Containing a Six-Membered Ring Having Two N-Atoms in the Same Ring, e.g., Purine Based Mononucleotides, etc.:

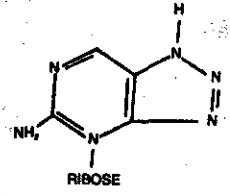
84. Preparing Nitrogen-Containing Saccharide:
Processes under subclass 72 wherein the product synthesized has a nitrogen-containing group bonded to a chain carbon of the saccharide or polysaccharide.

85. N-Glycoside:
Processes under subclass 84 wherein the product synthesized is a glycosidic derivative of the cyclic forms of saccharides or polysaccharides in which the aglycone portion is attached through nitrogen to the saccharide moiety by substituting it for the hemiacetal hydroxyl of the sugar.

(1) **Note.** The aglycone can be noncyclic.

(2) **Note.** N-glycosides in which the aglycone is purine or pyrimidine in which the ring structure is intact are provided for in subclasses 87 and 89. Compounds such as

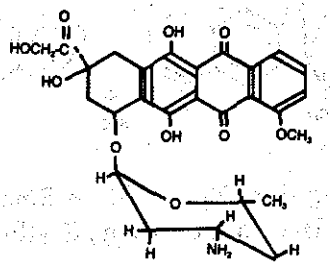
6-azauracil riboside  or

8-azaguanine riboside  are

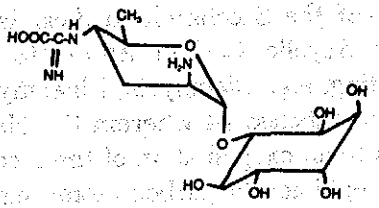
not considered to be within this meaning and thus, are here in subclass 85.

86. Cobalamin, i.e., Vitamin B_{12}, LLD Factor:
Processes under subclass 85 wherein the product synthesized has the following structure:

78. Oxygen Atom of the Saccharide Radical Is Directly Bonded to a Condensed Ring System Having Three or More Carbocyclic Rings, e.g., Dauomycin, Adriamycin, etc.:
Processes under subclass 74 wherein a condensed ring system having three or more carbocyclic rings is directly bonded to an oxygen atom of the saccharide radical, e.g.,



79. Oxygen Atom of the Saccharide Radical Is Bonded to a Cyclohexyl Radical, e.g., Kasugamycin etc:
Processes under subclass 74 wherein a cyclohexyl radical is bonded to an oxygen atom of the saccharide radical, e.g.,



80. Cyclohexyl Radical Is Substituted by Two or More Nitrogen Atoms, e.g., Destomycin, Neamin, etc.:
Processes under subclass 79 wherein two or more nitrogen atoms are attached to the cyclohexyl radical [formula omitted].

81. Cyclohexyl Radical Is Attached Directly to a Nitrogen Atom of Two or More N—C(=N)—N Radicals, e.g., Streptomycin, etc.:
Processes under subclass 80 wherein nitrogen atoms of two or

(2) **Note.** The aglycone is a nonsaccharide material, e.g., benzene, indoxyl, anthracene, etc.

(3) **Note.** On complete hydrolysis S-glycosides yield one or more monosaccharides, and a mono or a polyhydric thiol or thiol phenol.

(4) **Note.** The cyclic sugars referred to in the definitions are normally pyranoses or furanoses.

(5) **Note.** Glycosides derived from aldoses are referred to as aldosides, and those from ketoses are ketosides.

74. Preparing O-Glycoside, e.g., Glucosides, etc.:
Processes under subclass 72 wherein the product synthesized is an acetal derivative of a cyclic form of sugars in which the hydrogen atom of the hemiacetal hydroxyl has been replaced by an alkyl, aralkyl, or aryl group.

(1) **Note.** An O-glycoside is a compound having a sugar moiety connected to an aglycone moiety via oxygen.

(2) **Note.** The aglycone is a nonsaccharide material, e.g., benzene, indoxyl, anthracene, etc.

(3) **Note.** On complete hydrolysis O-glycosides yield one or more monosaccharides, and a mono or polyhydric alcohol or phenol.

(4) **Note.** The cyclic sugars referred to in the definitions are normally pyranoses or furanoses.

(5) **Note.** Glycosides derived from aldoses are referred to as aldosides, and those from ketoses are ketosides.

75. Oxygen of the Saccharide Radical Is Directly Bonded to a Nonsaccharide Ring or a Fused- or Bridged-Ring System Which

formed by hydrolysis of a peptide bond and contains at least one peptide bond.

(1) **Note.** A peptide bond is defined as an amide linkage between two amino acid residues.

70. Having a Known Sequence of Two or More Amino Acids, e.g., Glutanthione, etc.:
Processes under subclass 68 wherein the product contains two or more amino acids linked by a peptide bond and has a known sequence of at least two amino acids.

(1) **Note.** This subclass will provide for partially sequenced polypeptides where only parts of the whole structure have been elucidated so long as the sequence of at least two amino acids is known.

(2) **Note.** The concept of known sequence is not limited to the disclosure in a given document. Available structures in the literature should always be consulted.

71. Cyclic or Bridged Peptide or Polypeptide, e.g., Bacitracin, etc.:
Processes under subclass 70 wherein the product synthesized contains a ring structure composed of four or more amino acids linked by peptide bonds.

72. Preparing Compound Containing Saccharide Radical:
Processes under subclass 41 wherein the product synthesized contains a saccharide or polysaccharide, the monomeric units of which contain at least five-carbon atoms, or their reaction products wherein the carbon skeleton of the saccharide or polysaccharide of the unit is not destroyed.

(1) **Note.** Included herein is cellulose, derivatized cellulose, starch, derivatized starch, sugars, lignins, tannins, o-glycosides, n-glycosides, and s-glycosides.

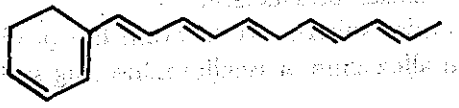
(2) **Note.** Processes wherein the product synthesized is a degradation product which contains fewer than five-carbon

(2) **Note.** Saccharide derivatives are excluded herefrom.

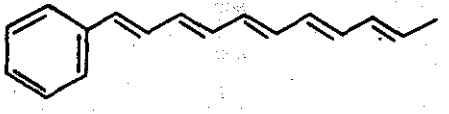
Search This Class, Subclass:

72+, for saccharide derivatives of these compounds.

67. Preparing Compound Containing a Carotene Nucleus, i.e., Carotene:
Processes under subclass 41 wherein the product synthesized contains



or



(1) **Note.** Caroteniods having a cyclic group are properly classified here.

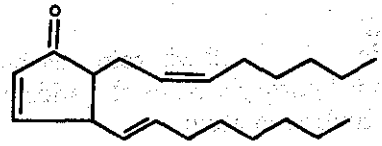
(2) **Note.** Structures above can be partially hydrogenated such as Phytofluene.

Search This Class, Subclass:

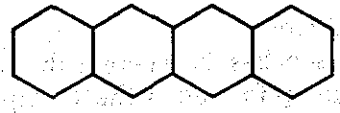
166, for the acyclic carotenoid, lycopene.

68. Preparing Peptide or Proteins:
Processes under subclass 41 wherein the product is a high molecular weight polypeptide of alpha amino acids or consists of two or more amino acids linked by a peptide bond.

most one bond to halogen, and the other side-chain having at least one oxygen atom bound in position to the ring, i.e., prostaglandins having the structure,



64. Preparing Compound Other than Saccharide Containing a Tetracycline Nucleus, e.g., Naphthacene, etc.:
Processes under subclass 41 wherein the product synthesized contains a naphthacene ring system, i.e.,



and nonsaccharide ring unsaturated derivatives thereof.

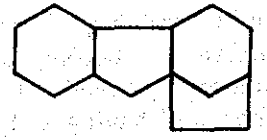
(1) **Note.** Tetracyclines are properly classified here.

(2) **Note.** Saccharide derivatives are excluded herefrom.

Search This Class, Subclass:

78, for saccharide derivatives.

65. Preparing Compound Other than Saccharide Containing a Gibberellin Nucleus, i.e., Gibbane:
Processes under subclass 41 wherein the product synthesized contains



other than the saccharide.

(1) **Note.** The phenanthrene ring system contains more hydrogen than is present in phenanthrene.

(2) **Note.** Common atoms of two rings are considered to belong to the rightmost ring.

(3) **Note.** Homo derivatives wherein the D-ring is expanded to 6-carbons such as in Hellebrin are found here.

53. Containing Heterocyclic Ring:
Processes under subclass 52 wherein the cyclopentenophenanthrene ring system synthesized contains an additional ring which is a hetero ring.

(1) **Note.** The hetero ring may be fused or bridged with the cyclopentenophenanthrene ring system.

54. Action on D-Ring:
Processes under subclass 52 wherein the product synthesized is formed by biochemical transformation within the D-ring.

(1) **Note.** The 13-and-14 positions are considered to be on the D-ring.

55. Acting at 17-Position:
Processes under subclass 54 wherein the product synthesized is formed by biochemical transformation at the 17-position.

(1) **Note.** This subclass includes cleavage of the 17-side chain with the formation of keto or hydroxy groups at the cleaved position.

56. Hydroxylating at 17-Position:
Processes under subclass 55 wherein the product synthesized has a hydroxyl group at the 17-position and is formed by the addition of an oxygen atom to the pendant hydrogen atom.

57. Hydroxylating at 16-Position:

must contain the 1-thia-4-aza-bicyclo heptane ring system compound.

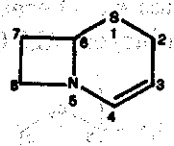
44. By Desacylation of the Substituent in 6-Position:
Processes under subclass 43 wherein the product synthesized is prepared by the hydrolysis of an acetyl group in the 6-position.

45. By Acylation of the Substituent in 6-Position:
Processes under subclass 43 wherein the product synthesized is prepared by substituting an acyl group in the 6-position.

(1) **Note.** The media of the processes included herein must contain the 1-thia-4-aza-bicyclo heptane ring system compound.

46. In Presence of Phenyl Acetic Acid or Phenyl Acetamide or Their Derivatives:
Processes under subclass 43 wherein phenyl acetic acid or substituted phenyl acetic acid or salts thereof or phenyl acetamide or substituted phenyl acetamide or salts thereof is present during the synthesis.

47. Preparing Compounds Having a 1-thia-5-aza-bicyclo (4.2.0) Octane Ring System, e.g., Cephalosporin, etc.:
Processes under subclass 41 wherein the product synthesized contains a 1-thia-5-aza-bicyclo (4.2.0) octane polycyclic ring system, i.e.,



48. Di-Substituted in 7-Position:
Processes under subclass 47 wherein the polycyclic ring system synthesized contains two substituents other than hydrogen in the 7-position.

tinomycetales unicellular, algae plant cells actinomycetales, and protozoa.

(2) **Note.** Synthesis for purposes of this subclass involves the preparation of a composition or compound which did not exist in the starting material, and does not include an ancillary operation wherein a material is chemically modified by an enzyme, cell free or immobilized, or microorganism or animal or plant cell so as to degrade or change the chemical structure thereof so that another material which is in initial intimate contact with the modified material can be recovered in a nonmodified form. See in particular, subclasses 262+ of this schedule for such liberation or purification processes.

(3) **Note.** As between Class 260 and this class (435) provide an original home for all synthesis which include action by a microorganism or enzyme.

(4) **Note.** Enzymes for the purpose of this subclass are polypeptides or proteins or material containing the same which are capable of chemically transforming matter, e.g., oxidation, etc., without undergoing a transformation itself.

(5) **Note.** Processes for producing an enzyme or microorganism are excluded herefrom and are found in subclasses 183+ and 243+.

(6) **Note.** Processes for the production of products in which the structure is not disclosed should be placed in this and the indented subclasses in the first appearing subclass which takes an identified constituent of the product. Should such a placement prove impossible, then placement is on the basis of the microorganism's identity.

Search Class:

204, Chemistry, Electrical and Wave Energy, for chemical processes including electrical or wave energy methods.

(1) **Note.** Included herein are test media that contains chemicals which change or remain unchanged in color or other physical appearance due to the action of or the absence of action of the microorganisms on the test media.

(2) **Note.** This subclass includes but is not restricted to testing of biological samples.

(3) **Note.** Test media includes culture media plus a chromophore.

(4) **Note.** This subclass includes determining the metabolic character of a microorganism, *i.e.*, the production or consumption of a particular metabolite.

Search This Class, Subclass:

32 and 33, for similar process used to test for antimicrobial sensitivity.

35. Using Radioactive Material:
Subject matter under subclass 34 where the test media contains an assimilable radioactive labeled compound.

36. Streptococcus; Staphylococcus:
Subject matter under subclass 34 where the microorganisms involved are Streptococcus or Staphylococcus or the agent is specific for indicating the presence or absence of Streptococcus or Staphylococcus.

37. Nitrate to Nitrite Reducing Bacteria:
Subject matter under subclass 34 where the microorganisms involved are nitrite forming bacteria or the agent is specific for indicating the presence or absence of nitrite forming bacteria.

(1) **Note.** It should be generally presumed that the presence of the nitrite is due to bacterial conversion of nitrate to nitrite.

subclass 3 for a process of staining cells or a tissue sample for purposes of microscopic examination.

427, Coating Processes, subclass 2 for coating a biological specimen for a medical test.

30. Methods of Sampling or Innoculating or Spreading a Sample; Methods of Physically Isolating an Intact Microorganism: Processes under subclass 29 in which (a) a series of sampling steps are claimed in which a sample containing a microorganism is separated or recovered from a larger body of material before or while performing a measurement or test, or (b) a sample is brought into contact with a measuring or testing media to result in a particular geometric pattern or at a particular varying flow rate.

(1) **Note.** This subclass provides for sampling when claimed by a *series* of sampling process steps, i.e., not sampling by name only.

(2) **Note.** This subclass provides for applying the sample in a particularly claimed varying flow rate or pattern or path other than merely a single straight line.

(3) **Note.** Mere nonpattern applications such as dipping or spaying is not included herein.

(4) **Note.** Included in this subclass is a test or measurement which includes a swab streaking procedure or centrifugal density separation step.

Search This Class, Subclass:

243, for sampling, innoculating, spreading a sample or physical isolation of samples which are not claimed as part of a test.

292, for innoculation and sampling apparatus.

sured or tested contains cholinesterase or acetylcholinesterase or the agent used for the measurement or tests contains cholinesterase or acetylcholinesterase.

21. Involving Phosphatase:
Subject matter under subclass 19 where the material to be measured or tested contains a phosphatase or the agent used for the measurement or test contains a phosphatase.

(1) **Note.** Phosphatase includes all of the phosphoric monoester hydrolases (ICE classification 3.1.3) including the phytases and the nucleotidases.

22. Involving Amylase:
Subject matter under subclass 18 where the material to be measured or tested contains amylase or the agent used for the measurement or test contains amylase.

23. Involving Proteinase:
Subject matter under subclass 18 where the material to be measured or tested contains proteinase (endopeptidase) or the agent used for the measurement or test contains a proteinase (endopeptidase).

(1) **Note.** Enzymes included in this subclass are trypsin, pepsin, ficin, bromelin, papain, renin.

(2) **Note.** Where the hydrolytic activity of an enzyme on a protein or polypeptide is unclear it should be presumed to be an endopeptidase, classifiable in subclass 23.

24. Involving Peptidase:
Subject matter under subclass 18 where the material to be measured or tested contains a peptidase (exopeptidase) or the agent used for the measurement or test contains a peptidase (exopeptidase).

25. Involving Oxidoreductase:
Subject matter under subclass 4 where the material to be mea-

8. Involving Luciferase:
Subject matter under subclass 4 where the material to be measured or tested contains luciferase or the agent used for the measurement or test contains luciferase.

(1) **Note.** Firefly extract or firefly lantern extract contains luciferase.

9. Geomicrobiological Testing, e.g., for Petroleum, etc:
Subject matter under subclass 4 where the measurement or test is for the presence or absence of mineral deposits or for the presence of microorganisms which thrive in the presence of such minerals.

(1) **Note.** This subclass provides for detection of underground deposits of petroleum or natural gas.

10. Involving Uric Acid:
Subject matter under subclass 4 where the material to be measured or tested contains uric acid or the agent used for the measurement or test contains uric acid.

11. Involving Cholesterol:
Subject matter under subclass 4 where the material to be measured or tested contains cholesterol or the agent used for the measurement or test contains cholesterol.

12. Involving Urea or Urease:
Subject matter under subclass 4 where the material to be measured or tested contains urea or urease or the agent used for the measurement or test contains urea or urease.

13. Involving Blood Clotting Factor, e.g., Involving Thrombin, Thromboplastin, Fibrinogen, etc.:
Subject matter under subclass 4 where the material to be measured or tested contains a blood clotting factor or the agent used for the measurement or test contains a blood clotting factor.

Search Class:

346, Recorders, subclass 1 for recording processes per se.

350, Optics, Systems and Elements, subclasses 92-95 for transparent microscope slides with means to contain and support the life functions of a microorganism.

356, Optics, Measuring and Testing, especially subclasses 4, 28, 141, 152, 205+, and 218 for methods and apparatus for optical testing with a photoelectric light detector with either an indicator or structure to support or contain the specimen or sample under test. Class 356 provides for methods and apparatus for visual counting of bacteria colonies, etc., with a scale or spacer to aid the eye without an optical element or statistical analysis procedures for the sizing and counting of particles, such as bacteria colonies by visible light and the counting of particles one by one with a microscope having a graticule rather than a cross hair or recticle.

364, Electrical Computers and Data Processing Systems, subclass 496 for data processing systems or calculating computer designed for use in chemistry, chemical engineering or other areas of engineering or for the solution of problems in these areas.

424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 2+ for a composition or method of in vivo testing (diagnosing) a living body or for an in vivo method of testing or analyzing a composition of that class (424).

5. Involving Virus or Bacteriophage:
Subject matter under subclass 4 where the material to be measured or tested contains a virus or bacteriophage or the agent used for the measurement or test contains a virus or bacteriophage.

6. Involving Nucleic Acid:
Subject matter under subclass 4 where the material to be tested or the composition in which the test is conducted contains nu-

presence or absence of the designated chemical compound, microorganism, plant or animal cell or enzyme.

(2) Note. The enzyme herein can be free or immobilized or present in a cell, tissue, or organ.

(3) Note. Compositions herein may include inert carriers that have either a single or multiple zones of chemical agents. Included as carriers are bibilous or absorbent materials and films.

Search This Class, Subclass:

174+, for immobilized enzymes per se.

183+, for enzymes.

188, for stabilized enzymes, enzyme conjugates or compositions thereof.

235+, for viruses per se.

287+, for apparatus for measuring and testing.

Search Class:

23, Chemistry, Analytical and Physical Processes, subclasses 230+ for processes for analysis involving steps for causing or promoting a chemical reaction, regulating or controlling a chemical reaction. This includes tests dependent upon the chemical, i.e., proteinaceous reactivity of an enzyme as opposed to its catalytic functioning provided for in Class 435. Measurements and tests when claimed in association with chemical processes provided for in other Classes, e.g., 435, 208, 260, 423, etc., are classified in the class providing for the chemical process.

(2) **Note.** This subclass provides for compositions for artificial insemination.

Search This Class, Subclass:

235+, where the tissue or cell culture is concommitant with virus propagation.

243+, for culture media for propagating microorganism.

Search Class:

62, Refrigeration, for methods of maintaining the viability of living tissue and cells including sperm under refrigeration or in a frozen state. These processes may include the addition of chemical agents to prevent or minimize cellular damage from the refrigeration.

128, Surgery, appropriate subclasses for a method of blood transfusion or artificial insemination.

424, Drug, Bio-Affecting and Body Treating Compositions, subclass 88 for therapeutic compositions containing a living cell which functions as an antigen; and subclass 101 for therapeutic compositions containing viable blood cells and a therapeutically active ingredient. Class 424 further provides for processes of radioactive labeling of blood cells for radio pharmaceutical use such as visualization of internal organs and the composition for such use. Class 424 also provides for cell histology compositions whereas Class 435 provides for the use of such compositions.

3. Condition Responsive Control Process:
Process under the class definition in which a process parameter is measured and that or another process parameter is varied responsive to such measurement.

(1) **Note.** The measurement should be by a nonsubjective

pounds other than an immobilized or insolubilized enzyme or an enzyme per se. Production of metal or ammonium salts of a compound are classified with the production of that compound.

Amino Acid Residues—If upon hydrolysis of an unidentified product the only residues are amino acids, it should be presumed that the product is a protein or peptide. If other organic moieties are present after hydrolysis of the product then placement should be made upon the basis of the presence of such structure in the product.

Presumption—In the absence of a clearly claimed step of killing or inactivating a microorganism in an antigen-antibody test the microorganism should be treated as a living antigen.

SUBCLASSES

1. Differentiated Tissue or Organ Other than Blood Per Se or Differentiated Tissue or Organ Maintaining; Compositions Therefor; Apparatus Therefor:
Processes, apparatus or compositions under the class definition for the maintenance of differentiated tissue or organs or the differentiated tissue or organ per se.

(1) **Note.** Maintenance includes keeping an organ under conditions in which it produces a product, *e.g.*, hormone, etc., which is later recovered.

(2) **Note.** Tissue is presumed to be undifferentiated in the absence of a clear showing to the contrary. The fact that a tissue continues to produce hormones, etc., is to be taken as an indication that the tissue retains its differentiation.

(3) **Note.** For a process to be classified in this subclass, the tissue must be maintained in a viable state (*e.g.*, in a nutrient or life sustaining media) and the tissue must contain an intergral cell wall. Thus, the preservation of blood plasma provided for in subclass 2 is excluded from this subclass.

		281, 283, 311
215		287, 298, 299
235		4
250	II B	29
252	II A	4, 262, 264
259	II B	266, 281
260	II A, B	4, 68, 72, 155, 174, 262, 272, 274, 277
261		266, 283
264		174
299		281
324		4, 289, 291
346		4, 289, 291
350		4, 39
356		4
364		3, 4, 289
422		288, 304, 306, 310, 311, 312
423	II B	262, 283
424	II A	2, 4, 29, 68, 173, 235, 236, 245, 255, 269
426	II A	41, 68, 140, 155, 174, 243, 248, 255, 257
427		29
428		68, 174
429	II A	
430	II A	
432		312
536		72

V. Glossary

Activity—Rate of metabolic or anabolic action, speed or efficiency. Mere suppression of competing strains is not viewed as increasing the activity.

Biochemical—By means of a bacteria, yeast, animal or plant cell, or virus, or the parts thereof.

Condensed—Bridged or fused.

in part IVA of the headnotes to classes providing for similar subject matter.

Class 435 provides for the use of radiant energy to alter the genetic structure of a microorganism as part of a measuring and testing process or in combination with microbial growth or enzymology.

Class 366 provides for apparatus and processes restricted to causing fluid or particulate material to move irregularly and commingle.

Class 435 provides for apparatus with agitators claimed or solely disclosed as useful for microorganism propagation or enzymology and for processes of microorganism propagation or enzymology which may include an agitation step.

Class 260, Chemistry, Carbon Compounds, provides for organic compounds per se and methods of synthesizing them by means other than a microorganism or enzyme.

Class 423, Chemistry, Inorganic, provides for processes of purification of fermentation off gas by chemical means as well as the recovery of metal values by means other than microorganisms or enzymes.

Class 435 provides for processes of synthesis of organic or inorganic compounds involving a microorganism or enzyme.

III. Search Class Notes

In general, in subclasses 84+ indented, subclasses 95, 96, 98, and 99 compounds are produced by hydrolysis of larger structures with subclasses 97 and 100 thru 105 providing for building up from smaller saccharide units, while subclass 94 is reserved for the enzymatic interconversion of isomers.

IV. Index to Line and Search Notes in Class Definitions Sections and Subclasses of This Class

an enzyme in a testing composition functions catalytically until rebutted.

Class 435 provides for in vitro testing by or for a microorganism or enzyme or tests involving the propagation of a microorganism or catalytic use of an enzyme. Class 435 provides for antigen-antibody tests wherein a living antigen, *i.e.*, a microorganism is involved or an enzyme label is present.

Class 34, Drying and Gas or Vapor Contact with Solids, provides for processes and apparatus for drying of a solid which may include a microorganism enzyme or media composition.

Class 435 provides for processes of culture or propagation of microorganism including the production of enzymes and media and provides for the combination of culture or production with drying or another Class 34 operation.

Class 48, Gas, Heating and Illuminating, for gaseous compositions for heating or illuminating by combustion which may be the result of a process using a microorganism or enzyme.

Class 73, Measuring and Testing, provides for processes and apparatus for determining the physical properties of the product of fermentation or enzymology and include process and apparatus for measuring the rate of sedimentation of elements in blood.

Class 435 provides for processes and apparatus and material for measuring and testing blood which involve the propagation of a microorganism or catalytic functioning of an enzyme.

Class 99, Foods and Beverages: Apparatus, for apparatus adapted for the preparation of a beverage or beverage intermediate by carrying out primary ethyl alcoholic fermentations and apparatus for the aging, refining, and purification of alcholic beverages.

croorganism or using an enzyme to produce a drug or bio-affecting composition. Class 435 provides for virus culture and attenuation, for the virus or microorganism per se and their culture and propagation and for in vitro diagnostic tests involving a microorganism or enzyme and antigen antibody tests which involve a living microorganism or use of an enzyme label.

Class 426, Food or Edible Material: Processes, Compositions and Products, provides for fermentation processes that are solely disclosed or claimed as preparing an edible, and for mixtures of enzymes or ferments solely disclosed or claimed as edible or used in the preparation of an edible. Class 426 provides for compositions and processes of preparation relating to compositions which have the capacity to ferment and produce an edible, but which are claimed as being in an inactive state, and also provides for compositions which are undergoing a fermentation to produce an edible product. See especially subclasses 11+ for alcoholic beverages, or other beverages, milk or other alimentary articles or compositions, when the beverage or other alimentary articles contain bacteria or enzymes; processes of making the same which include microorganisms or enzymes. Processes of autolysis or microbial or enzymic destruction of yeasts or other living organisms are in Class 435, subclasses 262+, but processes of preparing foods including such autolysis are in Class 426. Processes of making vinegar by methods including use of a microorganism or enzyme are in Class 426.

Class 435 provides for processes and apparatus of production of nonpotable ethanol and acetic acid and for processes and apparatus for diastatic mashing as well as fermentation other than primary fermentations. Class 435 also provides for compositions and processes of producing a microorganism containing starter culture useful in the production of an edible product.

Class 435, will provide for production of protein from a single source by fermentation or enzymology even if the product is claimed as having a Class 426 utility. For an

or enzyme is measured by change in electrolytic action; for electrolytic or electrophoretic or electroosmotic separation and purification of an enzyme; for the use of electrolytic or electrophoretic or electroosmotic techniques to immobilize an enzyme; for processes of use of an electrode containing a microorganism or enzyme and for the apparatus, which may include a microorganism or enzyme, for the above processes.

Class 435 provides for processes and apparatus for measuring or testing in which a microorganism is cultured or an enzyme functions catalytically when a nonelectrical property is measured for processes of purification and immobilization of enzymes and for processes using an enzyme to produce a product.

Class 210, Liquid Purification or Separation, provides for processes of treating impure liquids by processes including a microorganism, *e.g.*, bacteriological digestion of sewage including the use of an immobilized microorganism and the apparatus for such processes, as well as methods of physical separation of microorganisms and viruses from liquid media.

Class 435 provides for the growth of a microorganism on a liquid media and the apparatus therefor as well as providing for process utilizing an immobilized microorganism and the immobilized microorganism per se.

Class 252, Compositions, provides for detergent compositions containing enzymes.

Class 435 provides for process of production of enzymes and enzymes per se and enzyme compositions not otherwise provided for.

Class 260, Chemistry, Carbon Compounds, provides for the synthesis and liberation and purification by chemical or physical means of compounds and extracts falling within the class definition of Class 260 where such processes do not include a step of treatment by a microorganism or enzyme. Processes of making chemical compounds that include the use of a microorganism or

processes of obtaining free metals from metal compounds or ores.

Class 75, in particular, provides for processes of hydrometallurgy processes of beneficiating ores or recovery of elemental metal from waste in which a microorganism or enzyme is used when the reduction to elemental metal is claimed.

Class 435 provides for the process of producing a microorganism or enzyme useful in ore treating and for processes of cultivating microorganisms on sulfur containing media.

Class 106, Compositions, Coating or Plastic, provides for processes which use an enzyme or microorganism to produce a coating or plastic composition.

Class 435 provides for the use of a microorganism or enzyme to produce a product which may be a composition not otherwise provided for.

Class 127, Sugar, Starch and Carbohydrates, provides for the hydrolysis of carbohydrates including their conversion to sugar by chemical means or process using an enzyme or microorganism only where the hydrolysis by microorganism or enzyme is followed by steps of concentration purification or treatment (such as crystallization) to make a sugar or syrup. Additionally, Class 127 provides for the products of such processes.

Class 435 provides for hydrolysis of a carbohydrate by a microorganism or enzyme when not followed by steps of concentration, purification, or treatmentto make a sugar or syrup. Class 435, also, provides for hydrolysis by any method when followed by treatment with a microorganism or enzyme to produce alcohol.

Class 128, Surgery, appropriate subclasses provide for methods of blood transfusion and insemination by artificial means as well as for methods of treatment of the living body or a test which involves contact with a body and apparatus used in the inspection and treatment of

provides for a measurement or test in which an enzyme reacts chemically, *i.e.*, non-catalytically and antigen antibody tests for the identification of chemical species that are non-diagnostic and do not involve a living antigen.

Class 435, provides for a test or measurement involving a microorganism or enzyme which functions catalytically as well as antigen antibody tests involving a living microorganism.

(1) **Note.** The burden of showing an enzyme is functioning non-catalytically is in Class 23, *i.e.*, the presumption, as between Class 435 and Class 23, is that an enzyme in a test functions catalytically until rebutted.

Class 47, Plant Husbandry, which provides for mushrooms or processes of or apparatus for cultivating or culturing mushrooms; sprouting or germinating seeds for planting, or testing the sprouting or germinating power of seeds; articles or compositions that include seeds and either a microorganism or enzyme and process of making such articles or compositions; processes of cultivating or culturing seed plants, or other nonfungal plants that include the use of a microorganism or enzyme, articles, compositions, or apparatus, for use in the above processes, or in making articles or compositions, that include seeds and microorganism or enzymes or processes of making articles or compositions for use in the above noted processes.

Class 435 provides for materials that contain germinated seeds, for processes that include germinating seeds or for apparatus for use therein, *e.g.*, malting grain and malting apparatus, etc., as well as processes involving propagation of unicellular algae or undifferentiated plant cells where there is no plant propagation and for the extraction of enzymes from plants or plant products.

Class 435, also, provides for the production of starter culture for mushrooms or for the propagation of undifferentiated plant cells as well as the culture of unicellular algae.

the presence or identity of a compound or composition in a sample.

(2) A microorganism is identified by propagation.

(*Text continued on page App.1-23*)

883 . . . Staphylicoccus aureus
884 . . . Staphylococcus epidermidis
885 . . Streptococcus
886 . . Streptomyces
887 . . . Streptomyces albus
888 . . . Streptomyces antibioticus
889 . . . Streptomyces aureofaciens
890 . . . Streptomyces aureus
891 . . . Streptomyces bikiniensia
892 . . . Streptomyces candidus
893 . . . Streptomyces chartreusis
894 . . . Streptomyces diastatochromogenes
895 . . . Streptomyces filipinensigs
896 . . . Streptomyces fradiae
897 . . . Streptomyces griseus
898 . . . Streptomyces hygroscopicus
899 . . . Streptomyces lavendulae
900 . . . Streptomyces lincolnensis
901 . . . Streptomyces noursei
902 . . . Streptomyces olivaceus
903 . . . Streptomuces platensis
904 . . . Streptomyces rimosus
905 . . . Streptomyces sparogenes
906 . . . Streptomyces venezuelae
907 . . Streptosporangium
908 . . Streptovirticillium
909 . . Vibrio
910 . . Xanthomonas
911 . Using fungi
912 . .Absidia
913 . . Aspergillus
914 . . . Aspergillus awamori
915 . . . Aspergillus flavus
916 . . . Aspergillus fumigatus
917 . . . Aspergillus niger
918 . . . Aspergillus oryzae
919 . . . Aspergillus ustus
920 . . . Aspergillus wenti
921 . . Candida

SUBCELLULAR PARTS OF MICROORGANISMS
. Using fungi
. . Candida

922 . . . Candida albicans

802 LOGARITHMIC GROWTH PHASE
803 PHYSICAL RECOVERY METHODS, *E.G.*, CHROMATOGRAPHY, GRINDING
804 SINGLE CELL PROTEIN
805 TEST PAPERS
806 FERTILITY TESTS
807 GAS DETECTION APPARATUS
808 OPTICAL SENSING APPARATUS
809 INCUBATORS OR RACKS OR HOLDERS FOR CULTURE PLATES OR CONTAINERS
810 PACKAGED DEVICE OR KIT
811 INTERFERON
812 FOAM CONTROL
813 CONTINUOUS FERMENTATION
814 ENZYME SEPARATION OR PURIFICATION
815 . By sorption
816 . By solubility
817 ENZYME OR MICROBE ELECTRODE
818 AERATION OR OXYGEN TRANSFER TECHNIQUE
819 FERMENTATION VESSELS IN SERIES
820 SUBCELLULAR PARTS OF MICROORGANISMS

MICROORGANISMS CROSS-REFERENCE ART COLLECTIONS

822 . Using bacteria or actinomycetales
823 . . Acetobacter
824 . . Achromobacter
825 . . Actinomadura
826 . . Actinomyces
827 . . Actinoplanes
828 . . Aerobacter
829 . . Alcaligenes
830 . . Arthrobacter
831 . . Azotobacter
832 . . Bacillus
833 . . . Bacillus brevis
834 . . . Bacillus cereus
835 . . . Bacillus circulans
836 . . . Bacillus licheniformis
837 . . . Bacillus megaterium
838 . . . Bacillus polymyxa
839 . . . Bacillus subtilis

249 . . Aliphatic
250 . . . Having five or less carbon atoms
251 . Utilizing media containing waste sulphite liquor
252 . Utilizing media containing cellulose or hydrolysates thereof
253 . Bacteria; media therefor
254 . Fungi; media therefor
255 . . Yeast; media therefor
256 . . . Bakers or brewers yeast
257 . Unicellular algae; media therefor
258 . Protozoa; media therefor
259 . Lysis of microorganism
260 . Preserving or maintaining microorganism
261 . Separation of microorganism from culture media
320 . Plasmids, per se, phage vectors, per se, and subcellular parts of microorganisms, *e.g.*, organelles, etc.
262 PROCESS OF UTILIZING AN ENZYME OR MICROORGANISM TO LIBERATE, SEPARATE, OR PURIFY A PREEXISTING COMPOUND OR COMPOSITION THEREFORE; CLEANING OBJECTS OR TEXTILES
263 . Textile treating
264 . Cleaning using a microorganism or enzyme
265 . Depilating hides, bating or hide treating using enzyme or microorganism
266 . Treating gas, emulsion, or foam
267 . Treating animal or plant material or microorganism
268 . . Treating organ or animal secretion
269 . . Treating blood fraction
270 . . Removing nucleic acid from intact or disrupted cell
271 . . Glyceridic oil, fat, ester-type wax or higher fatty acid recovered or purified
272 . . Proteinaceous material recovered or purified
273 . . . Collagen or gelatin
274 . . Carbohydrate material recovered or purified
275 . . . Pectin or starch
276 . . . Sugar, *e.g.*, molasses treatment, etc.
277 . . . Cellulose, *e.g.*, plant fibers, etc.
278 . . . . Producing paper pulp
279 . . . . Hemp or flax treating
280 . Resolution of optical isomers or purification of organic compounds or composition containing same
281 . Petroleum oil or shale oil treating
282 . . Desulfurizing
283 ORGAN PERFUSION APPARATUS

209 . . . Acting on beta-1, 4-glucosidic bond, *e.g.*, cellulase, etc. (3.2.1.4)
210 . . . Acting on alpha-1, 6-glucosidic bond, *e.g.*, isoamylase, pullulanase, etc.
211 . . . . Dextranase (3.2.1.11)
212 . . Acting on peptide bond, *e.g.*, thromboplastin, leucine amino-peptidase, etc., (3.4)
213 . . . Trypsin; chymotrypsin
214 . . . Thrombin
215 . . . Urokinase
216 . . . Streptokinase
217 . . . Plasmin, *i.e.*, fibrinolysin
218 . . . Elastase
219 . . . Proteinase
220 . . . . Derived from bacteria
221 . . . . . Bacteria is Bacillus
222 . . . . . Bacillus subtilus or Bacillus lichenoformis
223 . . . . Derived from fungi
224 . . . . . From yeast
225 . . . . . From Aspergillus
226 . . . . Derived from animal tissue, *e.g.*, rennin, etc.
227 . . Acting on carbon to nitrogen bond other than peptide bond (3.5)

ENZYME, *E.G.*, LIGASES (6.), ETC., PROENZYME; COMPOSITIONS THEREOF; PROCESS FOR PREPARING, ACTIVATING, INHIBITING, SEPARATING, OR PURIFYING ENZYMES

. Hydrolase (3.)
. . Acting on carbon to nitrogen bond other than peptide bond (3.5)
228 . . . Acting on a linear amide linkage in linear amide
229 . . . . Asparaginase
230 . . . . Penicillin amidase
231 . . . Acting on amide linkage in cyclic amides, *e.g.*, penicillinase, etc. (3.5.2)
232 . Lyase (4.)
233 . Isomerase (5.)
234 . . Glucose isomerase
235 VIRUS; BACTERIOPHAGE; COMPOSITION THEREOF; PREPARATION OR PURIFICATION THEREOF PRODUCING VIRAL SUBUNITS
236 . Inactivation or attenuation; producing viral subunits
237 . . By serial passage of virus
238 . . By chemical treatment
239 . Recovery or purification

150 . . . . Acetone containing product
151 . . . . . Substrate contains grain or cereal material
152 . . . . . Substrate contains protein as nitrogen source
153 . . . . . Substrate contains inorganic nitrogen source
154 . . . . . Substrate contains inorganic compound, other than water
155 . . Containing hydroxy group
156 . . . Aromatic
157 . . . Acyclic
158 . . . . Polyhydric
159 . . . . . Glycerol
160 . . . . Butanol
161 . . . . Ethanol
162 . . . . . Multiple stages of fermentation; multiple types of microorganisms or reuse of microorganisms
163 . . . . . Produced as by-product, or from waste, or from cellulosic material substrate
164 . . . . . Substrate contains sulphite waste liquor or citrus waste
165 . . . . . Substrate contains cellulosic material
166 . Preparing hydrocarbon
167 . . Only acyclic
168 . Preparing element or inorganic compound except carbon dioxide
169 . Using actinomycetales
170 . Using bacteria
171 . Using fungi
172.1 MUTATION OR GENETIC ENGINEERING
172.2 . Fused or hybrid cell formation
172.3 . Recombination
173 TREATMENT OF MICROORGANISM OR ENZYME WITH ELECTRICAL OR WAVE ENERGY, *E.G.*, MAGNETISM, SONIC WAVES, ETC.
174 CARRIER-BOUND OR IMMOBILIZED ENZYME OR MICROBIAL CELL; CARRIER-BOUND OR IMMOBILIZED CELL; PREPARATION THEREOF
175 . Multi-enzyme system
176 . Enzyme or microbial cell is immobilized on or in an inorganic carrier
177 . Enzyme or microbial cell is immobilized on or in an organic carrier
178 . . Carrier is carbohydrate
179 . . . Carbohydrate is cellulose or derivative thereof

95 . . Produced by the action of a beta-amylase, *e.g.*, maltose by the action of beta-amylase or amylose, etc.
96 . . Produced by the action of an exo-1.4 alpha glucosidase, *e.g.*, dextrose by the action of glucoamylase on starch, etc.
97 . . Produced by the action of a glycosyl transferase, *e.g.*, alpha, beta, gamma-cyclodextrins by the action of glycosyl transferase on starch, etc.
98 . . Produced by the action of an alpha-1, 6-glucosidase, *e.g.*, amylose, debranched amylopectin by the action of pullulanase, etc.
99 . . Produced by the action of a carbohydrase, *e.g.*, maltose by the action of alpha amylase on starch, etc.
100 . . Disaccharide
101 . . Polysaccharide of more than five saccharide radicals attached to each other by glycosidic bonds
102 . . . Pullulan
103 . . . Dextran
104 . . . Xanthan, *i.e.*, Xanthomonas-type heteropolysaccharides
105 . . Monosaccharide
106 . Preparing alpha or beta amino acid or substituted amino acid or salts thereof
107 . . Proline; hydroxyproline; histidine
108 . . Tryptophan; tyrosine; phenylalanine; 3,4 dihydroxyphenylalanine
109 . . Aspartic acid (asparaginic acid); asparagine
110 . . Glutamic acid; glutamine
111 . . . Utilizing biotin or its derivatives
112 . . . Utilizing surfactant, fatty acids or fatty acid esters, *i.e.*, having seven or more atoms
113 . . Methionine; cysteine; cystine
114 . . Citrulline; arginine; ornithine
115 . . Lysine; diaminopimelic acid; threonine; valine
116 . . Alanine; leucine; isoleucine; serine; homoserine
117 . Preparing heterocyclic carbon compound having only O, N, S, Se, or Te as ring hetero atoms
118 . . Containing two or more hetero rings
119 . . . Containing at least two hetero rings bridged or fused among themselves or bridged or fused with a common carbocyclic ring system, *e.g.*, rifamycin, etc.
120 . . Nitrogen or oxygen hetero atom and at least one other diverse hetero ring atom in the same ring
121 . . Nitrogen as only ring hetero atom
122 . . . Containing six-membered hetero ring

48 . . Di-substituted in 7-position
49 . . Cephalosporin C
50 . . By acylation of the substituent in the 7-position
51 . . By desacylation of the substituent in the 7-position
52 . Preparing compound containing a cyclopentanohydrophenanthrene nucleus; nor-, homo- or D-ring lactone derivatives thereof
53 . . Containing heterocyclic ring
54 . . Acting on D-ring
55 . . . Acting at 17-position
56 . . . . Hydroxylating at 17-position
57 . . . Hydroxylating at 16-position
58 . . Hydroxylating
59 . . . At 11-position
60 . . . . At 11 alpha position
61 . . Dehydrogenating; dehydroxylating
62 . . . Forming an aryl ring from "A" ring
63 . Preparing compound containing a prostaglandin nucleus
64 . Preparing compound other than saccharide containing a tetracycline nucleus, *e.g.*, naphacene, etc.
65 . Preparing compound other than saccharide containing a gibberellin nucleus, *i.e.*, gibbane
66 . Preparing compound other than saccharide containing alloxazine or isoalloxazine nucleus
67 . Preparing compound containing a carotene nucleus, *i.e.*, carotene
68 . Preparing peptide or protein
69 . . Produced by the hydrolysis of a peptide bond
70 . . Having a known sequence of two or more amino acids, *e.g.*, glutathione, etc.
71 . . . Cyclic or bridged peptide of polypeptide, *e.g.*, bacitracin, etc.
72 . Preparing compound containing saccharide radical
73 . . Preparing S-glycoside, *e.g.*, lincomycin, etc.
74 . . Preparing O-glycoside, *e.g.*, glucosides, etc.
75 . . . Oxygen of the saccharide radical is directly bonded to a nonsaccharide heterocyclic ring or a fused- or bridged-ring system which contains a nonsaccharide heterocyclic ring, *e.g.*, coumermycin, novobiocin, etc.
76 . . . . The hetero ring has eight or more ring members and only oxygen as ring hetero atoms, *e.g.*, erythromycin, spiramycin, nystatin, etc.
77 . . . Oxygen atom of the saccharide radical is directly linked

The PTO will decide the questions as to patentable subject matter under 35 U.S.C. 101 on a case-by-case basis following the tests set forth in *Chakrabarty, e.g.,* that "a nonnaturally occurring manufacture or composition of matter" is patentable, etc. It is inappropriate to try to attempt to set forth here in advance the exact parameters to be followed.

The standard of patentability has not and will not be lowered. The requirements of 35 U.S.C. 102 and 103 still apply. The tests outlined above simply mean that a rational basis will be present for any § 101 determination. In addition, the requirements of 35 U.S.C. 112 must also be met. In this regard, *see* § 608.01(p).

App.1.02 Classification Scheme of the U.S. Patent and Trademark Office

[1] Class 435 Chemistry: Molecular Biology and Microbiology (November 1987)

1 DIFFERENTIATED TISSUE OR ORGAN OTHER THAN BLOOD PER SE OR DIFFERENTIATED TISSUE OR ORGAN MAINTAINING; COMPOSITIONS THEREFOR, APPARATUS THEREFOR

2 MAINTAINING BLOOD OR SPERM IN A PHYSIOLOGICALLY ACTIVE STATE OR COMPOSITIONS THEREOF OR THEREFOR OR METHODS OF IN VITRO BLOOD CELL SEPARATION OR TREATMENT

3 CONDITION RESPONSIVE CONTROL PROCESS

4 MEASURING OR TESTING PROCESS INVOLVING ENZYMES OR MICROORGANISMS; COMPOSITION OR TEST STRIP THEREFORE; PROCESSES OF FORMING SUCH COMPOSITION OR TEST STRIP

5 . Involving virus or bacteriophage

6 . Involving nucleic acid

7 . Involving antibody binding assay, *e.g.,* antigen-antibody reaction, etc.

8 . Involving luciferase

9 . Geomicrobiological testing, *e.g.,* for petroleum, etc.

10 . Involving uric acid

11 . Involving cholesterol

12 . Involving urea or urease

13 . Involving blood clotting factor, *e.g.,* involving thrombin, thromboplastin, fibrinogen, etc.

In view of this decision the Office is issuing these guidelines as to how 35 U.S.C. 101 will be interpreted.

The Supreme Court made the following points in the Chakrabarty opinion:

1. Guided by these cannons of construction, this Court has read the term "manufacture" in § 101 in accordance with its dictionary definition to mean "the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery."

2. In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.

3. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." V Writings of Thomas Jefferson, at 75-76. *See Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S. Rep. No. 1979, 82d Cong. 2d Sess., 5 (1952).

4. This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.

5. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.

6. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity "having a distinctive name, character [and] use."

7. Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's microorganism is the result of human ingenuity and research.

8. After reference to *Funk Seed & Kalo Co.*, 333 U.S. 127 (1948), "Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's hand-

tional Bureau shall indicate that date in the international publication of the international application if the indication has been furnished to it before the completion of technical preparations for international publication.

13bis.5 References and Indications for the Purposes of One or More Designated States; Different Deposits for Different Designated States; Deposits with Depositary Institutions other than Those Notified

(a) A reference to a deposited microorganism shall be considered to be made for the purposes of all designated States, unless it is expressly made for the purposes of certain of the designated States only; the same applies to the indications included in the reference.

(b) References to different deposits of the microorganism may be made for different designated States.

(c) Any designated Office shall be entitled to disregard a deposit made with a depositary institution other than one notified by it under Rule 13*bis*.7(b).

13bis.6 Furnishing of Samples

(a) Where the international application contains a reference to a deposited microorganism, the applicant shall, upon the request of the International Searching Authority or the International Preliminary Examining Authority, authorize and assure the furnishing of a sample of that microorganism by the depositary institution to the said Authority, provided that the said Authority has notified the International Bureau that it may require the furnishing of samples and that such samples will be used solely for the purposes of international search or international preliminary examination, as the case may be, and such notification has been published in the Gazette.

(b) Pursuant to Articles 23 and 40, no furnishing of samples of the deposited microorganism to which a reference is made in an international application shall, except with the authorization of the applicant, take place before the expiration of the applicable time limits after which national processing may start under the said Articles. However, where the applicant performs the acts referred to in Articles 22 or 39 after international publication but before the expiration of the said time limits, the furnishing of samples of the deposited microorganism may take place, once the said acts have been performed. Notwithstanding the previous provision, the furnishing of samples from the deposited microorganism may take place under the

ingly, the Patent and Trademark Office will accept the following as complying with the requirements of § 112 for an adequate disclosure of the microorganism required to carry out the invention:

(1) The applicant, no later than the effective U.S. filing date of the application, has made a deposit of a culture of the microorganism in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted, under conditions which assure (a) that access to the culture will be available during pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (b) that all restrictions on the availability to the public of the culture so deposited will be irrevocably removed upon the granting of the patent;

(2) Such deposit is referred to in the body of the specification as filed and is identified by deposit number, name and address of the depository, and the taxonomic description to the extent available is included in the specification; and

(3) The applicant or his assigns has provided assurance of permanent availability of the culture to the public through a depository meeting the requirements of (1). Such assurance may be in the form of an averment under oath or by declaration by the applicant to this effect.

A copy of the applicant's contract with the depository may be required by the examiner to be made of record as evidence of making the culture available under the conditions stated above.

NOTE.—For problems arising from the designation of materials by trademarks and trade names, *see* § 608.01(v).

[2] MPEP § 1823.01 [Reference to Deposited Microorganism][R-3]

PCT RULE 13BIS
MICROBIOLOGICAL INVENTIONS

13bis.1 Definition

For the purposes of this Rule, "reference to a deposited microorganism" means particulars given in an international application with respect to the deposit of a microorganism with a depositary institution or to the microorganism so deposited.

13bis.2 References (General)

Any reference to a deposited microorganism shall be made in accordance with this Rule and, if so made, shall be considered as satisfying the requirements of the national law of each designated State.

letter was primarily to insulate the supplier from liability arising from the recipient's use of the materials. It also encouraged the recipient to enter into licensing negotiations with the supplier if an invention with commercial potential resulted. A similar letter was prepared for use in connection with the distribution of antibodies. The drafters noted that "several journals require such releases as a condition for publishing a paper describing the antibodies." The third document they drafted, however, was cut from a different cloth. It provided that the material would not be distributed or released to anyone other than a coworker working under the recipient's direct supervision at the same location, without the consent of the supplier. The recipient received an expressly qualified license to use the material for "academic or not-for-profit purposes," specifically excluding use in research subject to consulting or licensing obligations to another corporation. The recipient was required to inform the supplier of the research results obtained utilizing the material and to provide the supplier, in conjunction with his institutional employer, with an opportunity to evaluate and perhaps license any resulting patentable invention. Finally, it contained a provision designed to insulate the supplier from liability, but this provision was more elaborate than in the short letters previously alluded to.[124]

It may also be helpful to remind corporate counsel that agreements with consultants and employees that merely assign patent rights should be modified to formally convey the tangible property rights in the biological materials developed for the company by these employees and consultants. Of course, corporate ownership of these materials may be implicit in the relationship, but explicitly identifying the owner may avoid litigation. Another reason for making this express identification is that under the Budapest Treaty, only the owner of a deposit has the right to replace a nonviable culture. In the absence of an express conveyance of title, problems may be created if an employee makes a deposit as the "owner," and

[124] Kelly and Jaworski, Agreements Covering Exchanges of Biological Materials, AAAS Annual Meeting, May 25, 1984; published in Trends in Biotechnology 3: 22-27 (January 1985).

curiosity, when in fact they utilized his blood and bodily substances in the production of a unique T-lymphocyte cell line, the "Mo" line, which was patented by the researchers' employer, the University of California.[122]

It is appropriate to discuss the measures which a company may take to avoid these legal hazards. Conlin has suggested that consent forms could be modified to include the following provision:

> I hereby transfer to (name of recipient) all of my right, title and interest to the organ or tissue removed and any part thereof and any product produced thereby, including, without limitation, cells and parts thereof, cell lines and subclones and progeny thereof, compounds and parts thereof, and products produced by or from any of the above, alone or in conjunction with other tissues, cells, organisms, compounds (e.g., DNA, RNA) or parts thereof.[123]

When a company is receiving a cell line or microbial strain from a consultant, pursuant to a consultation or licensing agreement, it should at least require a warranty of title from the consultant. It would be even better if the consultant were required to set forth the history and genealogy of the material to such extent that it was clear that he in fact had title to the

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[122] The Complaint filed in Moore v. Regents of the University of California, Case No. C513755 (September 11, 1984, Cal. Super. Ct. L.A.) appears in 3 Biotechnology Law Report 242-46 (November 1984). The "Mo" cell line is covered by U.S. Patent No. 4,438,032. An attempt to remove the case to federal court failed for lack of federal jurisdiction, since the plaintiff did not seek any relief under the patent laws. 3 Biotechnology Law Report 271 (December 1984).

[123] Conlin, *supra* at B-14. Of course, a patient might seek to rescind such a contract at a later date, arguing duress or mistake. Duress might arise if the performance of the operation were made conditional on the agreement to transfer, the removal of the tissue were necessary to preserve life, and there was no reasonably feasible alternative to having the operation performed at the institution in question. Mutual mistake as to whether the tissue produced any commercially useful substance might make enforcement of the contract unjust. *See* Sherwood v. Walker, 66 Mich. 568 (1887) (supposedly barren cow, arguably sold just for meat value, proved to be pregnant). Finally, the agreement could be attacked as a contract of adhesion. *See* 7 Williston on Contracts, 3d ed., Sec. 900 at n. 19.

La-Roche employee, and genetic material from these cell lines was utilized by Hoffman-La Roche and Genentech in the construction of an interferon expression vector and production strain. The counterclaimants alleged that

> Roche and Genentech have jointly and severally employed and unlawfully converted to their own use and profit counterclaimants' proprietary cell line. Specifically, and not by way of limitation, Roche and Genentech have utilized and converted plaintiff's proprietary cell line and its unique interferon producing properties as the basis for claiming inventions on which Roche and or Genentech have filed one of more applications for U.S. Letters Patent in the names of and for the benefit of Roche and/or Genentech. Upon information and belief, the inventions and patent applications are directed to interferon and interferon production methods developed from the genes derived from the proprietary cell line.[117]

The counterclaimants called for the return of the cell lines, together with "all component parts thereof whether living or dead, all accessions thereto including but not limited to any organisms made through genetic engineering and incorporating interferon producing genes or copies thereof derived from the proprietary cell line, all products produced therefrom, and inventions and patent applications relating thereto."[118] Alternatively, they called for the imposition of a "constructive trust" on this allegedly converted property.

Roche's position was that "for David Golde to claim that he in some way created the interferon that is being made by Hoffman-La Roche and Genentech is like someone who lent a pen to Shakespeare claiming he wrote Hamlet."[119]

On January 4, 1981, Dr. Heideaki Hagiwara came to Dr. Ivor Royston at UCSD.[120] Dr. Royston was attempting to develop a hybridoma cell line which would secrete antibodies to

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[117] Answer to Amended Complaint and Counterclaim for Conversion, etc., in Hoffman La-Roche Inc. v. Golde et al., Civil Action No. C-80-3601-AJZ, (N.D. Cal., June 17, 1981), para. 16.

[118] Id., Prayer for Relief, para. 2.

[119] 1 Biotechnology Law Report 6 (January 1982).

[120] The story which follows is based on the account in 2 Biotechnology Law Report 24-27 (February 1983).

> When 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; who must, however, reimburse the value of the residue to the other owner, or surrender the whole to him.[111]

The provision for reimbursement is a notable departure from the common law application of this doctrine.

The California legislators recognized that it could be difficult to ascertain which element was "principal." They came up with a putative statutory solution:

> 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 case, require it to be separated and returned to him, though some injury shall result to the thing to which it has been united.[112]

> If neither part can be considered the principal, within the rule prescribed by the last section, the more valuable, or, if the values are nearly equal, the more considerable in bulk, is to be deemed the principal part.

The other form of accession dealt with by the California Code is that of the union of materials and workmanship.

> If one makes a thing from materials belonging to another, the latter may claim the thing on reimbursing the value of the workmanship, unless the value of the workmanship exceeds the value of the materials, in which case the thing belongs to the maker, on reimbursing the value of the materials.[113]

The civil law principles of confusio and commixtio have their place in the California Code, too:

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[111] Cal. Civ. Code, Sec. 1025.

[112] Cal. Civ. Code, Secs. 1026, 1027.

[113] Cal. Civ. Code, Sec. 1028. Here again we find a deviation from the common law, which tended to eschew a strict "relative value" test.

As a general rule, the recipient of a biological material will attempt to manipulate it to enhance its value. Assuming that his possession of that material was not rightful, is the true owner entitled: (1) to the value of the enhanced property; (2) to the value of the enhanced property, less the value of the labor and material invested by the recipient (but not subtracting more than the value added by the wrongdoer); or (3) to the value of the property at the time of conversion? The general rule in actions for conversion is that the damages are to be equated with the value of the property at the time of the conversion, but it is safe to say that there is no agreement among the courts as to the proper measure of damages in the case of an "innocent" wrongdoer.[105]

Do we measure the value of a tumor to a patient when it is still within his body, when it has been excised but not cultured, or after it has been successfully cultured?

When the operation to remove the tumor was authorized, but the culturing of the tumor (for any purpose) was not, the time for valuing the converted property would appear to be when the tumor was excised but before it was cultured. When the culturing of the tumor for research purposes was condoned by the patient, the time of conversion would appear to be the time it was put to a commercial use. Thus, paradoxically, the use of a pre-operative agreement to obtain a subject's consent to the research use of his tissues may be commercially detrimental to the recipient, since the value of the tissues will be much greater after they are cultured.

There is a line of 19th century British cases which deal with the conversion of coal by taking it surreptitiously out of a mine. According to these cases, which were cited with approval by the U.S. Supreme Court, the measure of damages is "the value of the coal as it was in the mine before it was disturbed, and not its value when dug out and delivered at the mouth of the

[105] The full value of the enhanced property was allowed in Everson v. Seller, 4 N.E. 854 (Ind. 1886); the enhanced value, less expenditures, in Eaton v. Langley, 47 S.W. 123 (Ark. 1898); and the time-of-conversion value in Kirby Lumber Co. v. Temple Lumber Co., 83 S.W.2d 638 (Tex. 1935).

criticized the rule of Justinian,[97] which was the owner of the product was the owner of the starting material if the product could be reduced to the starting material: "No one would say, if a man take the flax of another, worth but one dollar, and make lace of it, worth $1,000, the owner of the flax ought to have all the lace; and yet there would be no difficulty in reducing the lace to flax."[98]

Judge Mills, in turn, rejected the use of a "relative value" test in that it could not be applied in a manner consistent with established precedent. For example, a seaworthy boat far exceeds the value of its timber, yet it was accepted that the owner of misappropriated timber took title to the boat constructed from the latter.

Mills suggested the following test:

> [I]f the material be so essentially changed as to prevent its renovation, . . . the owner has lost his right to it; and that if the elements of the material have not been changed, but the specific thing which they constituted cannot be reproduced identically, by individual operation, the owner of the material does not own the new species.[99]

Mills thus distinguished the conversion of corn into meal, or grapes into wine, from the conversion of timber into planks or silver bullion into spoons. In the latter examples, the identity of the thing had changed but the material of which it was composed, be it wood or silver, was constant. Insofar as the rights of the parties before him were concerned, Mills observed: "A well wrought brick has very few of the qualities of the unwrought clay. It has not its consistency, its ductility, its compressibility, its tenacity; it can be applied to none of the uses to which clay is adapted. . . . [T]he inherent qualities of the clay have been transmuted by burning." Mills was not moved by evidence that bricks could be decomposed. "The animal, vegetable and mineral kingdoms are all nothing but a combination of certain particles, which existed in an elementary state, and unorganized form. They may all be decom-

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[97] Institutes of Justinian, Book II, Title 1, para. 75.

[98] 24 Ky. (J.J. Marsh) 454, 457 (Ky. Ct. App. 1828).

[99] Lampton v. Preston, *supra* at 464.

The law also recognizes situations in which either of the two predicate elements of Latin accessio are missing. Confusio was the irreversible mixture of materials of different owners where neither material was principal. Under Roman law, the owners became tenants in common of the mixture. Commixtio occurred when separable objects belonging to different owners were combined, the classic example being flocks of sheep. Here, according to the Latins, there was no change of ownership.[92]

Separability is of course dependent on technological advancement. According to the Romans, two things soldered together were separable (plumbatura) while two things welded together (ferruminatio) were not.[93]

If a hybridoma cell line is constructed using the myeloma cell line of *A* and the immunocyte cell line of *B*, the ownership of the hybridoma cell line seemingly would be decided under the principles of confusio. Neither contribution could be regarded as principal, and the fusion cannot be undone.

On the other hand, if a promoter sequence obtained from *A* is linked to a structural gene obtained from *B*, by a conventional restriction-ligation procedure, property rights in the resulting expression system would be adjudged according to the principles of commixtio, since the two sequences could be separated by cleavage with the same restriction enzyme used to create complementary ends on the respective starting materials.

Adiunctio is when one component is subordinate to another, yet easily separable from the latter, whether it be a wheel on a chariot or a tire on a car.[94]

Yet another civil law concept of relevance to biotechnology is specification. Specification was the means by which one who created a wholly new thing out of materials belonging to others acquired ownership of the finished product. Thus, the Institutes of Gaius declare that

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92 Thomas, *supra* note 77, at 169.

93 Buckland, A Manual of Roman Private Law 140 (1953).

94 Thomas, *supra* note 77, at 169; Rabtoay General Tire Co. v. Colorado Kenworth Corp., 309 P.2d 616 (Colo. 1957).

and the latter were annuals such as wheat, corn, rye and potatoes. The distinction was based on the fact that crops fructus industriales owed their final perfection and abundance to the care by man, while crops fructus naturales were not planted each year and were allowed to grow and mature with a minimum of care.[83] Modern courts, because of the more capital- and labor-intensive nature of present-day fruit farming, tend to regard fruit as crops fructus industriales.[84]

The rule is that severed crops fructus industriales belong to their gardener, while severed crops fructus naturales belong to the landowner.[85] As to unsevered crops, title to these always remains in the landowner.[86] Cell cultures would appear to be analogous to crops fructus industriales, since they are difficult to maintain. It would therefore seem that the rule as to crops favors the researcher over the patient.

Absent a contrary agreement, the offspring of animals normally belongs to the owner of the mother under the maxim "partus sequitur ventrem" ("the birth comes from the womb").[87] This may be harmonized with the doctrine of accession if the mother's contribution is considered to be the principal one.

May one recover for the loss of the milk of a converted cow, the egg of a misappropriated hen, or the wool of a lost lamb? If so, it may be argued that one may recover for the loss of the interferon produced by one's wrongfully taken cell line.

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[83] Key v. Loder, 182 A.2d 60 (D.C. Mun. Ct. App. 1962); Casner, American Law of Property, Vol. 5, Sec. 19.16, at 64 n.1 (1952).

[84] Id. *See generally* 21 Am. Jur. 2d, Crops, Secs. 2 and 4.

[85] 21 Am. Jur. 2d, Crops, Sec. 32. *Cf.* Golden Valley Land and Cattle Co. v. Johnstone, 128 N.W. 691 (N.D. 1910)(adversor possessor gained title to severed crops). *But cf.* Kaufman v. Stenger, 30 A.2d 239 (Pa. Super. 1943)(dictum).

[86] 21 Am. Jur. 2d, Crops, Sec. 31.

[87] Wickahoney Sheep Co. v. Sewell, 273 F.2d 767 (9th Cir. 1959); Arkansas Valley Land & Cattle Co. v. Mann, 130 U.S. 69 (1889). Normally, a person merely having possession of the animal acquires no rights in the offspring. The most important exception is when the animal has been hired for a limited period; the increase during that period belongs to the lessee. Connolley v. Power, 232 P.744 (Cal. Ct. App. 1924). But the increase of gratuitiously loaned animals does not belong to the borrower. Allen v. Delano, 55 Me. 113 (Me. 1969).

The doctrine of accession is an amalgamation of several related concepts of the civil law: accessio; adiunctio; confusio; commixtio; and specificatio.

Accessio occurred when materials owned by different parties were united inseparably and it could be said that the contribution of one party was the principal one. Civil law then held that the union belongs to the contributor of the principal material.

Of course, it is not necessarily easy to decide which is the principal contribution. Roman jurists declared that jewels acceded to the ring in which they were set, and that thread acceded to the garment into which it was woven. Seemingly, the test applied for which element was the principal one was "which element gives its name to the product?"[77] One famous, and puzzling, distinction is alluded to in the Institutes of Gaius:

> 77. [W]hatever anyone has written on my paper or parchment, even in letters of gold, is mine, because the letters are merely accessory to the paper or parchment. . . .
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> 78. If, however, anyone paints anything on a tablet belonging to me, as for instance, a portrait, the contrary rule is adopted, for it is said that the tablet is accessory to the painting; but a good reason for this difference hardly exists.[78]

Modern case law on accession is sparse. In *Fanderlik-Locke Co. v. United States* (1960), it was held that in the case of a painted building, title to the paint passed to the owner of the building under the doctrine of accession.[79] It is interesting and helpful to note that the principal contribution may be labor, rather than materials. In *Sound/City Recording Corp. v. Solberg* (1978), it was decided that in the case of a recording of a vocal performance, the contribution of the musicians and technicians acceded (and, one would think, the tape itself) acceded to the contribution of the singer.[80] Moreover, there is

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[77] Thomas, Textbook of Roman Law 170 (1976).

[78] Scott, The Civil Law, Vol. I, at 120 (1932).

[79] 285 F.2d 939, 947 (10th Cir. 1960).

[80] 443 F. Supp. 1374, 1383 (W.D. La. 1978), applying Art. 529 of the Louisiana Civil Code. (The most direct descendant, in this country, of the old Roman law.)

cian. The physician who puts this material to use for the physician's benefit may then be compared to an agent who absconds with the property of his principal.

If the res nullius argument is based on the "cadaver" cases, rather than on the law of ferae naturae, this counterargument is avoided.

A second defense is that of implied consent. How many of us ask the barber to save for us our shorn hair, the manicurist, our clipped nails, or the physician, our tested blood or urine? It is understood that the disposition of these materials is left to the actor.

Some informed consent forms specifically provide for consent to research use of the patient's specimens. Such provisions are double-edged. While they immunize the researcher from liability in tort for research use of the specimens, it may be argued that acts beyond those expressly consented to are left beyond the pale. Of course, a distinction may be drawn between use of a specimen under circumstances in which commercial motives were dominant from the time of the operation and use of the specimen for research purposes which only later were realized to possess commercial significance.

A third defense might be that there is no interference with the property of the patient (the original biological material) because the researcher may, at any time, at the request of the patient, supply the patient any desired quantity of cells of the type removed. This defense is an extension of the *Pearson v. Dodd* defense, discussed earlier. The case law of conversion offers little guidance as to the appropriate treatment of chattels having the extraordinary fecundity of cells in culture. Cases on the conversion of animals are not very helpful, since the span of animal generations is measured in years while that of cells is measured in minutes or hours.

In particular cases, there may be equitable defenses, such as waiver, ratification, estoppel, acquiescence, and laches, against an action for conversion. In addition, the action for conversion may be barred under the local statute of limitations for such actions.

Also a recipient may find that the best defense is a good offense. There is, for example, the cause of action variously known as "defamation of title," "disparagement of property,"

"battery." As the D.C. Circuit said in *Canterbury v. Spence* (1972);

> It is the settled rule that therapy not authorized by the patient may amount to a tort—a common law battery—by the physician. And it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification.[73]

In my view, the act of removing the tissues for an immediate diagnostic or therapeutic purpose accepted by the patient is severable from the subsequent act of utilizing the tissues for a commercial purpose. The first act is not "battery" because there is "consent." The second act is not battery because the tissues are no longer in contact with the patient's person.[74]

Biological materials may also be transferred among researchers. Clearly, such transfers impliedly convey consent to research use of the transferred material, whereas implied consent to even research use may be a matter of dispute in the "patient-to-researcher" situation.

Biological materials are routinely exchanged within the academic community. Looking through a 1983 issue of DNA, I found numerous references to biological and biochemical materials obtained from colleagues: "cultured pituitary cells," "a plasmid consisting of pBR322 plus 1176-bp of amylase-coding sequences," "a rat genomic library . . . consisting of 10-20-kb Hae III fragments cloned into the EcoRI site of Charon 4A using Eco RI linkers," a "murine MT-1 plasmid," and "antiovine growth hormone."[75]

When biological materials are given by one researcher to another, questions arise as to whether the recipient may in

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[73] 464 F.2d 772 (D.C. Cir. 1972). Federal regulations require that informed consent be obtained from subjects. *See, e.g.*, 21 C.F.R. §§50.20-50.27 (1983). 21 C.F.R. §50.25 describes the elements of informed consent. There is no reference to informing the patient of the final disposition of the abstracted biological materials.

[74] *See* Restatment of Torts, Section 18.

[75] DNA, Vol. 2, No. 1 (Mary Ann Liebert, Inc.: 1983). About half of this slim issue was devoted to abstracts from the Third Annual Recombinant DNA Congress, and therefore would not be expected to provide acknowledgments of the use of others biological materials.

formulated by appellee for the conduct of commerce," or otherwise "information held in any way for sale by appellee," the court refused to recognize any further property interest in the papers that the defendants might have interfered with. Accordingly, the court of appeals reversed the ruling that appellants were guilty of conversion.[70]

In my view, it does not really matter whether the trespassers made the copies and replaced the originals, as in *Pearson*, or the remaining originals, by their own procreative propensities, replaced the loss themselves. In either case, the useability of the original was not diminished.

I would further suggest that the *Pearson* precedent may be pertinent, not only to the subculturing situation, but to the initial culturing of a tumor or pathogen from the body. It is doubtful, after all, that the tumor or pathogen will have been eradicated so that additional cultures could not be obtained.

Indeed, the *Pearson* precedent may be more valuable to a researcher defending against an action for conversion brought by a patient than against one brought by another researcher. A researcher plaintiff could fairly argue that the culture is an article representing a trade secret of commercial value to the researcher. A plaintiff patient would find it more difficult to make such an argument.

There are several forms of transfer of biological materials which may have legal repercussions: (1) landowner-to-researcher; (2) patient-to-researcher; and (3) researcher-to-researcher. The first form of transfer arises when a microbiologist collects soil and water samples on private property. Assuming that the microbiologist isolates from these samples a microbial strain of industrially significant characteristics, may the landowner assert any property interest in the isolated strain? It is settled law that a landowner may consider wild animals which are found on his land to be his property ratione soli, that is, property by reason of his ownership of the soil. That property right is a qualified one, insofar as wild animals are concerned, in that the landowner's interest vanishes when the animal leaves his land of its own volition. One who trespasses on the land cannot obtain any rights to the animal by

[70] Pearson v. Dodd, 410 F.2d 701, 707-08 (D.C. Cir. 1969).

Based on the UAGA statutes and the toleration of the sale of regenerative body parts, Conlin argues that "in the absence of a statute to the contrary, body parts, organs, etc. constitute personalty, which can be sold (or supplied as part of a service for a fee."[67] However, as we shall see, there are arguments which may be adduced against the treatment of tumors in vivo as "property."

Any intentional interference with the personal property of another is considered "trespass to chattel." Liability exists, however, only if there are actual damages.

According to the Restatement of Torts, 2d, Section 222A, "Conversion is 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."

The distinction between trespass and conversion is an important one, since the "measure of damages in trespass is not the whole value of the property interfered with, but rather the actual diminution in its value caused by the interference."[68]

In determining whether a trespass constitutes a conversion, consideration of the following factors is suggested by Section 222A:

> (a) the extent and duration of the actor's exercise of dominion or control; (b) the actor's intent to assert a right in fact inconsistent with the other's right of control; (c) the actor's good faith; (d) the extent and duration of the resulting interference with the other's right of control; (e) the harm done to the chattel; (f) the inconvenience and expense caused to the other.

Admittedly, when biological material is saved for research purposes, no harm is done to it. Indeed, the material is encouraged to reproduce, so that an increase in the chattel results from the research. Still, the use of the biological material in commercially motivated or exploited research might nonetheless be considered a "conversion." It is settled law that

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[67] Conlin, Property Right in Microorganisms, Cells and Their Technology, in Genetically Engineered Microorganisms and Cells: The Law and Business, B-13 (1981).

[68] Pearson v. Dodd, 410 F.2d 701 (D.C. Cir. 1969).

surgeon."[56]

For historical reasons, which some have credited to the fear of the supernatural and the influence of the church, testamentary and other post mortem sales or donations of cadaver tissues and organs have been subject to severe legal restrictions. At common law, the theft of a cadaver was not larceny, the sale of a cadaver was a common law crime, and the heirs had no right of replevin to regain a body taken from them or a cause of action in trespass for the mutilation of the body.[57] As Blackstone said, "though the heir has a property in the monuments and escutcheons of his ancestors, yet he has known in their bodies or ashes."[58] In America, the (sometimes conflicting) wishes of decedents and next-of-kin to control the handling of the corpse has been recognized, but mainly as the wishes relate to the determination of the place and manner of burial or the authorization of an autopsy.[59] "The unauthorized removal of a portion of the body by one authorized to examine it and his refusal to return such portion are actionable."[60]

To discourage the theft of cadavers by medical students, and even the murder of travellers by "organleggers," limited anatomical gift laws were enacted in Great Britain and in much of the United States. In more recent times, many states have adopted the provisions of the Uniform Anatomical Gift Act. The UAGA defines the lawful classes of donors (Sec. 2) and donees (Sec. 3), the purposes for which anatomical gifts may be made (Sec. 3), the manner of executing the gift, delivering the document of gift, and amending or revoking the gift (Secs. 4-6);

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[56] Dukeminier, 849. The law is said to have been amended in 1967 to permit kidney transplants.

[57] Human Body Parts, *supra* at 1242-45; 22 Am. Jur. 2d, Dead Bodies, Sec. 4; Sideman and Rosenfeld, Legal Aspects of Tissue Donations from Cadavers, 21 Syr. L. Rev. 825, 826 (1970). The authors note that ownership interests have been recognized in mummies, cadavers of scientific interest, and durable constituents such as bones and hair. It is reported that a coroner's office employee who sold pituitary glands from cadavers to a research institute was given, in 1966, a thirty day jail sentence for malicious mischief. Dukeminier, *supra* at 848 n. 139.

[58] Blackstone, Commentaries 428, 429, cited in Sideman and Rosenfeld, *supra* at 831.

[59] Sideman and Rosenfeld, *supra* at 833-35.

[60] 22 Am. Jur. 2d, Dead Bodies, Sec. 31.

State Code	*Section*	*Imprisonment/Fine*
Pa. Stat. Ann	18 §3930	5 yrs/$10,000 7 yrs/$15,000
Tenn. Code Ann.	§39-4239	1-7 yrs/$1,000-$5,000
Tex. Penal Code Ann.	§31.05	2-10 yrs/$5,000
Wisc. Stat. Ann.	§943.205	2 yrs/$10,000

§ 11.03 Tangible Property Rights in Cell Lines

> Go with me to a notary, seal me there your single bond; and in a merry sport if you repay me not on such a day, in such a place, such sum or sums as are express'd in the condition, let the forfeit be nominated for an equal pound of your fair flesh, to be cut off and taken in what part of your body pleases me. [Shakespeare, *The Merchant of Venice,* Act I, scene iii.]
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> The ox knoweth his owner. [Isaiah, I, 3.]

Biotechnology companies must carefully scrutinize the manner in which they receive and disseminate biological materials. Wrongful use of materials received from others may be deemed a tortious act. Careless dissemination of one's own biological materials may vitiate trade secrets and render one helpless to prevent unintended use of those materials by their recipients.

When biological material is transferred under a written or oral agreement, an aggrieved transferor may institute an action for breach of contract against an erring transferee. If the recipient's breach was induced by a third party, the latter may be the object of a suit for damages for tortious interference with contractual relations.

To the extent that the biological material is recognized as personal property, its owner may treat its misuse by another as a trespass against the chattel, or, when there is substantial interference with the owner's rights, as a conversion of the chattel.

In some states, property rights in certain biological materials are recognized by statute. In Illinois, for example, "property"

row limb if it is bearing so weighty a gift as a copyright under the new Act. In *Herbert Rosenthal Jewelry Corp.*, the owner of a copyright on a jeweled bee pin was told that he "confuses the balance Congress struck between protection and competition under the Patent Act and the Copyright Act," when he argued that his copyright was infringed by "defendant's entire line of a score or more jeweled bees in three sizes decorated with from nine to thirty jewels of various sizes, kinds and colors."[49]

[7] Nor Can the Originator of a Novel Gene Sequence Complain if Another Independently Develops the Same Sequence

Another limitation on the value of a "gene" copyright is the familiar doctrine that the independent development of a work is not an infringement.[50] If two biologists independently concatenate natural sequence *A* with natural sequence *B*, then the second is not "reproducing" the sequence originated by the first within the meaning of the copyright law.

Thus, in conclusion, gene sequences are not copyrightable because they are not "works of authorship" and because they are not "compilations." If they were copyrightable, copyright protection would be so tightly constrained by the doctrines eschewing protection of works, for which the range of expression is extremely limited, as tantamount to preemption of an idea, *e.g.*, the "forms," "recipes," "rules," "plans," and "useful articles" cases, as to be worthless. Moreover, copyright protection might not cover the replication of independently synthesized DNA sequences. Finally, the courts will not be likely to allow unpatentable works to obtain legal significance far outweighing that conferred by the patent system.

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[49] Herbert Rosenthal Jewelry Corp. v. Kalpakian, 446 F.2d 738 (9th Cir. 1971).

[50] Fred Fisher Music Co., Inc. v. Dillingham, 298 Fed. 145 (S.D.N.Y. 1924); Arnstein v. Edward B. Marks Music Corp., 82 F.2d 275 (2d Cir. 1936); *But see* Gross v. Seligman 212 Fed. 930 (2d Cir. 1914) and *compare* Franklin Mint Corp. v. Nat'l Wildlife Art Exchange, Inc., 197 U.S.P.Q. 721 (3d Cir. 1978).

category of § 102 which applies to such structures. (Of course, they are not otherwise similar to these works.)

It might also be argued that a "useful article," for the purpose of the "functionality" rule, is defined as "an article having an intrinsic utilitarian function that is not *merely* to portray the appearance of the article or *to convey information,*" and that DNA molecules "convey information." However, since DNA molecules do not "merely" convey information, this argument distorts the definition beyond the statutory intent. The definition recognizes that a pictorial, graphic or sculptural work whose "function" is to fix in a tangible medium of expression a literary work should be protected.[47] An example would be a quotation silk-screened on a T-shirt. On the other hand, many objects can "convey information" but are outside the congressional intent. Litmus paper turns pink in the presence of acid; a plate of glass, viewed between crossed polarizing filters, reveals the stresses to which it is subjected; and the height of a woman's dress hem is believed in some circles to say something about her morals. Each of these examples, like the DNA molecule, has a significant utilitarian function.

The DNA molecule is a substrate or template onto which enzymes, such as DNA-directed RNA polymerase (RNA transcriptase), attach and assemble molecules of mRNA. In its turn, mRNA serves as a template for tRNA molecules, which carry with them the various amino acids to be linked into a protein. The DNA molecule is no more a nonfunctional structure in the copyright sense than is the layered structure of dyes, couplers, and substrates in color film. (The latter is a medium for conveying information, but is not a work in itself.)

It may be beneficial to compare a DNA sequence to a "blueprint" or an "architectural plan," since it, too, provides instructions for the construction of a structure. Somewhat less agilely, a DNA molecule may be compared to a scale model of a structure. Architectural plans and models may, themselves, be copyrightable, but the author's rights do not allow him to enjoin construction of structures based on these plans or

[47] A gracefully shaped pitcher does not "convey information," it creates a mood.

structions for playing a game), to a recipe (a set of instructions for making a complex chemical substance), and to a blueprint or architectural plan (a set of instructions for constructing a physical structure). The DNA molecule itself may be compared to a three dimensional work of applied art. These analogies will now be explored.

The common "GCAT" representation of the sequence of bases in a DNA molecule is not a proper subject of copyright. This representation falls within the old Copyright Office prohibition of registrations for a "mere listing of ingredients or contents," sometimes referred to as the "recipe" exception (37 C.F.R. §202.1(a) (1959)). While there is case authority for the copyright protection of recipes,[42] Professor Nimmer persuasively argues against it:

> [T]he contents of recipes are clearly dictated by functional considerations, and therefore may be said to lack the required element of originality, even though the combination of ingredients contained in the recipes may be original in a non-copyright sense.

The base sequence of a DNA molecule is, certainly, dictated by functional considerations.

Of course, a particular *diagrammatic* representation of the DNA molecule may be protectible as a literary or a graphic work, but this should not be confused with protection of the representation as a "recipe" for the *construction* of a DNA molecule.

The foregoing comments regarding the "GCAT" representation of a DNA molecule apply with equal force to the molecule itself, since it serves in a sense as a recipe for the construction of mRNA, tRNA, and protein molecules.

This prohibition may well be of constitutional dimensions. In the *Trademark cases*, the Supreme Court held that labels designating or describing the articles to which they are attached are not protectible under the Patent and Copyright

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[42] Belford, Clarke & Co. v. Scribner, 144 U.S. 488 (1892); Fargo Mercantile Co. v. Brechet & Richter Co., 295 F.2d 823 (8th Cir. 1924); Superfine Prods., Inc. v. Denny, 54 F. Supp. 148 (N.D. Ga. 1943).

DNA molecule. The "expression" of that DNA, in a molecular biology sense, is *not* expression in a copyright sense, but rather the actual carrying out of the method. The DNA molecule per se, and the conventional "GCAT" representation thereof, may be viewed as alternative means of fixing the expression (the sequence) in a tangible medium.

Professor Kayton's article viewed gene sequences as "information systems" similar to computer programs.[41] The House Committee Report clarifies, to some degree, the "idea"/"expression" dichotomy as it relates to computer programs. In answer to Professor Nimmer's question, "is it possible to render protectible the 'expression' of a program without necessarily granting a monopoly in its 'idea,' *i.e.*, the methodology or processes adopted by the programmer," it states:

> Some concern has been expressed lest copyright in computer programs should extend protection to the methodology or processes adopted by the programmer, rather than merely to the "writing" expressing his ideas. Section 102(b) is intended among other things, to make clear that the expression adopted by the programmer is the copyrightable element in a computer program, and that the actual processes or methods embodied in the program are not within the scope of the copyright law.

The *Baker v. Selden* issue is less easy to dispose of in the case of gene sequences. First, the "idea" underlying the gene sequence expression is not formulated by the molecular biologist with the kind of clarity apparent in a programmer's algorithm. At best, the biologist knows that a particular subsequence is a "promoter region," or an "operator," or a "repressor," that the coding for the structural gene begins at *A* and ends at *B*, and that protein *X* is coded for by that gene. He does not know why, say, alanine is the third amino acid coded for in constructing that protein. Thus, great care must be taken in interpreting § 102(b) to prevent the would-be copyright owner from appropriating subject matter he did not originate. Second, it may be that even a slightly different sequence of DNA base pairs (even among what present theory currently holds to be "redundant"

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[41] H. Rept. No. 94-1476 (94th Cong. 2d Sess.) 57 (1976).

molecule to obtain a copyright on the sequence and to control the manufacture of his unpatentable DNA molecule under the copyright laws, for a period longer than the patent term, is clearly contrary to the intent of 17 U.S.C. §102(b). Thus, even if a gene sequence could be copyrighted, the copyright would not be infringed by someone's use of the corresponding DNA molecule in an organism to manufacture a particular protein.

[4] The Process by Which a DNA Molecule "Expresses" a Protein Cannot Be Appropriated by Copyrighting the Base Sequence Which Describes the Process

Copyright protection of gene sequences runs afoul of another aspect of 17 U.S.C. §102(b):

> In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.

It is, of course, possible to take the view that certain clearly copyrightable "expressions" are in fact "procedures." A musical score gives a "procedure" for playing notes; a choregraphic score gives a "procedure" for moving the body. It is, however, evident that the thrust of 17 U.S.C. § 102(b) is toward attempts to appropriate business or scientific procedures. A DNA sequence falls into the latter category.

The Senate Committee report states that "§ 102(b) in no way enlarges or contracts the scope of copyright protection under the present law. Its purpose is to restate . . . that the basic dichotomy between expression and idea remains unchanged."

This remark would have been more meaningful if the case authority on this dichotomy were clearer. The seminal case is *Baker v. Selden*,[35] involving a book explaining a new method of bookkeeping. The Supreme Court indicated that when a book teaches an "art" requiring the copying of the forms pre-

[35] 101 U.S. 99 (1879).

of preexisting materials or of data that are selected, coordinated, or arranged in such a way that the resulting work as a whole constitutes an original work of authorship" (17 U.S.C. §§101-103). Unfortunately, the legislative history mandates a more restrictive interpretation of the term "compilation." Specifically, Congress stated that "[a] compilation or derivative work is copyrightable if it represents an original work of authorship *and* falls within one or more of the categories *listed* in § 102." In other words, the word "includes" in § 102 offers no comfort to one trying to compile materials which do not fall into any of the seven *listed* categories, and a DNA sequence certainly does not.

[3] The "Discovery" of the Functions of a Novel DNA Molecule Cannot Be Appropriated by Copyrighting the Base Sequence

The basis for copyright protection is Art. I, Sec. 8, cl. VIII of the Constitution. As many commentators have observed, two threads run through this clause. The first links the words "science," "authors," and "writing," and the second links the words "useful arts," "inventors," and "discoveries." The Copyright Act makes it clear that "discoveries," even when embodied in a "writing," are not copyrightable.

First, it carefully distinguishes between an "expression," which may be copyrighted, and the material object in which that expression is fixed, which cannot be copyrighted. It is not a cassette tape which is copyrighted, it is the auditory work

(*Text continued on page 11-21*)

a silicon chip. If a court is willing to accept electronic levels as suitable media of expression, it should not have too much difficulty with molecular media.[33.4]

This passage illustrates how easy it is to confuse the message (the copyrightable literary work) with the medium (the material object from which the message may be perceived with the aid of a machine). There is no doubt that a DNA molecule could be used as a medium of expressing a sequence of words or numbers, provided there was some accepted convention for deciphering the DNA sequence in that manner. But what would be protected would be the message thus perceived, not the DNA sequence itself.

To illustrate my point, consider the following DNA telegram:

The DNA Telegram:

ACT CAT GAA ATG GAA GAT ATT TGA ATG
ATT AGT AAT TAA ACT ACT CAT GAA
ATG GAA AGT AGT GCT GGT GAA

Utilizing the "universal genetic code," one may determine the corresponding amino acid sequence. If each amino acid in the sequence is assigned a single letter in accordance with the conventional single letter amino acid code, we will be able to perceive the message encrypted by this DNA molecule.[33.5]

[33.4] Goldstein, *supra* note 33.1.

[33.5] The "nearly universal" genetic code may be found in Figure 31-5 of Lehninger, Biochemistry 718 (1970). Mitochondrial codes differ slightly.

The single letter amino acid code may be found in Table 4-1, Id. at 67. The stop codons umber and ochre were assigned symbols "U" and "O", respectively. The missing letters are therefore "X" and "J". These symbols are believed to have been adopted by the IUPAC-IUB Commission on Biochemical Nomenclature, J. Biol. Chem. 243: 3557-3559 (1968).

as a "notation," but it is not a notation in which mathematical operations may be carried out. He speaks of the expression product of DNA (a protein) as something "useable by people" in the same manner that the decimal output of a computer is useable, though it has significance to people only through its biological activity.

DNA molecules are not analogous to computer programs because they do not express ideas by means of words or numbers, however symbolized or indicated, as do computer programs (and other literary works).

Nimmer was of the opinion that "sound recordings" (category 7) were not analogous to "any of the other six categories of works," even, presumably, "motion pictures and audiovisual works" (category 6) or "musical works, including any accompanying words" (category 2). A fortiori, a DNA molecule is not analogous to the enumerated categories of "works of authorship" and is "completely outside the present congressional intent."

Dr. Goldstein agrees that

> extending the Act to DNA sequences is probably too radical a step for a court to take, even though the Copyright Act may be forward-looking. Computer programs were expressly included in the law only after much controversy, and it took specific mention by Congress to make this clear to the courts. It is one thing to say that computer programs are now analogous to literary works, but yet another thing to convince a court that genetic sequences are, in turn, analogous to computer programs.[31.2]

The statutory phrase "now known or later developed" does not permit any expansion of the concept of a "work of authorship," since its antecedent is the phrase "fixed in any tangible medium of expression." Again, this is made clear by the Committee report, which carefully distinguishes between "works," "copies," and "phonorecords." A "copy" or a "phonorecord" is a tangible object *embodying* a "work" (an original expression of an idea). As the report states, "a 'book' is not a work of

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[31.2] Goldstein, Copyrightability of Genetic Works, Bio/Technology 138, 139 (February 1984).

Act does not sanction the march of copyright law into the molecular biologist's petri dish.

[1] A DNA Sequence Is Not a "Work of Authorship" Within the Meaning of the Copyright Act

In order to obtain copyright protection, the putative "author" must originate a "work of authorship" and fix it in a "tangible medium of expression." A DNA molecule is not a "work of authorship" in the statutory sense. 17 U.S.C. §102 states that

> Works of authorship include the following categories: (1) literary works; (2) musical works; including any accompanying words; (3) dramatic works, including any accompanying music; (4) pantomimes and choreographic works; (5) pictorial, graphic, and sculptural works; (6) motion pictures and other audiovisual works; and (7) sound recordings.

Those unfamiliar with the legislative history of the Act may overly stress the word "include." While the statute indeed states that "the terms 'including' and 'such as' are illustrative and not limitative" (17 U.S.C. §101), this is not to say that the statutory concept of a "work of authorship" is coextensive with the constitutional concept of "writings." Congress deliberately refrained from using the broader constitutional term. According to the Senate Committee Report

> [T]he Committee's purpose is to avoid exhausting the constitutional power of Congress to legislate in this field . . . . The bill does not intend either to freeze the scope of copyrightable subject matter at the present stage of communications technology or to allow unlimited expansion into areas completely outside the present Congressional intent. Section 102 implies neither that that subject matter is unlimited nor that new forms of expression within that general area of subject matter would necessarily be unprotected. . . . Although the coverage of the present statute is very broad, . . . there are unquestionably other areas of existing subject matter that this bill does not propose

§ 11.02 Copyright Protection Not Available for Gene Sequences or Molecules

In 1979, Tom Kiley suggested that gene sequences could be copyrighted under the Copyright Act of 1976.

> Genes are probably the most efficient mechanism ever seen for the storage of information. We are now capable of "authoring" new genes. The very act by which the information stored in a gene is put to work is called "expression." The gene is a "tangible" medium of expression and with the aid of a machine or a device the information contained in a gene can be deciphered. Section 102 of the new Copyright Act purports to extend copyright protection to any original work of authorship "fixed in any tangible medium of expression, now known or later developed," which has such characteristics. If one can copyright a sound recording, how about a "protein recording?" There is no logical reason why it could not be done, at least under the language of the Act. If the Copyright Act is extensible to works which embody computer programs, as seems likely the case, then why not also to original plasmids and other genes? It is irrelevant that the Framers of the constitutional underpinnings of the copyright system foresaw neither computer programs nor the authorship of genes. It is pretty likely that they didn't have motion pictures or sound recordings in mind either.
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> Lawyers skilled in the art of copyright will find speculation on the copyrightability of genetic information an interesting exercise. As one example, what better example of actual copying could be imagined than the infringer who cultures another's microorganism. In that case, and under the direction of the infringer, the microorganism "copies" itself! And all will be familiar with the common practice among authors of burying misspellings and other typographical errors in their texts which, if reproduced, provide an unerring telltale of the copyist's hand. Now, not every portion of a genetic plasmid expresses protein. "Nonsense" information can easily be placed within portions of the plasmid that more or less go along for the ride when organisms containing the plasmid reproduce. Found in another's hand, the plasmids of a copied organism will contain that selfsame telltale, and it can be decoded. Who knows? Just

the transportation of copies of the original American Cyanamid documents describing the use of the cultures was also within the coverage of NSPA. While this case does not shed any light on the protectibility of cultures as trade secrets, it does remind trade secret owners that they have a powerful criminal sanction in reserve.

A final consideration pertaining to trade secrets in the realm of biotechnology is that of governmental disclosure requirements. As Tom Kiley states:

> Early perceptions of biohazard, though now largely dissipated, have left in their wake a regulatory structure that requires the disclosure to the National Institutes of Health of key information about particular organisms and inserted genes before certain experiments can be conducted. The National Institute of Occupational Safety and Health is conducting an industry-wide survey of both laboratory and manufacturing practices with a view toward promulgating standards for worker protection in the area. Pharmaceutical and many agricultural applications will require submission of large bodies of data for grant of regulatory approvals. Environmental Impact Statements may be required for scaled-up manufacturing approvals. Each different agency can be expected to adopt a different stance with respect to honoring trade secret "exceptions" to Freedom of Information Act initiatives, depending upon its resources and the balance of public vs. private interest its mission requires that it strike. And where investor interest is high while stock market volatility persists as a characteristic of an evolving industry, SEC requirements for public disclosure may require more of smaller companies than larger players because criteria of "materiality" are related to size and perceived stability.[24]

Since public disclosure is antithetical to the existence of a trade secret, a trade secret can reside in material submitted to a government agency only if the material is exempted from the Freedom of Information Act and treated as secret under 18 U.S.C. §1905. Agencies vary considerably in the degree to which they reassure submitters in this regard. In the *Chevron*

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[24] Speech, *supra,* note 6 at 6.

> of the present paper. Suffice it to say that at least in the Ninth Circuit property interests are not the basis of trade secret protection, Monolith Portland Midwest Co. v. Kaiser Alum & Chem. Co., 407 F.2d 288 (9th Cir. 1959). It is breach of trust or other wrongful taking that must be shown.[21]

Both the Restatement of Torts and the Uniform Trade Secret Act define a "trade secret" in a manner which fails to emphasize the distinction between information per se and an article from which the information may be obtained, whether it be a written recipe for a new beverage or the beverage itself. The "information" is the "trade secret."

On the other hand, the misappropriation of an article representing a trade secret may certainly be considered misappropriation of the trade secret itself. The knowledge of which strain of Streptomyces will produce the highest yield of penicillin is valuable commercial information, and this knowledge may be gleaned by stealing a culture of that strain. For trade secret purposes, secret cultures may be compared to secret catalysts and sources of supply, which have been considered protectible as trade secrets.

Assume, for example, that an antibiotic is secretly manufactured with the aid of culture *X*. One who knows of the use of culture *X*, but does not possess it, cannot make the antibiotic. It is the appropriation of culture *X* that is necessary for the appropriation of the secret method. The culture may be compared to a catalyst. None would question that the unlawful acquisition, for purposes of analysis, of a secret catalyst used in a proprietary process would be an appropriation of a trade secret.

The culture may also be deemed a "source of supply" for the antibiotics. One's secret knowledge of a "source of supply," whether it be the knowledge of which company can supply a

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[21] Speech, *supra* note 6 at 11-12.

		Patents	*Trade Secrets*
			If enough discover the secret by proper means other than confidential disclosure, the secret becomes lost.
8.	*Cost of Protection*	Filing, issue, and maintenance fees	Security expenses; personnel dissatisfaction; legal fees if misappropriation occurs.
9.	*Licensing and Assignment*	Encouraged	Discouraged—seller wants guarantee before making a disclosure, buyer reluctant to buy a "black box."
10.	*Remedies*	Civil suit for patent infringement	Civil suit for misappropriation, conversion, unjust enrichment, breach of contract, or breach of trust; possible criminal prosecution for theft of property.

In *Hoffman-La Roche, Inc. v. Golde*,[19] defendants Golde, Koeffler, and the Regents of the University of California, charged Hoffman-La Roche, Inc. and counterdefendant Genentech, Inc. with conversion, misappropriation, unjust enrichment, inducement of breach of contract, and breach of contract in connection with the use by HLR and Genentech of the KG-1 and KG-1A cell lines, allegedly belonging to defendants, while they were entrusted to the care of an employee of the National Cancer Institute, Dr. Robert Gallo. Defendants allege that in May, 1978, they sent live test samples of these

[19] Civ. Action No. C-80-3601-AJZ (N.D. Cal.)

trade secrets.[12]

There would be little purpose in recounting this episode in the history of pharmacy if it were not instructive. First, it teaches that biotechnology companies must be alert to any signs of employee dissatisfaction—Sidney Fox and John Cancelarich were unhappy employees. Indeed, a note in Fox's personal file warned that "he seems to be a man who lives beyond his means and he may cause . . . salary problems."[13] Second, it emphasizes the need for strictly limiting and monitoring access to the company's culture collection and technical data. Cancelarich asked Joe Gerace to give him a sample of the tetracycline mash lying on the floor around the experimental lab fermentors.[14] Valuable interests may be at stake; the conspirator's fees ranged from $50,000 to $110,000,[15] and Lederle claimed $5,000,000 in damages.[16]

A company may lose a secret through advertising, sale, or publication, if its secret may be fathomed from these legitimate sources of information. Thus, Mycalex Corporation's process secret was lost because of a catalogue advertisement explaining "how Mycalex is made," and a collapsible fishing rod and a ventilating blackout screen for ship portholes were deemed unprotectable in that any competent mechanic, lawfully possessing a sample, could obtain the "secret" by examination and analysis.[17] Several cases suggest that if "reverse engineering" is sufficiently arduous, the trade secret still exists.[18]

A comparison of patent and trade secret protection may be helpful.

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[12] Chemical Week, January 18, 1964 at 24.

[13] Pearson, *supra* note 10 at 89.

[14] Id., 161

[15] Chemical Week *supra* note 11.

[16] 140 U.S.P.Q. at 200.

[17] Mycalex Corp. of Am. v. Pemco Corp., 64 F. Supp. 420 (D. Md. 1946) aff'd 159 F.2d 907 Wissman v. Boucher (4th 1947).

[18] Space Aero Prods. Co. v. R. E. Darling Co., 738 Md. 93, 208 A.2d 74, 80, 81, 145 U.S.P.Q. 356 (1965); Pachmayr Gun Works, Inc. v. Olin Mathieson Chem. Corp., 502 F.2d 802, 804-05, 807-08 (9th Cir. 1974); Analogic Corp. v. Data Transl., Inc., 358 N.E.2d 804, 806-07 (Mass. 1976).

espionage, such as that involved in *duPont v. Christopher.*[8] The Christophers were hired to fly over a duPont plant, then under construction, and photograph it. The company's secret methanol process technology was visible from above. This should serve as a further warning of the need for stringent plant and lab security.

Unfortunately, secrecy has its price. Key employees, particularly those accustomed to an easy-going academic environment, may become resentful, and vent their feelings either by leaving, or by actively seeking to frustrate the security arrangements. Milgrim suggests that "rather than comply with elaborate security precautions, a laboratory employee might rely on estimation rather than the precise formula," thus paving the way for "accidents or other mishaps." According to Tom Kiley,

> Because until recently the new alchemy was attempted only in the university and related contexts, workers forming the limited talent pool from which industry must draw are unused to typical industry practice with regard to the preservation of proprietary information. The scientist qua scientist is raised in a tradition of information-sharing and of seeking peer approval by publication. Informal seminars and international meetings are key parts of the information network of science, both on and off the podium. The publish-or-perish syndrome is deeply engrained. Unfamiliarity with industrial practices breeds suspicion. "Big industry" employment is viewed askance.
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> Companies obliged to approach publication conservatively will be disadvantaged in recruiting the best scientists from academia, where they presently predominate. Less hidebound companies, particularly those start-up concerns that offer a more collegial atmosphere and opportunities for cross-talk with scientists elsewhere, are better positioned to attract new scientific hires—but do so at the cost of not keeping information of appreciable value in-house. Patents become necessary alternatives.[9]

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[8] 431 F.2d 1012 (5th Cir. 1970).

[9] *Supra* note 6 at 2-4.

Assuming that the trade secret is the type of subject matter which a court would be willing to protect, the trade secret owner may be required to establish (1) actual use of the secret in a trade or business; (2) the cost of development of the secret; (3) the extent to which the trade secret owner has sought to maintain secrecy; and (4) the extent to which the secret may have been disclosed by sales, displays, and publications, especially U.S. or foreign patents.

Because it is difficult to determine whether an unused idea will afford its deviser a "competitive advantage," some courts have suggested that actual use of the secret, at least in the past, should be shown; but recent decisions appear to treat this rule more as a rebuttable inference that the idea is unsound than as a rule of law that it is unprotectible.[2] The concept of "use," moreover, can be expanded to encompass other forms of "commercial implementation" such as leases and licenses.[3]

Moving to the issue of expense, it seems likely that the cost of development will have at least a "subliminal" effect on the judicial mind. A number of courts have taken pains to stress the expenditure of time and money involved in developing a trade secret,[4] and one court rubbed salt into the wounds of a would-be trade secret owner by suggesting that its proofs might have been more convincing had its expenditures been presented.[5]

For a number of reasons, the owner of a trade secret is well advised to take reasonable measures to ensure its secrecy. Not only does slipshod security invite trade secret theft, difficult to detect and rectify, it may actually forfeit legal rights: "one may not venture on liberties with his own secret, may not lightly or voluntarily hazard its leakage or escape, and at the same time hold others to be completely obligated to observe it."

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[2] Ferroline Corp. v. Gen'l Aniline Film Corp., 207 F.2d 912, 921 (7th Cir. 1953)("respectable authority" for "use" requirement not persuasive under N.J. law); Harris Mfg. Co. v. Williams, 157 F. Supp. 779, 787 (W.D. Ark. 1957).

[3] Milgrim at 2-17.

[4] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974)(over $1 million); W. R. Grace & Co. v. Hargadine, 392 F.2d 9, 14 (6th Cir. 1968).

[5] Filler Dynamic Int'l, Inc. v. Astron Battery, Inc., 19 Ill. App. 3d 299, 311 N.E.2d 386, 400-401, 183 U.S.P.Q. 102 (2d Dist. 1974); Mancs v. Melton, 358 Mich. 500, 100 N.W.2d 235, 239, 124 U.S.P.Q. 144 (1960).

patented and therefore publicly known invention; or (3) to protect, for a considerable length of time, a commercially important technology which is either unpatentable or which can only awkwardly or ineffectually be shielded by patent protection. It is difficult, if not impossible, to decide whether trade secret protection of a biotechnology innovation is appropriate without deciding which of these purposes is to be served by that approach.

For example, if the invention is the actual product which is to be sold, as might be the case with a novel restriction endonuclease, a food processing enzyme, a transfer vector, or a microbial pesticide, the product may be "reverse-engineered" as soon as it is commercialized. The trade secret right is, in such circumstances, ephemeral, and ultimate reliance must be placed on the patent law.

The same conclusion holds true if the trade secret is a novel therapeutic or diagnostic method. Typically, what is sold by the inventor is a reagent, test kit, or apparatus for use in practising the method. The method must, of course, be disclosed to the buyer, and therefore cannot be maintained as a trade secret.

An expression vector, a production organism, or a manufacturing method need not be disclosed by one who is merely selling the final product. These types of innovations are suitable for longterm trade secret protection. However, reliance on trade secret protection may not be desirable if the field is one of great activity. Trade secrets law offers no protection against independent developers.

The classical definition of a "trade secret" is offered by the American Law Institute's Restatement of Torts, Section 757, comment "b":

> b. Definition of trade secret. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (*see* §759) in that it is not simply information as to single or ephemeral events in