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; and subclasses 304+ for a stock material in the form of a composite web or sheet embodying a component which is porous or cellular.

521, Synthetic Resins, subclasses 25+ for an ion exchange resin and the processes of making or regenerating them; and subclasses 50+ for cellular or porous resinous bodies and the process of preparing them.

175. Multi-Enzyme System:
Subject matter under subclass 174 wherein two or more functionally different enzymes are immobilized on the same support material.

(1) **Note.** The use of a microorganism as a carrier is excluded herefrom.

(2) **Note.** Functionally different means possessing differing catalytic activities.

176. Enzyme or Microbial Cell Is Immobilized on or in an Inorganic Carrier:
Subject matter under subclass 174 wherein the carrier is an inorganic compound or metal or alloy.

177. Enzyme or Microbial Cell Is Immobilized on or in an Organic Carrier:
Subject matter under subclass 174 wherein the support material is an organic compound.

178. Carrier Is Carbohydrate:
Subject Matter under subclass 177 wherein the support material is a carbohydrate.

(1) **Note.** Derivatized starch, derivatized cellulose, and deriva-

182. Enzyme or Microbial Cell Is Entrapped Within the Carrier, e.g., Gel, Hollow Fibre:
Subject matter under subclass 180 wherein the enzyme or microbial cell is physically trapped in a reticulated polymer structure.

183. Enzyme, e.g., Ligases (6.), etc., Proenzymes, Compositions thereof; Process for Preparing, Activating, Inhibiting, Separating, or Purifying Enzymes:
Enzymes per se, compositions under the class definition containing enzymes, processes for synthesizing enzymes, and preparing enzyme compositions, processes for separating enzymes from a source material, or purifying enzymes or processes under the class definition for treating enzymes.

(1) **Note.** Enzymes, for the purpose of this class, are defined as proteinaceous materials which cause a chemical change in a starting material without being consumed in the reaction with the remaining amount of enzyme generally, after the reaction, the same as originally present.

(2) **Note.** Processes wherein a microorganism is propagated and an enzyme recovered therefrom or processes wherein a microorganism is cultivated in the presence of a compound or composition which induces or stimulates enzyme formation are included in this subclass.

(3) **Note.** The chemical changes catalyzed by an enzyme include oxidation-reduction, transfer of methyl or phosphate groups from one molecule to the next, hydrolysis, nonhydrolytic bond cleavage, isomerization, bond formation in the presence of a nucleotide, etc.

(4) **Note.** Enzymes conjugates, i.e., enzymes which are labeled with relatively small organic molecules compared to the enzyme, are included in this subclass.

(5) **Note** Processes for treating enzymes include but are not limited to processes for inactivating an enzyme, processes

*Search Class:*

127, Sugar, Starch and Carbohydrates, for processes of hydrolysis of carbohydrates which include the action of diastase only when the hydrolysis is followed by steps of concentration, purification, or treatment, such as crystallization to make a sugar or syrup.

186. Pancreatin:
Subject matter under subclass 183 wherein the product contains a mixture of amylopsin, trypsin and steapsin (lipase) obtained from a pancreas.

187. Preparing Granular- or Free-Flowing Enzyme Composition:
Subject matter under subclass 183 wherein an enzyme is treated to produce a solid flowable product or to produce a product in the form of small discrete particles.

188. Stabilizing an Enzyme by Forming a Mixture, an Adduct or a Composition or Formation of an Adduct or Enzyme Conjugate:
Subject matter under subclass 183 wherein (a) the enzyme is contacted with an extraneous material to impart to the enzyme a resistance to loss of activity, or (b) the enzyme is reacted with a nonenzymatic material to form a complex or a chemically modified enzymatic compound, e.g., conjugate, ligand, etc.

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

(2) **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.

190. Acting on CHCH Group as Donor, e.g., Glucose Oxidase, Lactate Dehydrogenase (1.1):
Subject matter under subclass 189 wherein the donor is a compound containing a hydroxyl group, i.e., -C-OH.

191. Acting on Nitrogen-Containing Compound as Donor (1.4, 1.5, 1.7):
Subject matter under subclass 189 wherein the donor is a nitrogen compound.

(2) **Note.** In the absence of a clear showing to the contrary, a recitation of amylase is presumptively alpha-amylase.

*Search This Class, Subclass:*

205, for hydrolases capable of hydrolyzing both alpha-1, 4 and alpha-1, 6 glucan bonds.

192. Acting on Hydrogen Peroxide as Acceptor (1.11):
Subject matter under subclass 189 wherein the acceptor is hydrogen peroxide.

193. Transferase Other than Ribonuclease (2.):
Subject matter under subclass 183 wherein the enzyme catalyzes the transfer of a functional group from one molecule to another, e.g., $AR + B \rightleftharpoons BR + A$, etc.

(1) **Note.** Elements, e.g., hydrogen, oxygen, etc., electrons, or water per se, are not considered for the purposes of this subclass to be a functional group.

(2) **Note.** Functional groups include but are not limited to methyl, hydroxyl methyl, formyl, carboxyl, carbamoyl, amidino, acyl, amino acyl, hexosyl, pentosyl, glycosyl, amino, oximino, phosphate, sulfur, sulpho, etc.

(3) **Note.** Transaminases, transacetylases, and kinases that

Subject matter under subclass 195 wherein the enzyme catalyzes the hydrolysis of an ester bond.

197. Carboxylic Ester Hydrolase (3.1.1):
Subject matter under subclass 196 wherein the ester bond which is hydrolyzed was formed by

a carboxylic acid and an alcohol, i.e., 

198. Triglyceride Splitting, e.g., Lipase, etc. (3.1.1.3):
Subject matter under subclass 197 wherein the enzyme catalyzes the hydrolysis of the ester bond in triglyceride fats.

199. Ribonuclease (3.1.4):
Subject matter under subclass 196 wherein the enzymes are phosphoric diester hydrolases that act on nucleotides and nucleic acids.

200. Acting on Glycosyl Compound (3.2):
Subject matter under subclass 195 wherein the enzyme catalyzes the hydrolysis of O-glycosyl bonds or N-glycosyl bonds or S-glycosyl bonds.

(1) **Note.** Enzymes which hydrolyze mucin are classifiable in this subclass.

201. Acting on Alpha-1, 4-Glucosidic Bond, e.g., Hyaluronidase, Invertase, Amylase, etc. (some 3.2.1):
Subject matter under subclass 200 wherein the enzyme catalyzes the hydrolysis of an alpha-1, 4-glucosidic bond.

(1) **Note.** Amylase from Bacillus maceraus characterized by its ability to degrade starch in part to crystalline nonreducing substances known as Schardinger dextrins is included in this subclass.

this subclass is defined as an enzyme which hydrolyzes alpha-1, 4-glucan bonds and alpha-1, 6-glucan bonds in carbohydrates removing successive glucose units from the ends of carbohydrate chains.

206. Acting on Beta-1, 4 Link Between N-Acetylmuramic Acid and 2-Acetylamino 2-Deoxy-D-Glucose, e.g., Lysozyme, etc.:
Subject matter under subclass 200 wherein the enzyme hydrolyzes a beta-1, 4 glycoside bond between N-acetylmuramic acid and 2-acetyl amino 2-deoxy-D-glucose moieties.

(1) **Note.** The hydrolysis of this subclass is usually of a mucopolysaccharide, mucopolypeptide, or chitin.

(2) **Note.** Lysozyme is an example of an enzyme appropriate for this subclass.

(3) **Note.** Cell lytic, bacteriolytic, lytic enzymes are presumptively included in this subclass unless the document indicates that the lysis (hydrolysis) is not of the bond specified.

207. Acting on Beta-Galatose-Glycoside Bond, e.g., Beta-Galactosidase, etc.:
Subject matter under subclass 200 wherein the enzyme catalyzes the hydrolysis of beta-galactose-glycoside bonds.

208. Acting on Alpha-Galatose-Glycoside Bond, e.g., Alpha-Galactosidase, etc.:
Subject matter under subclass 200 wherein the enzyme catalyzes the hydrolysis of alpha-galactose-glycoside bonds.

209. Acting on Beta-1, 4-Glucosidic Bond, e.g., Cellulase, etc. (3.2.1.4):
Subject matter under subclass 200 wherein the enzyme catalyzes the hydrolysis of beta-1, 4-glucan bonds in polysaccharides.

210. Acting on Alpha-1, 6-Glucosidic Bond, e.g., Isoamylase, Pullulanase, etc.:
Subject matter under subclass 200 wherein the enzyme cata-

group of alpha-arginine and alpha-lysine or an aromatic alpha-amino acid with another amino acid or peptide.

214. Thrombin:
Subject matter under subclass 212 wherein the enzyme catalyzes the hydrolysis of fibrinogen to fibrin.

215. Urokinase:
Subject matter under subclass 212 wherein the source of the enzyme which converts plasminogen to plasmin is mammalian blood or urine.

216. Streptokinase:
Subject matter under subclass 212 wherein the source of the enzyme which catalyzes the hydrolysis of amide bonds and converts plasminogen to plasmin in hemolytic streptococci.

217. Plasmin, i.e., Fibrinolysin:
Subject matter under subclass 212 wherein the enzyme catalyzes the hydrolysis of amide bonds which connect alpha-arginine or alpha-lysine to another amino acid or peptide and converts fibrin to water soluble products.

218. Elastase:
Subject matter under subclass 212 wherein the enzyme catalyzes the hydrolysis of amide bonds connecting a neutral amino acid to another amino acid or peptide.

219. Proteinases:
Subject matter under subclass 212 wherein the enzyme catalyzes the hydrolysis of amide bonds within a polypeptide chain, i.e., the amide bonds of nonterminal amino acids.

(1) **Note.** Endopeptidases are examples of enzymes for this subclass, e.g., ficin, bromelin, etc.

(2) **Note.** Where the peptide hydrolase activity is unclear (e.g., if it cannot be determined whether exopeptidase or en-

228. Acting on a Linear Amide Linkage in Linear Amide:
Subject matter under subclass 227 wherein the enzyme catalyzes the hydrolysis of a linear amide bond, i.e., an amide bond which is not part of a cyclic ring.

(1) **Note.** Acylases, such as cephalosporin amidase, which can also act as deacylases by hydrolysis of a linear amide bond are included in this subclass.

229. Asparaginase:
Subject matter under subclass 228 wherein the enzyme catalyzes the hydrolysis of alpha-asparagine forming alpha-aspartate and ammonia.

230. Penicillin Amidase:
Subject matter under subclass 228 wherein the enzyme catalyzes the hydrolysis of penicillin forming a carboxylic acid anion and penicin.

(1) **Note.** Penicillin amidase (acylase) also acts in the reverse direction producing penicillins from 6-aminopenicillanic acid and an appropriate side chain.

*Search This Class, Subclass:*

228, for acylases and amidases which attack the 7-position in cephalosporins.

231. Acting on Amide Linkage in Cyclic Amides, e.g., Penicillinase, etc. (3.5.2):
Subject matter under subclass 227 wherein the enzyme catalyzes the hydrolysis of an amide bond which is part of a ring structure.

232. Lyase (4. ):
Subject matter under subclass 183 wherein the enzyme catalyzes the nonhydrolytic cleavage of bonds, e.g., AB⟷A + B, etc.

*Search This Class, Subclass:*

1, for process of maintaining tissue in a viable state or media therefor.

2, for process of maintaining blood or sperm in a physiologically active state.

172, for processes in which the genetic material of a microorganism is altered.

240, for tissue or cell culture processes.

284, for tissue or virus culture apparatus.

*Search Class:*

424, Drug, Bio-Affecting and Body Treating Compositions, subclass 86 for a process involving the step of administering a virus to an animal to produce a serum antibody followed by the step of obtaining the antibody serum from the animal. See subclass 89 for an immunologic composition containing a virus, e.g., vaccines, etc. Where there is a doubt as to whether or not virus propagation takes place in preparing a vaccine, the process will be classified in Class 424, subclass 89. The mere use of the word vaccine is insufficient basis for placement in Class 424.

236. Inactivation or Attenuation; Producing Viral Subunits: Subject matter under subclass 235 in which the virulence of the virus is decreased or the virus is reduced to its component parts.

(1) **Note.** This subclass includes methods of attenuation by physical means, e.g., freezing, etc.

(2) **Note.** Viral subunits include the virus protein coat, viral nucleic acid and viral enzymes.

Processes under the class definition of inducing the formation of spores or their recovery.

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:
Subject matter under the class definition including microorganisms, compositions containing, processes under the class definition for propagating, processes under the class definition for preserving or maintaining, processes under the class definition for isolating, processes under the class definition for preparing compositions containing and, compositions under the class definition for use in propagation of microorganisms.

(1) **Note.** Microorganisms for the purpose of this subclass include actinomycetales, unicellular algae, bacteria, fungi (yeast and molds), and protozoa. Virus propagation is provided for in subclass 235 and animal or plant cell cultivation in subclass 240.

(2) **Note.** The mere propagation of a microorganism to produce a recoverable chemical product is excluded herefrom.

*Search This Class, Subclass:*

29+, for measuring or testing processes which involve viable microorganisms and the use of selective media to identify a particular microorganism.

41+, for propagation processes which produce a recoverable chemical product.

42, for the symbiotic propagation of genetically dissimilar microorganisms to produce a product.

173, for the use of magnetic or wave energy to alter microbial growth or activity.

245. Adaptation or Attenuation of Cells:
Processes under subclass 243 wherein the virulence of a microorganism is reduced or a microorganism's ability to propagate on a given substrate is increased or growth requirements are altered by a series of sequential cultivation steps.

(1) **Note.** The dividing line between adaptation and mutation is that an adapted microorganism will not retain its ability to flourish in a hostile media when cultured in a normal growth media and returned to the hostile media.

*Search This Class, Subclass:*

172, for mutation and genetic engineering.

246. Foam Culture:
Subject matter under subclass 243 wherein media of the process is in the form of a foam.

247. Utilizing Media Containing Lower Alkanols, i.e., Having One to Six Carbon Atoms:
Subject matter under subclass 243 wherein a microorganism is propagated on a media containing an alkanol having six or less carbon atoms or the media per se.

248. Utilizing Media Containing Hydrocarbon:
Subject matter under subclass 243 wherein the microorganism is propagated on a media containing a hydrocarbon or the media per se.

*Search This Class, Subclass:*

281, for processes of growing microorganisms on petroleum oil containing media.

propagated or treated is a bacteria including actinomycetales or two media for the propagation of bacteria including actinomycetales or a composition containing a bacteria or actinomycetales or a process for making the composition or the culture media.

(1) Note. This subclass takes "bacteriological" media.

254. Fungi; Media Therefor:

Subject matter under subclass 243 wherein the microorganism propagated or treated is a fungi or media for the propagation of fungi, or the composition contains a fungi or processes for producing the composition or the media.

(1) Note. Fungi includes yeast and molds.

*Search Class:*

47, Plant Husbandry, subclasses 1.1+ for the cultivation of mushrooms per se.

255. Yeast; Media Therefor:

Subject matter under subclass 254 wherein the fungi is a yeast.

(1) Note. Disposition of yeast patents claimed or disclosed (a) as an edible, (b) as a component in an edible, or (c) as a single source material for producing protein useful in making an edible.

(a) Yeast with a claimed or solely disclosed utility as a foodstuff in the form it is produced by a 435 process is classifiable in 426.

(b) Yeast claimed or disclosed as a component of an edible is classifiable in 426 if the claim or disclosure is that the yeast is a food supplement and is not medicative (i.e., used to alleviate a disease) in which case placement in 424 is proper.

propagation of undifferentiated plant cells where there is a further step of differentiation into a plant.

426, Food or Edible Material: Process, Compositions and Products, appropriate subclasses, particularly subclasses 7+, 61+, and 531+ for edible compositions containing algae.

258. Protozoa; Media Therefor:
Subject matter under subclass 243 wherein the microorganism propagated or treated is a protozoa or the media for the propagation of protozoa, or the composition or the method for preparing such composition or media.

259. Lysis of Microorganism:
Processes under the subclass 243 wherein the microorganism is ruptured by added material or mechanical means.

(1) **Note.** This subclass does not provide for autolysis which is generally part of the processes included in subclasses 262+.

260. Preserving or Maintaining Microorganism:
Processes under subclass 243 wherein a viable microorganism is rendered reversibly dormant.

(1) **Note.** This subclass includes preparing solvent dried and freeze dried cells.

*Search This Class, Subclass:*

1, for processes of maintaining differentiated tissue or an organ in a viable state.

2, for processes or media for maintaining blood or sperm in a physiologically active state.

261. Separation of Microorganism from Culture Media:

34, Drying and Gas or Vapor Contact with Solids, provides for processes of separating liquids from solids or slurries, i.e., drying as well as the contact of solids with either, or both, gases and vapors. If the starting material is in the form of a liquid suspension or solution even if the process is continued to the point of complete dryness, Class 159, Concentrating Evaporators, will take the process.

55, Gas Separation, includes processes of physical separation of a gas and solid or liquid particle entrained therein; a liquid and the gas entrained therein; or a plurality of gases, provided that such separation is not effected by a chemical reaction or by use of refrigeration. Class 55 also provides for subject matter in which the gas mixture is treated to change its makeup, but no real separation occurs such as a process of agglomeration of small particles in a gas stream provided no other basis for classification exists.

62, Refrigeration, includes processes which include removing heat by refrigeration from a substance whether solid, liquid, or vapor. In particular, Class 62, subclasses 8+ will take processes of making a solidified or liquefied gaseous product provided the gas has a normal boiling point below 32° (methane, ethane, propane) and Class 62, subclasses 532+ will take processes wherein a solution or mixture is cooled to solidify a constituent which is then removed from the mixture.

127, Sugar, Starch and Carbohydrates, for processes wholly peculiar to processes of extracting or purifying natural starch, natural sucrose, or other natural carbohydrates except cellulose, processes of hydrolyzing carbohydrates or processes of purifying the products of such hydrolysis. The chemical manufacture or synthesis of sugar or of carbohydrates by any other process than that of hydrolysis is not included in Class 127. Molecular rearrangement of one carbohydrate to form any other carbohydrate is excluded. Such processes are provided for in Class 260.

159, Concentrating Evaporators, provides for processes pecul-

the separation or purification of a constituent from a flowable liquid mixture by dialysis, sorption, ion exchange, liquid extraction, gravitational separation, or filtration, as well as purification of a liquid mixture by destruction or conversion of a constituent. Processes directed to the purification of a particular compound or composition (including solutions of either the compound or composition in water), are classified with the particular compound or composition. Insofar as the treatment of liquids with ion exchange or sorption materials are concerned, the following lines will be maintained.

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

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

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

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

(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).

(3) Purification or separation of liquids by flocculation only are classified in Class 210.

(4) Processes wherein all claims are limited to the deposition of specific materials on ion-exchangers or sorbents with subsequent recovery of the specific materials are classified with materials so operated upon.

Class 210 is superior to Class 55 and takes separating processes

source and is recovered from an undesired extraneous material originally contained in the macroscopic material's surface.

(1) **Note.** This subclass includes processes of using a microorganism or enzyme *per se* to remove adherent matter from an object.

*Search Class*

8, Bleaching, and Dyeing; Fluid Treatment and Chemical Modification, for process of cleaning and laundering textile fabrics and fibers, including a fluid or chemical treatment. Includes also combinations and aftertreatments incidental to such operations not elsewhere classifiable.

134, Drying and Gas or Vapor Contact with Solids, for processes of cleaning textiles and fibers not involving chemical or fluid treatment and including the mechanical cleaning of textiles and fibers and cleaning by a gas blast or suction (which is not considered a fluid treatment for Class 8).

252, Compositions, subclasses 89+ for enzyme containing detergent compositions.

265. Depilating Hides, Bating or Hide Treating Using Enzyme or Microorganism:
Processes under subclass 262 wherein the preexisting material treated is a hide or a skin of an animal.

*Search Class:*

8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, subclasses 1+ for a dyeing process employing fermentation or an enzyme; subclasses 94.1+ for processes of tanning hides or skins by fermentation with subsequent tanning of the hides or skins or subsequent operations that are preliminary and peculiar to making leather. Class 435 provides for a fermentation

252, Compositions, subclass 321 for a process not combined with distillation for inhibiting foam and Search Class thereunder; subclass 358 for compositions for use in breaking colloids; and subclass 361 for apparatus means for breaking foam.

261, Gas and Liquid Contact Apparatus, appropriate subclasses for gas-liquid scrubbing devices.

267. Treating Animal or Plant Material or Microorganism:
Processes under subclass 262 wherein the preexisting material is obtained directly from an animal or plant source or microorganism.

(1) Note. Included herein are processes of isolating a hormone from an organ or a compound from a fruit by means of an enzyme or microorganism.

*Search This Class, Subclass:*

239, for treatment of animal tissue or organs to recover a virus.

268. Treating Organ or Animal Secretion:
Processes under subclass 267 wherein the preexisting material is an organ or animal secretion.

(1) Note. Animal secretion includes blood, urine, feces, hormones, etc.

269. Treating Blood Fraction:
Processes under subclass 267 wherein the preexisting material is blood or a blood fraction.

(1) Note. A blood fraction is considered to include plasma, red blood cells, white blood cells, nonenzymatic proteins, serum.

*Search This Class, Subclass:*

an unbroken chain of more than seven carbon atoms bonded to a carboxylic group, e.g., lauric, palmitic, stearic, oleic, ricinoleic, linoleic acid, etc. Where there are several unbroken chains of carbon atoms bonded to the carboxyl group, one of the chains must contain a chain of seven or more carbon atoms.

272. Proteinaceous Material Recovered or Purified:
Processes under the subclass 267 wherein the preexisting material is a proteinaceous material.

*Search This Class, Subclass:*

239, for methods of separating virus and protein contaminants by various methods, e.g., sorption, precipitation, etc.

*Search Class:*

8, Bleaching, and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, subclasses 94.1+ for fluid or chemical treatment of hides, skins, feathers, and animal tissues, not otherwise provided for; subclass 127.5 for processes of chemically modifying proteinaceous fibers; and subclass 138 for processes for fluid or chemical treatment of silk for the removal of sericin, or other naturally occurring gum or wax. Processes classifiable in this subclass (2) generally include the production of a fiber pulp from a raw proteinaceous fibrous material (e.g., leather).

134, Cleaning and Liquid Contact with Solids, for processes of chemically removing coatings, such as wax, from a paper base without otherwise affecting the base, where the coating is not recovered.

260, Chemistry, Carbon Compounds, subclass 112 for proteins and their reaction products and, in particular, subclass 123.7 for chemical treatment of natural protein containing material.

8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, for chemical modification and fluid treatment of fibers and textiles, not otherwise provided for.

162, Paper Making and Fiber Liberation, for processes of liberation, recovery or purification of cellulose or animal fibers as individual fibers or fibrous pulp by the use of a reagent which exerts some solvent or chemical action upon fibrous material and the reagent compositions employed in such processes.

260, Chemistry, Carbon Compounds, particularly subclasses 212+ for processes of chemically modifying cellulose in which its fibrous nature is destroyed, e.g., in the production of cellulose esters.

278. Producing Paper Pulp:
Processes under subclass 277 wherein the material which is liberated is paper pulp.

*Search Class:*

162, Paper Making and Fiber Liberation, for processes of making a paper pulp by chemical action.

279. Hemp or Flax Treating:
Processes under subclass 277 wherein the preexisting material which is liberated is hemp or flax.

*Search Class:*

19, Textiles, Fiber Preparation, for the mechanical treatment of fibers to put them in condition for use.

280. Resolution of Optical Isomers or Purification of Organic Compounds or Composition Containing Same:
Processes under subclass 262 wherein a racemic mixture is

more than the mere thermal effects of the electrical or wave energy.

208, Mineral Oils: Processes and Products, for processes of treating and preparing mineral oils including their separation from sands, coal, or shales.

210, Liquid Purification or Separation, for processes and apparatus for separating liquids including mineral oils involving no chemical treatment of the mineral oil.

252, Compositions, particularly subclasses 319+ and 359+ for processes and apparatus for breaking emulsions including petroleum emulsions where there is no additional treatment of the oil.

299, Mining or In Situ Disintegration of Hard Material, for a process or apparatus for treating oil or oil bearing minerals while in situ in a tunnel or excavation.

423, Chemistry, Inorganic, subclass 41 for the recovery of metal containing compounds without the reduction of the compound to pure metal.

282. Desulfurizing:
Processes under subclass 281 wherein sulfur or sulfur containing compounds are removed from petroleum or shale oil.

283. Organ Perfusion Apparatus:
Apparatus under the class definition with means for maintaining an organ in vitro in a viable state by perfusion of the organ with an oxygen rich fluid.

*Search This Class, Subclass:*

1, for related processes.

*Search Class:*

285. With Means Providing Thin Layers:
Apparatus under subclass 284 in which the surface upon which cellular or viral reproduction takes place is surface extending means typically one or more planar elements or one or more hollow cylindrical elements.

*Search This Class, Subclass:*

312, for propagation apparatus of general utility which rotates.

313+, for apparatus with means to increase gas liquid contacts in a process of general propagation.

286. With Means Providing Suspensions:
Apparatus under subclass 284 which has means for suspending cells or maintaining cells in a suspended condition.

(1) **Note.** Roller bottles are presumed to provide for growth in thin layers in the absence of a clear showing to the contrary.

187. Apparatus:
Apparatus under the class definition.

(1) **Note.** Excluded herefrom are kits that are claimed as kits but have no claimed structure but instead recite the ingredients of the kit. Such subject matter should be considered test media and classified in subclasses 4+.

*Search Class:*

29, Metal Working, subclasses 400+ for methods of assembling the apparatus provided for in this class.

47, Plant Husbandry, for processes and apparatus for growing a mushroom or edible fungi except yeast, multicellular algae, or a plant.

(1) **Note.** Excluded herefrom is an enzyme merely immobilized on a carrier where the carrier has no claimed structural features other than rod or cylinder.

(2) **Note.** Examples of the type of structure provided for here are hollow tubular structures of immobilized enzymes ultra-filtration apparatus, fluidized beds, fixed beds, flow-through columns, constant stir apparatus, etc.

*Search This Class, Subclass:*

174, for immobilized enzymes or processes for immobilization.

183, for enzymes per se.

289. Including Condition or Time Responsive Control:
Apparatus under subclass 287 with means to sense a process parameter which actuates means to alter a process parameter, or timing means which actuates means which alter one or more process parameters.

(1) **Note.** Included herein is a programmed computer and associated detection and actuation devices for process control.

*Search Class:*

73, Measuring and Testing, for apparatus for making tests and measurements not otherwise provided for. See particularly subclass 36 for testing illuminating fluids for flash point, vapor pressure and end point; and subclasses 190+ for calorimeters.

137, Fluid Handling, subclasses 88+ for systems for controlling the mixture of a plurality of fluids in response to the sensing of a condition or characteristic of the mixture,

291. Including Measuring or Testing with Condition Sensing or Measuring Means:
Apparatus under subclass 287 with means to test or measure a condition or property in a sample.

(1) Note. This subclass is intended to provide for automated analysis devices which perform one or more tests or measurements on a sample and is not intended to include subjective inspection or sensing by a human agency.

*Search Class:*

73, Measuring and Testing, for apparatus for making tests and measurements not otherwise provided for. See particularly subclass 36 for testing illuminating fluids for flash point, vapor pressure and end point; and subclasses 190+ for calorimeters.

137, Fluid Handling, subclasses 88+ for systems for controlling the mixture of a plurality of fluids in response to the sensing of a condition or characteristic of the mixture, note particularly subclass 93 in which the control is in response to a sensing of a chemical property.

196, Mineral Oils: Apparatus, subclasses 132 and 141 for combinations of apparatus for making a test or measurement and means for controlling a reaction provided for in that class.

204, Chemistry, Electrical and Wave Energy, subclass 195 for apparatus specialized for the determination of hydrogen ion concentration of solutions.

324, Electricity, Measuring and Testing, appropriate subclasses for apparatus for testing an 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.

or swab attached to the cap or cover of a small bottle or dish.

*Search Class:*

206, Special Receptacle or Package, subclasses 205+ for containers of general utility with content contacting means.

295. Sampler or Innoculator is Swab:
Apparatus under subclass 294 wherein the means for effecting physical contact is a long slender rod carrying a bibulous or sorbent material for at least a portion of its length.

296. Tube or Bottle:
Apparatus under subclass 287 which is a tube or a bottle.

(1) **Note.** Included in this definition are test tubes, flasks, capillary tubes, etc.

297. Petri Dish:
Apparatus under subclass 287 which is a small shallow dish of thin transparent material with a loosely fitting overlapping cover.

298. Including Cover Seal:
Apparatus under subclass 297 including means to prevent the passage of liquid or gas to or from the interior of a Petri dish.

206, Special Receptacle or Package, various subclasses for receptacles of specialized utility which may contain a cover seal.

215, Bottles and Jars, subclasses 37+ for receptacle closures of general utility.

299. Containing or Adapted to Contain Solid Media:
Apparatus under subclass 287 which includes a solid cultivation media or which includes means adapted to retain a solid media.

ing, and Chemical Apparatus, subclasses 209+ for chemical reactors of general utility which rotate.

304. Cascade or Vertically Spaced Stages:
Apparatus under subclass 302 including a series of vertically spaced trays or weirs.

*Search This Class, Subclass:*

310, for similar fermentor structure not specially adapted to malting.

305. With Agitator or Mash Turner:
Apparatus under subclass 302 including means for mixing or stirring the mash.

*Search Class:*

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclasses 224+ for agitators in chemical reactors of general utility.

306. With Horizontal Axis of Rotation:
Apparatus under subclass 305 in which the axis of the mixing means is horizontal.

307. With Vertical Axis of Rotation:
Apparatus under subclass 305 in which the axis of the mixing means is vertical.

(1) **Note.** This subclass includes eccentrically moving mixing devices in which the rotating mixing means revolve in turn about an axis.

308. Rakes:
Apparatus under subclass 307 wherein the mixing means includes a bar with projecting pegs or prongs set transversely.

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclasses 1 + for processes of disinfecting or sterilizing of general utility.

312. Rotatably Mounted:
Apparatus under subclass 287 including means providing for motion of a vessel about an axis.

(1) Note. This includes eccentric motion produced by combined rotation and revolution.

*Search Class:*

366, Agitating, for agitation by use of a rotating receptacle.

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclass 209 for a rotating chemical reactor of general utility; and subclasses 209 and 270 for chemical reactors of general utility which revolve during use.

432, Heating, subclasses 203+ for a rotary drum furnace.

313. With Gas Introduction Means:
Apparatus under subclass 287 including means for introducing vapor phase material into a vessel.

*Search This Class, Subclass:*

285, for animal or plant cell growth apparatus in which gas is introduced through a permeable membrane.

*Search Class:*

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclass 168 for waste gas

(1) **Note.** This subclass provides for subcellular parts, plasmids and organelles such as mitochondria, microsomes and chloroplasts.

*Search This Class, Subclass:*

1, for apparatus for maintaining a tissue or organ in a viable state.

284+, for apparatus for the propagation of tissue.

*Search Class:*

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclass 162 for automatic analytical monitor and control of chemical processes; subclass 105 for control elements responsive to a sensed operating condition; subclasses 150+ for chemical analytical apparatus; and subclasses 163+ for chemical analytical apparatus with continuous sample movement.

CROSS-REFERENCE ART COLLECTIONS

800. *Elimination or Reduction of Contamination by Undesired Ferments, e.g., Aseptic Cultivation:*
Subject matter in which a culture is subjected to physical or chemical treatment to suppress or reduce the growth of a microorganism present in order to permit another microorganism to propagate.

801. *Anerobic Cultivation:*
Subject matter in which microorganism cultivation takes place in the absence of oxygen or oxygen bearing gas.

802. *Logarithmic Growth Phase:*
Subject matter in which the initial growth period of a microorganism culture is extended or controlled or is otherwise of interest.

Subject matter in which the formation of froth in fermentors is suppressed by physical or chemical treatment.

813. *Continuous Fermentation:*
Subject matter which is arranged to facilitate continuous operation.

814. *Enzyme Separation or Purification:*
Subject matter in which an enzyme is separated or purified.

815. By Sorption:
Subject matter under subclass 814 in which an enzyme is separated or purified by absorption or adsorption.

816. By Solubility:
Subject matter under subclass 814 in which an enzyme is separated or purified by manipulation of the relative solubility of the enzyme in a solvent.

817. *Enzyme or Microbe Electrode:*
Subject matter in which an enzyme or microbe is part of an electrode.

818. *Aeration or Oxygen Transfer Technique:*
Subject matter in which a fermentor is aerated or other process of oxygen transfer is disclosed.

819. *Fermentation Vessels in Series:*
Subject matter in which two or more fermentation vessels are connected in series.

820. *Subcellular Parts of Microorganisms:*
Subject matter in which the subcellular parts of a microorganism are isolated or treated.

822-948. *Microorganism Cross-Reference Collections:*
The bacteria terminology is based upon "Berger's Manual of

CLASSIFICATION DEFINITIONS
ADDENDA NO. 1 - ORDER NO. 692
JULY 17, 1979

D. CHANGES TO THE DEFINITIONS (Project No. C 1558)

CLASS 435 - CHEMISTRY: MOLECULAR BIOLOGY AND MICROBIOLOGY

*Definitions Established*

| *Class* | *Subclasses* |
|---|---|
| 435 | 1 - 317 |
| | Cross-Reference Art Collections |
| | 800 - 820; 822 - 948 |

New Definitions Separately Available

## D. CHANGES TO THE DEFINITIONS

### ADDENDA NO. 3

### CLASS 435 - CHEMISTRY: MOLECULAR BIOLOGY AND MICROBIOLOGY

### *ADDENDA NO. 2*

Reserve for future printing

### *ADDENDA NO. 3*

Classification Order 732
Effective Date: May 21, 1980

***Reference Updates* to Definitions or to Search Class Notes in Existing Subclasses***

| *In Subclass* | *Change reference from* | | *To* | |
|---|---|---|---|---|
| | *Class* | *Subclasses* | *Class* | *Subclass* |
| 265 - SEARCH CLASS | 8 | 1+ | 8 | 401 |

* Place these class and/or subclass updates in numerical sequence.

532 . . . Antigen or antibody attached to a carrier via bridging agent
533 . . . . Carrier is water suspendible particles (*e.g.*, latex, etc.)
534 . . . Carrier is water suspendible particles
535 . . Antigen or antibody entrapped within the carrier (*e.g.*, gel, hollow fibre, etc.)
536 INVOLVING IMMUNE COMPLEX FORMED IN LIQUID PHASE
537 . Signal modification or steric inhibition
538 . Separation of immune complex from unbound antigen or antibody
539 . . Involving precipitating reagent
540 . . . Double or second antibody
541 . . Absorbent column, particles or resin strip
542 . . Involving radioactive labeling
543 INVOLVING PRODUCING OR TREATING ANTIGEN OR HAPTEN
544 . Producing labeled antigens
545 . . Radioactive label
546 . . Fluorescent label
547 INVOLVING PRODUCTION OR TREATMENT OF ANTIBODY
548 . Monoclonal antibody
1 PROCESS OR COMPOSITION FOR STERILITY OR PACKAGE INTEGRITY TEST
2 PROCESS OR COMPOSITION FOR DETERMINATION OF PHYSICAL STATE OR PROPERTY BY MEANS INCLUDING A CHEMICAL REACTION
3 . Leak detection
4 . Of crystal or crystalline material
5 . Surface area, porosity, imperfection, or alteration
6 . Corrosion resistance or power
7 . By thermoparticulating composition
8 COMPOSITION FOR STANDARDIZATION, CALIBRATION, SIMULATION, STABILIZATION, PREPARATION OR PRESERVATION; PROCESSES OF USE IN PREPARATION FOR CHEMICAL TESTING
9 . Simulative of a gaseous composition
10 . Particle count or volume standard or control (*e.g.*, platelet count standards, etc.)
11 . Blood gas standard or control
12 . Bilirubin or uric acid standard or control
13 . Lipid, cholesterol, or triglyceride standard or control

53 . . With formation of a segmented stream
54 . With aspirator of claimed structure
55 CONDITION RESPONSIVE CONTROL
56 TRACERS OR TAGS
57 INCLUDING USE OF RADIOACTIVE PROPERTIES
58 . Dosage determination of high energy radiation, (*e.g.*, use of an X-ray dosimeter, etc.)
59 . Including pyrolysis of radioactive material
60 LUBRICANT, GREASE, MINERAL OIL, HYDROCARBON OIL PRODUCT, OR FATS OR LIPIDS FOR OXIDATION (*E.G.*, BREAKDOWN PRODUCTS OR CONTAMINATION, ETC).
61 . Acidity, basicity or neutralization number
62 OXYGEN DEMAND (*E.G.*, BOD, TOD, COD, ETC.)
63 BIOLOGICAL CELLULAR MATERIAL TESTED
64 CANCER
65 PREGNANCY OR OVULATION
66 HEMOGLOBIN, MYOGLOBIN, OR OCCULT BLOOD
67 . Glycosylated hemoglobin
68 BLOOD GAS (*E.G.*, OXYGEN, CARBON DIOXIDE, BLOOD, pH, ETC.)
69 CLOTTING OR CLOTTING FACTOR LEVEL TESTS
70 SEDIMENTATION RATE OR HEMATOCRIT
71 LIPIDS, TRIGLYCERIDES, CHOLESTEROL, OR LIPOPROTEINS
72 SILICON CONTAINING
73 METAL OR METAL CONTAINING
74 . Present in biological fluids (*e.g.*, blood, urine, etc.)
75 . Oxide or gas content of metal (*e.g.*, determination of dissolved gases, etc.)
76 . Organometallic compound determined
77 . . Group IVA (*e.g.*, Ge, Sn, Pb, etc.)
78 . Presence of a component of steel
79 . Group IA or IIA (e.g., Li, Na, K, Rb, Cs, Fr, Be, Mg, Ca, Sr, Ba, Ra, etc.)
80 . Group IB (*e.g.*, Cu, Ag, Au, etc.)
81 . Group IIB, IIIB, or Antinides, or Lanthanides (*e.g.*, Zn, Cd, Hg, Sc, Y, etc.)
82 . . Lanthanide or Actinide
83 . Group IVB, VB, VIB (*e.g.*, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, etc.)
84 . Group VIIB, VIII (*e.g.*, Mn, Tc, Re, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt)

123 . Total or elemental sulfur
124 HALOGEN CONTAINING
125 . In aqueous solution
126 . Carbon containing compound (*e.g.,* vinylchloride, etc.)
127 OXYGEN CONTAINING
128 . Carbonyl, ether, aldehyde or ketone containing
129 . . Carboxylic acid
130 . . Formaldehyde or acetone
131 . Hydroxyl containing
132 . . Ethanol
133 . Inorganic carbon compounds
134 . . Carbon monoxide only
135 . Ozone or peroxide
136 . Molecular oxygen
137 . . Fuel/air mixture or exhaust gas analysis
138 . . Dissolved or trace oxygen or oxygen content of a sealed environment
139 HYDROCARBON
140 . Aromatic
141 . Acyclic (*e.g.,* methane, octane, isoparaffin, etc.)
142 . . Unsaturated (*e.g.,* ethylene, diene, etc.)
143 . Total hydrocarbon, flammability, combustibility (*e.g.,* air-fuel mixture, etc.)
144 HYDROGEN, PER SE
145 CARBON CONTAINING
146 . In an aqueous solution (*e.g.,* TOC, etc.)
147 MEASUREMENT INCLUDES TEMPERATURE CHANGE OF THE MATERIAL BEING ANALYZED (*E.G.,* CALORIMETRY, ETC.)
148 MEASUREMENT INCLUDES CHANGE IN VOLUME OR PRESSURE
149 MEASUREMENT OF ELECTRICAL OR MAGNETIC PROPERTY OR THERMAL CONDUCTIVITY
150 . Of a liquid
151 . By means of a solid body in contact with a fluid
152 . . Solid body contains a combustion catalyst
153 . Of an ionized gas
154 . . Flame ionization
155 PYROLYSIS, COMBUSTION, OR ELEVATED TEMPERATURE CONVERSION
156 . Explosibility
157 . Multiple stages of heating or heating at multiple temperatures or application of temperature gradient

806 ELECTRICAL PROPERTY OR MAGNETIC PROPERTY
807 APPARATUS INCLUDED IN PROCESS CLAIM (E.G., PHYSICAL SUPPORT STRUCTURES, ETC.)
808 . Automated or kit
809 . Multifield plates or multicontainer arrays
810 . Tube, bottle, or dipstick
811 TEST FOR NAMED DISEASE, BODY CONDITION OR ORGAN FUNCTION
812 . Infectious mononucleosis
813 . Cancer
814 . Pregnancy
815 TEST FOR NAMED COMPOUND OR CLASS OF COMPOUNDS
816 . Alkaloids, amphetamines, and barbiturates
817 . Steroids or hormones
818 . . Human chorionic gonadotropin
819 MULTIFUNCTIONAL ANTIGEN OR ANTIBODY
820 HEPATITIS ASSOCIATED ANTIGENS AND ANTIBODIES
821 INVOLVING COMPLEMENT FACTORS OR COMPLEMENT SYSTEMS
822 IDENTIFIED HAPTEN
823 IMMUNOGENIC CARRIER OR CARRIER PER SE
824 IMMUNOLOGICAL SEPARATION TECHNIQUES
825 PRETREATMENT FOR REMOVAL OF INTERFERING FACTORS FROM SAMPLE
826 ADDITIVES (E.G., BUFFERS, DILVENTS, PRESERVATIVES)
827 LECTINS
828 PROTEIN A
829 LIPOSOMES (E.G., ENCAPSULATION, ETC.)

CROSS-REFERENCE ART COLLECTIONS RELATING TO CHEMICAL ANALYSIS

900 BREATH TESTING
901 DRUGS OF ABUSE (E.G., NARCOTICS, AMPHETAMINE, ETC.)
902 DOSIMETER
903 DIAZO REACTIONS
904 OXIDATION - REDUCTION INDICATORS
905 PHOTOCHEMICAL ACTIVATION OF REACTIONS
906 FERTILITY TESTS
907 FETAL LUNG MATURITY
908 GRAVIMETRIC ANALYSIS

29 . . . . . The hetero ring has exactly 13 ring carbons (*e.g.*, erythromycin, etc.)
30 . . . . . The hetero ring has exactly 15 ring carbons
31 . . . . . The hetero ring has 20 or more ring carbons (*e.g.*, nystatin, etc.)
32 . . . Oxygen of the saccharide radical bonded to a nonsaccharide hetero ring by acyclic carbon bonding
33 . . . Oxygen of the saccharide radical bonded directly to a polycyclo ring system of three or more carbocyclic rings
34 . . . . Oxygen of the saccharide radical bonded directly to a polycyclo ring system of four carbocyclic rings (*e.g.*, daunomycin, etc.)
35 . . . Oxygen of the saccharide radical bonded directly to a cyclohexyl ring
36 . . . . Two or more nitrogen atoms bonded directly to the cyclohexyl ring
37 . . . . . The nitrogen atoms are in N-C(=N)-N groups (*e.g.*, streptomycin, etc.)
38 . . . . . Two saccharide radicals bonded through only oxygen to adjacent ring carbons of the cyclohexyl ring
39 . . . . . Three or more saccharide radicals (*e.g.*, neomycin, etc.)
40 . . . . . Two saccharide radicals bonded through only oxygen to 4- and 6- positions of the cyclohexyl ring
41 . . . . . Kanamycin or derivative
42 . . N-glycoside
43 . . . Nitrogen containing hetero ring
44 . . . . Polynucleotide (*e.g.*, RNA, DNA, etc.)
45 . . . . Purines (including hydrogenated) (*e.g.*, adenine, guanine, etc.)
46 . . . . . Adenosine or derivative
47 . . . . . Phosphorus containing
48 . . . . . Phosphorus containing
49 . . . . Pyrimidines (including hydrogenated) (*e.g.*, cytosine, etc.)
50 . . . . . 2,4-diketone pyrimidine or derivative (*e.g.*, uracil, etc.)
51 . . . . . Phosphorus containing
52 . . . . Phosphorus containing (*e.g.*, Vitamin B12, etc.)
53 . . Dissaccharide
54 . . . Polysaccharide
55 . . . Chitin or derivative
56 . . . . Heparin or derivative
57 . . . Cellulose or derivative

90 . . . . Chalcogen in the six-membered hetero ring
91 . . . Hetero ring is five-membered
92 . . . . Two or more hetero atoms in the five-membered ring
93 . . . . . Triazoles (including hydrogenated)
94 . . . . . Diazoles (including hydrogenated)
95 . . Sulfur containing hetero ring
96 . . . Polycyclo ring system having the hetero ring as one of the cyclos
97 . . . Two or more sulfurs in the hetero ring
98 . . . Oxygen in the hetero ring
99 . . Oxygen containing hetero ring
100 . . . Polycyclo ring system having the hetero ring as one of the cyclos
101 . . . Two or more oxygen in the hetero ring
102 . . Two or more phosphorus atoms directly or indirectly bonded together by only covalent bonds
103 . . . Phosphorus acid ester of polyhydric alcohol or thioalcohol (*e.g.*, P-X-R-X-P group, etc., wherein X is chalcogen and R is the residue of the polyhydric alcohol or thioalcohol)
104 . . . . Benzene ring in the alcohol moiety
105 . . . Phosphorus is part of a ring
106 . . . P-O-P or P-S-P containing (*e.g.*, anhydrides, etc.)
107 . . . Benzene ring containing
108 . . . Acyclic and contains at least one carbon atom between the phosphorus atoms
109 . . P-X-X containing (X is chalcogen)
110 . . Phosphorus is part of a ring
111 . . . Polycyclo ring system having the phosphorus containing ring as one of the cyclos
112 . . Cyano or isocyano containing
113 . . . Cyano or isocyano bonded directly to a benzene ring
114 . . Nitrogen, other than nitro or nitroso, bonded indirectly to phosphorus
115 . . . N-C(=X)-N containing (X is chalcogen)
116 . . . Sulfur single bonded directly to nitrogen
117 . . . . N-(0=)S(=0) containing (*i.e.*, sulfonamides)
118 . . . Phosphorus single bonded directly to nitrogen
119 . . . C(=0)N containing
120 . . C=0 other than as ketone or aldehyde, attached directly or indirectly to phosphorus
121 . . . Plural C=0 groups, other than as ketone or aldehyde
122 . . . . Malathion
123 . . . . . With N-C(=0)-0 containing compound

. 3,10-dihydroxy-2-naphthacene carboxamide or derivative (*e.g.*, tetracycline, etc.) DOAI
154 . . With an additional active ingredient (excludes reaction product or complex)
155 . Para-N-benzene - sulfoxy-N containing DOAI, and said benzene ring is not part of a polycyclo ring system
156 . . Hetero ring containing
157 . . . The hetero ring is six-membered and includes at least two nitrogens and no other hetero atoms
158 . . . The hetero ring is five-membered
159 . Ortho-hydroxybenzoic acid (*i.e.*, salicyclic acid) or derivative DOAI
160 . . With additional ortho-hydroxybenzoic acid compound
161 . . With heterocyclic compound
162 . . With organic nitrogen containing compound
163 . . With carboxylic acid, ester or metal salt thereof
164 . . With organic oxygen containing compound
165 . . Aspirin per se (*i.e.*, 2-(acetyloxy)benozic acid)
166 . . Nitrogen containing (*e.g.*, anilides, etc.)
167 . 9,10-seco-cyclopentanohydrophenanthrene ring system (*e.g.*, vitamin D, etc.) DOAI
168 . . With a vitamin type active ingredient
169 . Cyclopentanohydrophenanthrene ring system DOAI
170 . . Plural Compounds containing cyclopentanohydrophenanthrene ring systems
171 . . With additional active ingredient
172 . . Hetero ring containing
173 . . . Spiro ring system
174 . . . O-C-O- is part of a hetero ring (e.g., acetonide, etc.)
175 . . . -C (=O) -O-is part of a hetero ring (e.g., lactone, etc.)
176 . . . Nitrogen containing hetero ring
177 . . Oxygen double bonded to a ring carbon of the cyclopentanohydrophenanthrene ring system
178 . . . Oxygen single bonded to a ring carbon of the cyclopentanohydrophenanthrene ring system
179 . . . . Modified C-ring (except methyl in 13-position) (*e.g.*, double bond containing, substituted, etc.)
180 . . . . . 9-position substituted
181 . . . . 21-position substituted
182 . . Oxygen single bonded to a ring carbon of the cyclopentanohydrophenanthrene ring system
183 . Heterocyclic carbon compounds containing a hetero ring having chalcogen (*i.e.*, O, S, Se or Te) or nitrogen as the only ring hetero atoms DOAI

216 . . . . Two of the cyclos share at least three ring carbons (*i.e.*, bridged)
217 . . . . Tricyclo ring system having the seven-membered hetero ring as one of the cyclos
218 . . . Hetero ring is seven-membered consisting of two nitrogens and five carbon atoms
219 . . . Polycyclo ring system having the seven-membered hetero ring as one of the cyclos
220 . . . . Tricyclo ring system having the seven-membered hetero ring as one of the cyclos
221 . . . . Bicyclo ring system having the seven-membered hetero ring as one of the cyclos
222 . . Hetero ring is six-membered and includes at least nitrogen and sulfur as hetero atoms
223 . . . Phenothiazines (including hydrogenated)
224 . . . . Plural hetero rings

DESIGNATED ORGANIC ACTIVE INGREDIENT CONTAINING (DOAI)

. Heterocyclic carbon compounds containing a hetero ring having chalcogen (i.e., O, S, Se or Te) or nitrogen as the only ring hetero atoms DOAI

. . Hetero ring is six-membered and includes at least nitrogen and sulfur as hetero atoms

225 . . . 1,4-benzothiazines (including hydrogenated)
226 . . . 1,3-thiazines
227 . . Hetero ring is six-membered and includes at least nitrogen and oxygen as hetero atoms
228 . . . Sulfur containing
229 . . . . Nitrogen bonded directly to the sulfur
230 . . . . Sulfur containing hetero ring
231 . . . . . Polycyclo ring system
232 . . . . Mercaptan, mercaptide or thioether
233 . . . C=O other than as ketone or aldehyde
234 . . . . N-C(=O) containing
235 . . . . . N-C(=O)-N containing
236 . . . . Carboxylic acid ester (including lactones)
237 . . . Acyclic nitrogen, other than nitro or nitroso, bonded to carbon
238 . . . Acyclic oxygen containing
239 . . . . Polycyclo ring system
240 . . . . The oxygen bonded directly to benzene ring
241 . . Hetero ring is six-membered consisting of three nitrogens and three carbon atoms

271 . . . . . Two or more barbituric acid compounds or with an additional active ingredient or stabilizer
272 . . . . . Nitrogen bonded directly to the 1,3-diazine at 2-position
273 . . . . . The nitrogen is part of a hetero ring
274 . . . . . Chalcogen bonded directly to pyrimidine at 2-position
275 . . . . Nitrogen bonded directly to the 1,3-diazine at 2-position by a single bond
276 . . . . Thiamines (*e.g.*, vitamin B1, etc.)
277 . . Hetero ring is six-membered consisting of one nitrogen and five carbon atoms
278 . . . Spiro ring system
279 . . . Polycyclo ring system having the six-membered hetero ring as one of the cyclos
280 . . . . Pentacyclo ring system having the six-membered hetero ring as one of the cyclos
281 . . . . . Two of the cyclos share at least three ring members (*i.e.*, bridged)
282 . . . . . One of the five cyclos is five-membered and includes ring chalcogen (*e.g.*, codeine, morphine, etc.)
283 . . . . . Ring nitrogen in the pentacyclo ring system is shared by five-membered cyclo and six-membered cyclo (*e.g.*, vincamine, etc.)
284 . . . . Tetracyclo ring system having the six-membered hetero ring as one of the cyclos
285 . . . . . Plural hetero atoms in the tetracyclo ring system (*e.g.*, acronycines, etc.)
286 . . . . . Two of the cyclos share at least three ring members (*i.e.*, bridged)
287 . . . . . Three or more hetero atoms in the tetracyclo ring system
288 . . . . . Ring carbon is shared by three of the cyclos
289 . . . . . Two of the cyclos share at least three ring members (*i.e.*, bridged) (*e.g.*, morphinans, etc.)
290 . . . . Tricyclo ring system having the six-membered hetero ring as one of the cyclos
291 . . . . . Plural hetero atoms in the tricyclo ring system
292 . . . . . Plural ring nitrogens in the tricyclo ring system
293 . . . . . Three or more hetero atoms in the tricyclo ring system
294 . . . . . Ring nitrogen is shared by two of the cyclos
. Heterocyclic carbon compounds containing a hetero ring having chalcogen (*i.e.*, O, S, Se or Te) or nitrogen as the only ring hetero atoms DOAI

319 . . . . . The additional ring is one of the cyclos in a polycyclo ring system
320 . . . . . Hetero ring in the polycyclo ring system
321 . . . . . Plural hetero atoms in the polycyclo ring system
322 . . . . . Plural ring nitrogens in the polycyclo ring system
323 . . . . . Ring nitrogen in the polycyclo ring system
324 . . . . . Ring sulfur in the polycyclo ring system
325 . . . . . Polycyclo ring system is tricyclo-carbocyclic
326 . . . . . The additional ring is a hetero ring
327 . . . . . Chalcogen bonded directly to ring carbon of the piperidine ring
328 . . . . . Plural chalcogens bonded directly to ring carbons of the piperidine ring
329 . . . . . Nitrogen attached directly to the piperidine ring by nonionic bonding
330 . . . . . C=X bonded directly to the piperidine ring (X is chalcogen)
331 . . . . . Nitrogen attached indirectly to the piperidine ring by nonionic bonding
332 . . . Plural six-membered hetero rings consisting of one nitrogen and five carbon atoms
333 . . . . Additional hetero ring other than the six-membered hetero rings
334 . . . . The six-membered hetero rings are bonded directly to each other
335 . . . . Chalcogen bonded directly to a ring carbon of the six-membered hetero ring
336 . . . Additional hetero ring containing
337 . . . . The additional hetero ring is one of the cyclos in a polycyclo ring system
338 . . . . . Plural hetero atoms in the polycyclo ring system
339 . . . . .Ring nitrogen in the polycyclo ring system
340 . . . . Ring nitrogen in the additional hetero ring (*e.g.*, oxazole, etc.)
341 . . . . . The additional hetero ring consists of two nitrogens and three carbons
342 . . . . . Ring sulfur in the additional hetero ring
343 . . . . . The additional hetero ring consists of one nitrogen and four carbons (*e.g.*, nicotine, etc.)
344 . . . Cyano bonded directly to the six-membered hetero ring
345 . . . Chalcogen bonded directly to ring carbon of the six-membered hetero ring
346 . . . . Chalcogen and acyclic nitrogen bonded directly to the same carbon

370 . . . . Nitrogen bonded directly to ring carbon of the thiazole ring
371 . . . . . C=X bonded directly to the nitrogen which is bonded directly to the thiazole ring (X is chalcogen)
372 . . . 1,2-thiazoles (including hydrogenated)
373 . . . . Polycyclo ring system having the thiazole ring as one of the cyclos
374 . . . 1,3-oxazoles (including hydrogenated)
375 . . . . Polycyclo ring system having the oxazole ring as one of the cyclos
376 . . . . Chalcogen bonded directly to ring carbon of the oxazole ring
377 . . . . Nitrogen bonded directly to ring carbon of the oxazole ring
378 . . . 1,2-oxazoles (including hydrogenated)
379 . . . . Polycyclo ring system having the oxazole ring as one of the cyclos
380 . . . . Chalcogen or nitrogen bonded directly to ring carbon of the oxazole ring
381 . . . Tetrazoles (including hydrogenated)
382 . . . . Additional chalcogen containing hetero ring
383 . . . 1,2,4-triazoles (including hydrogenated)
384 . . . . Chalcogen bonded directly to the triazole ring
385 . . . 1,3-diazoles
386 . . . . Divalent chalcogen or acyclic nitrogen double bonded directly to ring carbon of the diazole ring, or tautomeric equivalent
387 . . . . . Polycyclo ring system having the diazole ring as one of the cyclos
388 . . . . . Nitrogen double bonded directly at 2-position of the diazole ring, or tautomeric equivalent
389 . . . . . Divalent chalcogen or acyclic nitrogen double bonded directly at both 2- and 4- positions, or tautomeric equivalent (*e.g.*, hydantoin, etc.)
390 . . . . . Chalcogen or nitrogen bonded directly at 1-, 3-, or 5-position by nonionic bonding
391 . . . . . Benzene ring bonded directly to the diazole ring by nonionic bonding
392 . . . . . Divalent chalcogen or acyclic nitrogen double bonded at 2-position, or tautomeric equivalent
393 . . . . Polycyclo ring system having the diazole ring as one of the cyclos
394 . . . . . Benzo fused at 4,5-positions of the diazole ring

415 . . . . . The bicyclo ring system consists of the five-membered hetero ring and a benzene ring (*e.g.*, indole, etc.)
416 . . . . . The ring nitrogen is bonded directly to nonshared ring carbons of the five-membered hetero ring (*e.g.*, isoindole, etc.)
417 . . . . . Plural chalcogens bonded directly to ring carbons of the five-membered hetero ring (*e.g.*, phthalimide, etc.)
418 . . . . . Chalcogen bonded directly to ring carbon of the five-membered hetero ring
419 . . . . . C=X bonded directly or indirectly by an acyclic carbon or carbon chain to ring carbon of the five-membered hetero ring (*e.g.*, tryptophan, etc.) (X is chalcogen)
420 . . . . . Indomethacine per se or ester thereof
421 . . . . . Chalcogen bonded directly to ring carbon of the five-membered hetero ring (*e.g.*, adrenochrome, etc.)
422 . . . . Additional hetero ring
423 . . . . C=X bonded directly to the five-membered hetero ring by nonionic bonding (X is chalcogen)
424 . . . . Chalcogen bonded directly to the five-membered hetero ring by nonionic bonding
425 . . . . . Plural chalcogens bonded directly to the five-membered hetero ring by nonionic bonding
426 . . . . Nitrogen bonded directly to the five-membered hetero ring by nonionic bonding
427 . . . . Two double bonds between ring members of the five-membered hetero ring (*e.g.*, pyrrole, etc.)
428 . . . . Chalcogen bonded indirectly to the five-membered hetero ring by acyclic nonionic bonding
429 . . . . Carbocyclic ring bonded directly to the five-membered hetero ring
430 . . Sulfur containing hetero ring
431 . . . The hetero ring has at least seven members
432 . . . The hetero ring is six-membered
433 . . . . Plural hetero atoms in the hetero ring
434 . . . . . Polycyclo ring system having the hetero ring as one of the cyclos
435 . . . . . Three or more hetero atoms in the hetero ring
436 . . . . . Two ring sulfurs in the hetero ring
437 . . . . Tricyclo ring system having the hetero ring as one of the cyclos

469 . . . . . Bicyclo ring system having the hetero ring as one of the cyclos
470 . . . . . Chalcogen or nitrogen bonded directly to the hetero ring
471 . . . . Nitrogen containing
472 . . . . . The nitrogen bonded directly to the hetero ring
473 . . . . Chalcogen bonded directly to the hetero ring
474 . . . . . Ascorbic acid or derivative (*e.g.*, vitamin C, etc.)
475 . . . The hetero ring is three-membered
476 . N-C(=X)X containing (X is chalcogen) DOAI
477 . . N-C(=X)-X-N containing
478 . . N-C(=X)-X-C containing
479 . . . With an additional active ingredient
. N-C(=X)X containing (X is chalcogen) DOAI
. . N-C(=X)-X-C containing
480 . . . Polycyclo ring system attached by nonionic bonding
481 . . . . Naphthyl ring system
482 . . . N-C(=X)-N, N-C(=N)N, N-N, nitrogen directly bonded to oxygen by nonionic bonding or cyano containing
483 . . . Plural N-C(=X)-X groups
484 . . . Ring in acid moiety
485 . . . . The ring is a benzene ring
486 . . . . . Phenoxy in acid moiety
487 . . . . . The benzene ring is attached to nitrogen through an acyclic carbon or carbon chain
488 . . . . . Ring in alcohol moiety
489 . . . Ring in alcohol moiety
490 . . . . Ring attached directly to oxygen of oxygen of N-C(=O)-O
491 . . With an additional active ingredient
492 . Heavy metal containing DOAI
493 . . Tin
494 . . Zinc
495 . . Gold or silver
496 . . Mercury
497 . . . Nitrogen containing
498 . . Lead
499 . . Copper
500 . . . With an additional active ingredient
501 . . . Nickel or cobalt
502 . . Iron
503 . . Antimony or bismuth
504 . . Arsenic

537 . . . . . With an additional active ingredient
538 . . . . . Nitrogen bonded to carbon in Z moiety
539 . . . . . Plural separated benzene rings in Z moiety
540 . . . . . Nitrogen in Y moiety
541 . . . . . Aldehyde or ketone in Z or Y radical
542 . . . . . Z radical contains two or more nitrogen atoms at least one of which forms a C(=X)N group (X is chalcogen)
543 . . . . Z forms a phenoxy alkyl or phenoxy alkenyl radical
544 . . . . C(=O)O attached directly through the carbon to a benzene ring
545 . . . . Ketone in Z radical
546 . . . ZC(=O)OY, wherein Z is an acyclic radical bonded to the C=O by a carbon and Y is an organic radical bonded to the oxygen by a carbon
547 . . . . Compound contains two or more C(=O)O groups
548 . . . . . Ring is alcohol moiety
549 . . . . Z radical contains carbon to carbon unsaturation
550 . . . . Z radical contains sulfur or halogen
551 . . . . Z radical contains nitrogen
552 . . . . Z contains an unbroken chain of at least seven carbon atoms bonded directly to the C(=O) group
553 . Radical -XH acid, or anhydride, acid halide or salt thereof (X is chalcogen) DOAI
554 . . Amine addition salt of the acid
555 . . . Benzene ring in acid moiety
556 . . Inner quarternary ammonium salt (*e.g.*, betaine, etc.)
557 . . Carboxylic acid, percarboxylic acid, or salt thereof (*e.g.*, peracetic acid, etc.)
558 . . . Higher fatty acid or salt thereof
559 . . . . Ring containing
560 . . . . Carbon to carbon unsaturation
561 . . . Nitrogen other than as nitro or nitroso nonionically bonded
562 . . . . Sulfur nonionically bonded
563 . . . . RC(=O)N containing (i.e., carboxamide) (R is C or H)
564 . . . . Plural nitrogens nonionically bonded
565 . . . . . N-N or N=C(-N)-N containing (*e.g.*, hydrazines, hydrazones, or quanidines, etc.)
. Radical -XH acid, or anhydride, acid halide or salt thereof (X is chalcogen) DOAI
. . Carboxylic acid, percarboxylic acid, or salt thereof (*e.g.*, peracetic acid, etc.)

593 . . . . Sulfur is part of a substituent which contains additional nitrogen
594 . . . Additional C=O bonded directly to urea nitrogen
595 . . . Benzene ring containing
596 . . . . Benzene ring bonded directly to urea nitrogen
597 . . . . . Benzene ring is part of a substituent which contains nitrogen
598 . . . . . Benzene ring is part of a substituent which contains oxygen
599 . . Thiocarboxamides, (*i.e.*, C(=S)-N)
600 . . Sulfamides (*i.e.*, N-(O=)S(=O)-N)
601 . . Sulfonamides (*i.e.*, Q-(O=)S(=O)-N, wherein Q is a substituent and wherein any substituent attached to the nitrogen will be referred to as E)
602 . . . Q contains benzene ring
603 . . . . Nitrogen in Q
604 . . . . Q is monocyclic
605 . . . Q is acyclic and benzene ring in a substituent E
606 . . N-S-S containing
607 . . N-S-N containing or contains a nitrogen bonded directly to a S=O group (*e.g.*, sulfinamides, etc.)
608 . . Sulfur attached directly to amino nitrogen by nonionic bonding (*e.g.*, sulfenamides, etc.)
609 . . Cyanamides (*i.e.*, compounds containing cyano bonded directly to amino nitrogen)
610 . . Nitramines (*i.e.*, compounds containing nitro bonded directly to amino nitrogen)
611 . . Nitrosamines (*i.e.*, compounds containing nitroso bonded directly to amino nitrogen)
612 . . Haloamines (*i.e.*, compounds containing halogen attached directly to amino nitrogen by nonionic bonding)
613 . . Carboxamides (*i.e.*, R-C(=O)-N, wherein R is a radical having carbon bonded directly to the C(=O)-N or is hydrogen and wherein any substituent attached to nitrogen will be referred to as E)
614 . . . N-N containing (*e.g.*, aminimine, hydrazine, etc.)
615 . . . . R contains benzene ring
616 . . . Plural carboxamide groups or plural C=O groups bonded directly to the same nitrogen
617 . . . R contains benzene ring
618 . . . . Sulfur in R
619 . . . . Nitrogen in R
620 . . . . . The nitrogen in R is an amino nitrogen attached indirectly to a ring by acyclic bonding

650 . . . . The aryl ring or aryl ring system is bonded directly to another ring or ring system
651 . . . . Ether oxygen is part of the chain
652 . . . . . Alkanol group only between the amino nitrogen and an ether oxygen which is bonded directly to the aryl ring or aryl ring system (*i.e.*, aryloxy alkanol amines)
653 . . . . Hydroxy, bonded directly to carbon, attached directly or indirectly to the acyclic carbon or chain by acyclic nonionic bonding (*e.g.*, beta hydroxy phenethylamines, etc.)
654 . . . . The chain consists of two or more carbons which are unsubstituted or have acyclic hydrocarbyl substituents only
655 . . . . The aryl ring or aryl ring system and amino nitrogen are bonded directly to the same acylic carbon, which carbon additionally has only hydrogen or acyclic hydrocarbyl substituents bonded directly thereto
656 . . . Polycyclo ring system
657 . . . . Bicyclo ring system
658 . . . Two benzene rings bonded directly to the same nitrogen
659 . . Alicyclic ring or ring system and amino nitrogen are attached indirectly by an acyclic carbon or acyclic chain
660 . . Plural alicyclic rings
661 . . . Polycyclo ring system
662 . . . . Tricyclo ring system
663 . . Acyclic
664 . . . N-N containing (*e.g.*, aminimine, hydrazine, etc.)
665 . . . Sulfur containing
666 . . . Aldehyde or ketone containing
667 . . . C-O-group containing
668 . . . . . Polyether
669 . . . . Polyhydroxy
670 . . . . Monoether
671 . . . Carbon to carbon unsaturation
672 . . . Halogen bonded directly to carbon
673 . . . Plural amino nitrogens
674 . . . . Three or more amino nitrogens
675 . Ketone DOAI
676 . . Nitrogen containing
677 . . . Bicyclo ring system having a benzene ring as one of the cyclos
678 . . Benzene ring containing
679 . . . Plural rings

720 . . . . Acyclic carbon to carbon unsaturation
721 . . . . Plural benzene rings
722 . . Acyclic
723 . . . Plural oxygens
724 . C-O-group (e.g., alcohol, alcoholate, etc.) DOAI
725 . . Vitamin A compound or derivative
726 . . Diphenyl-substituted acyclic alcohol or alcoholate
727 . . Nitrogen containing
728 . . . C of C-O- group is nuclear C of a benzene ring (*e.g.*, phenol, phenolate, etc.)
729 . . Alicyclic ring containing
730 . . Benzene ring containing
731 . . . C of C-O- group is nuclear C of a benzene ring (*e.g.*, phenol, phenolate, etc.)
732 . . . . Polycyclo ring system (*e.g.*, naphthols, etc.)
733 . . . . Acyclic carbon to carbon unsaturation
. C-O-group (*e.g.*, alcohol, alcoholate, etc.) DOAI
. . Benzene ring containing
. . . C of C-O- group is nuclear C of a benzene ring (*e.g.*, phenol, phenolate, etc.)
734 . . . . Two or more separate aryl-O-groups
735 . . . . Nuclear halogenated
736 . . . . Additional benzene ring containing
737 . . . . Nuclear halogenated
738 . . Polyhydroxy
739 . . Carbon to carbon unsaturated
740 . Nitrogen containing compound DOAI
741 . . Benzene ring containing
742 . . Polynitro
743 . Halogenated hydrocarbon DOAI
744 . . Unsaturated aliphatic compound
745 . . . Alkyne
746 . . . Plural halogenated hydrocarbon compounds
747 . . Carbocyclic
748 . . . Two benzene rings directly attached to an acyclic hydrocarbon or acyclic halogenated hydrocarbon (*e.g.*, D.D.T., etc.)
749 . . . . Fluorine containing
750 . . . . With organic ether or -OH containing compound non-DOAI
751 . . . Benzene ring containing
752 . . . . Alkyne
753 . . . . Polycyclo ring system

800 LHRH LIKE
801 COLLAGEN, GELATIN OR DERIVATIVES THEREOF
802 FIBRINOPEPTIDES, BLOOD-COAGULATION FACTORS OR DERIVATIVES
803 KININ OR DERIVATIVES
804 PHECMYCIN SERIES OR DERIVATIVES
805 ADRENOCORTICOTROPIC HORMONE OR DERIVATIVES
806 SOMATOSTATIN OR DERIVATIVES
807 OXYTOXIN, VASOPRESSIN OR DERIVATIVES
808 CALCITONIN OR DERIVATIVES
809 ENKEPHALIN OR ENDORPHIN OR DERIVATIVES

**SPECIFICALLY DISCLOSED DISEASE CONDITION AND PHARMACEUTICAL EFFECT FOR PATENTS ISSUED SUBSEQUENT TO JAN 1, 1965**

810 ADDICTION
811 . Alcohol
812 . Narcotic
813 . Tobacco
814 ANEMIA
815 . Sickle cell
816 ANESTHETIC, GENERAL
817 ANESTHETIC, TOPICAL
818 ANESTHETIC, LOCAL
819 ANTACID, ORAL
820 . With antiflatulent
821 ANTIARRHYTHMIC
822 ANTICOAGULATION
823 ANTIDOTE
824 ARTERIOSCLEROSIS
825 ARTHRITIS
826 ASTHMA
827 ASTRINGENT, NONFACIAL
828 . Topical for the skin
829 BITE OR STING
830 . Insect
831 . Animal (nonpoisonous)
832 BLOOD SUBSTITUTE
833 BLOOD PLASMA EXTENDER
834 COAGULANT
835 CARIES
836 CHELATE

881 . Shampoo
882 HEMORRHOID PREPARATION
883 HODGKIN'S DISEASE
884 HYPOGLYCEMIA
885 IMMUNE RESPONSE AFFECTING DRUG
886 INFLAMMATION, SKIN
887 . Topical Treatment
888 INFLUENZA
889 INTERFERON INDUCER
890 IRRITANT (*e.g.*, tear gas, etc.)
891 KIDNEY STONE
892 LAXATIVE
893 LIVER DISORDER
894 . Hepatitis
895 MALARIA
896 MEASLES
897 . Rubella
898 MENINGITIS
899 MENSTRUAL DISORDER
MOUTH TREATMENT
900 . Periodontitis
901 . Mouthwash
902 . Gingival
903 MULTIPLE SCLEROSIS
904 MULTIPLE VITAMINS
905 . With mineral
906 MUSCLE RELAXANT
907 MUSCULAR DYSTROPHY
908 LEUKEMIA
909 OBESITY
910 . Anorectic
911 . Bulking agent
912 OPTHALMIC
913 . Glaucoma
914 . Inflammation
915 . Wetting agent
916 PYRETIC
917 RADIOACTIVE, ANTI-
918 REPELLENT
919 . Insect
920 . Mammal
921 SHOCK
922 SIDE EFFECT REDUCTION BY INCORPORATION OF A SECOND DESIGNATED INGREDIENT

OTHER THAN SUPPOSITORY TYPE (*E.G.*, FILMS, INSERTS, ETC.)
954 . Ocular
955 . . Biodegradable type
956 . Aural or otic (*i.e.*, ear)
GASEOUS OR GAS EMITTING CARRIER OR PROPELLANT
957 VAPOR EMITTING COMPOSITION
958 FOR SMOKING OR INHALING
959 BREATHING GASES PILL, LOZENGE, TABLET OR CAPSULE
960 SIGNIFICANT, TABLET FORMULATION (*E.G.*, DESIGNATED EXCIPIENT, DISINTEGRANT, GLYDENT OR LUBRICANT, ETC.)
961 . Binder therefor
962 CAPSULE (*E.G.*, GELATIN, ETC.)
963 . Microcapsule-sustained or differential release
964 SUSTAINED OR DIFFERENTIAL RELEASE TYPE
965 . Discrete particles in supporting matrix
SUPPOSITORY, BOUGIE OR BASE
966 RECTAL
967 VAGINAL
968 URETHRAL
969 OINTMENT OR SALVE BASE
SPECIAL DESIGNATED INGREDIENT
970 CONTAINING DESIGNATED INGREDIENT TO STABILIZE AN ACTIVE INGREDIENT
971 . Crystallization point depressant or cold stabilizer containing
972 . Ultraviolet light stabilizer containing
973 . Sulfur compound additive as stabilizer (*e.g.*, sulfites, etc.)
974 CONTAINING DESIGNATED INGREDIENT TO REDUCE NOXIOUS EFFECTS OF ACTIVE INGREDIENT (*E.G.*, TASTE MASKING, ODOR REDUCING, ETC.)
975 CHARACTERIZED BY THE DESIGNATED SURFACTANT USED

## App.1.03 Commissioner's Notices (Reprinted in 1014 O.G. 45-48)

### [1] Microorganisms—Patentable Subject Matter

The decision of the Supreme Court in *Diamond v. Chakrabarty*

ents and Trademarks, and each requesting depository promptly notified of the decision reached. Questions or inquiries concerning this notice may be addressed to the Office of Legislation and International Affairs, at the following address: Box 4, Commissioner of Patents and Trademarks, Washington, D.C. 20231. The telephone number of the Office of Legislation and International Affairs is (703) 557-3065.

The World Intellectual Property Organization, in Geneva, Switzerland, the Secretariat for the Paris Union, has provided a memorandum explaining the role and obligations of international depository authorities. This memorandum is reproduced below for the guidance of depositories in requesting recognition as an international depository authority.

## MEMORANDUM

### *For the purposes of prospective international depositary authorities under the Budapest Treaty*

### *Introduction*

1. This memorandum contains informations for the benefit of any depositary institutions (culture collections) that may wish to become "international depositary authorities" under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (done at Budapest on Apr. 28, 1977). Its brevity is such that it cannot be exhaustive. Any interested person requiring full information should refer to the relevant provisions of the Budapest Treaty and the Regulations under it (any reference hereinafter to an "Article" or to a "Rule" is a reference to an Article of the Budapest Treaty or to a Rule of the Regulations under it).

### *Objectives of the Budapest Treaty*

2. Disclosure of the invention is a generally recognized requirement for the grant of patents (for the purposes of this memorandum, the word "patent" also covers other titles of protection, such as inventors' certificates). Normally, an invention is disclosed by means of a written description. Where an invention involves the use of a microorganism that is not available to the public, such a description is not sufficient for disclosure, since the invention could not be used by a person skilled in the art. That is why in the patent procedure of an increasing number of countries it is necessary not only to file a written description but also to deposit, with a depositary institution,

positary institution has to meet in order to become a depositary authority are the following (Article 6(2) and Rule 2):

(a) The institution has to have a continuous existence. It has to be impartial and objective—which means among other things that it has to be free of any dependence on interests that are liable to prejudice the disinterested performance of its functions—and it has to be available, for the deposit of microorganisms, to any depositor under the same conditions. These requirements, which in fact seem self-evident, are designed to give the public in general and depositors in particular fundamental guarantees of reliability as to the smooth operation of the system. On the other hand, the legal status of the institution is irrelevant: it may be either public or private.

(b) The institution has to have the necessary staff and facilities to perform its scientific and administrative tasks, which consist among other things in:

(i) accepting for deposit any or certain kinds of microorganisms;

(ii) examining the viability of the microorganisms deposited with it and issuing a receipt to the depositor and any required viability statement (see paragraphs 7 and 8 below);

(iii) storing the deposited microorganism for at least 30 years (Rule 9(1)) in such a way as to keep them viable and uncontaminated;

(iv) providing for sufficient safety measures to minimize the risk of losing the deposited microorganisms.

(v) complying with respect to the microorganisms deposited under the Treaty with the requirement of secrecy which means giving no information to anyone on the question whether a microorganism has been thus deposited and giving no information to anyone (except to a person who is entitled to a sample—see paragraph 10 below) on any microorganism thus deposited (Rule 9(2));

(vi) furnishing, rapidly and in an appropriate manner, samples of the deposited microorganisms to all those who are entitled to such samples (see paragraph 10 below).

### *Handling of Microorganism Deposits by the International Depositary Authority*

6. *Reception of the microorganism.* The international depositary authority may require that the microorganism be deposited in an appropriate form and quantity, and that it be accompanied by a form established by that authority. In such a case, the said authority has to communicate its requirements (and any amendments to them) to the International Bureau in order that the latter may communicate them to all the depositors concerned (Rules 6.3 and 13.2(b)(v)). When it receives the microorganism, the international depository authority

whereby the industrial property office from time to time communicates to international depositary authorities lists of the accession numbers given to the deposit of the microorganisms referred to in the patents granted and published by it; the effect of this communication is to authorize those authorities to furnish samples of the microorganisms to anyone. It should be stressed that it follows from the foregoing that the international depositary never has to decide itself whether it has the right to furnish a sample since it only does so if it has the authorization of the depositor or of an industrial property office. The international depositary authority furnishes the sample in a container marked with the accession number given to the deposit and accompanied by a copy of the receipt for the deposit. It notifies the depositor of the furnishing of the sample.

11. *Communication of the scientific description and/or proposed taxonomic designation.* If the depositor has indicated a scientific description and/or proposed a taxonomic designation of the deposited microorganism, the international depositary authority must communicate it, on request, to any person entitled to receive a sample of the said microorganism (Rule 7.6).

12. *Fees.* For the procedure under the Treaty and the Regulations, the international depositary authority has the right to charge a fee in certain cases (specified in Rule 12.1). The two main fees are the fee for the storage of the microorganism (which is a single fee for the entire period of storage) and the fee for the furnishing of a sample (the furnishing of samples to industrial property offices is free of charge, however). The international depositary authority fixes the amounts of fees at its discretion, but they must not vary on account of the nationality or residence of the persons who have to pay them. July 14, 1978 [999 O.G. 2]

## [3] Entry into Force of the Budapest Treaty

The Patent and Trademark Office announces the entry into force on Aug. 19, 1980 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure with respect to the United States, Hungary, Bulgaria, France, and Japan. A copy of the Treaty was published in the Official Gazette on Aug. 23, 1977 (961 O.G. 21-36).

Following entry into force of the Treaty, each state adhering or acceding thereto will be authorized to nominate depositories on its territory to serve as international depository authorities. Upon compliance with certain procedural steps set forth in the Treaty, each

APPENDIX 2

# Selected International Materials


App.2.01 Budapest Treaty Materials
- [1] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
- [2] Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
- [3] Amendments to the Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
- [4] Parties to the Budapest Treaty

App.2.02 European Patent Convention Materials
- [1] EPC Article 53, Exceptions to Patentability
- [2] Excerpt from EPC Guidelines for Examination, Chapter II
- [3] Excerpt from EPC Guidelines for Examination, Chapter IV
- [4] Original Rule 28
- [5] Amended Rule 28 [Effective June 1, 1980]
- [6] Rule 28a [Effective June 1, 1980]
- [7] Information for PCT Applicants Designating EPO under the Pact
- [8] Names and Addresses of Collections Recognized by the European Patent Office and/or Recognized as International Depository Authorities Under the Budapest Treaty


## App.2.01 Budapest Treaty Materials

### [1] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

receives and accepts it, and any successor in title of the said natural person or legal entity;

(x) "Union" means the Union referred to in Article 1;

(xi) "Assembly" means the Assembly referred to in Article 10;

(xii) "Organization" means the World Intellectual Property Organization;

(xiii) "International Bureau" means the International Bureau of the Organization and, as long as it subsists, the United International Bureaux for the Protection of Intellectual Property (BIRPI);

(xiv) "Director General" means the Director General of the Organization;

(xv) "Regulations" means the Regulations referred to in Article 12.

## Chapter I

## Substantive Provisions

### ARTICLE 3
### RECOGNITION AND EFFECT OF THE DEPOSIT OF MICROORGANISMS

(1) *(a)* Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any international depositary authority. Such recognition shall include the recognition of the fact and date of the deposit as indicated by the international depositary authority as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism.

*(b)* Any contracting State may require a copy of the receipt of the deposit referred to in subparagraph *(a)*, issued by the international depositary authority.

(2) As far as matters regulated in this Treaty and the Regulations are concerned, no Contracting State may require compliance with requirements different from or additional to those which are provided in this Treaty and the Regulations.

### ARTICLE 4
### NEW DEPOSIT

(1)*(a)* Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular,

national depositary authority as long as that authority is in a position to furnish samples of such microorganism.

## ARTICLE 5
## EXPORT AND IMPORT RESTRICTIONS

Each Contracting State recognizes that it is highly desirable that, if and to the extent to which the export from or import into its territory of certain kinds of microorganisms is restricted, such restriction should apply to microorganisms deposited, or destined for deposit, under this Treaty only where the restriction is necessary in view of national security or the dangers for health or the environment.

## ARTICLE 6
## STATUS OF INTERNATIONAL DEPOSITARY AUTHORITY

(1) In order to qualify for the status of international depositary authority, any depositary institution must be located on the territory of a Contracting State and must benefit from assurances furnished by that State to the effect that the said institution complies and will continue to comply with the requirements specified in paragraph (2). The said assurances may be furnished also by an intergovernmental industrial property organization; in that case, the depositary institution must be located on the territory of a State member of the said organization.

(2) The depositary institution must, in its capacity of international depositary authority;

(i) have a continuous existence;

(ii) have the necessary staff and facilities, as prescribed in the Regulations, to perform its scientific and administrative tasks under this Treaty;

(iii) be impartial and objective;

(iv) be available, for the purposes of deposit, to any depositor under the same conditions;

(v) accept for deposit any or certain kinds of microorganisms, examine their viability and store them, as prescribed in the Regulations;

(vi) issue a receipt to the depositor, and any required viability statement, as prescribed in the Regulations;

(vii) comply, in respect of the deposited microorganisms, with the requirement of secrecy, as prescribed in the Regulations;

(viii) furnish samples of any deposited microorganism under the

## ARTICLE 8
## TERMINATION AND LIMITATION OF THE STATUS OF INTERNATIONAL DEPOSITARY AUTHORITY

(1)*(a)* Any Contracting State or any intergovernmental industrial property organization may request the Assembly to terminate, or to limit to certain kinds of microorganisms, any authority's status of international depositary authority on the ground that the requirements specified in Article 6 have not been or are no longer complied with. However, such a request may not be made by a Contracting State or intergovernmental industrial property organization in respect of an international depositary authority for which it has made the declaration referred to in Article 7(1)*(a)*.

*(b)* Before making the request under subparagraph *(a)*, the Contracting State or the intergovernmental industrial property organization shall, through the intermediary of the Director General, notify the reasons for the proposed request to the Contracting State or the intergovernmental industrial property organization which has made the communication referred to in Article 7(1) so that that State or organization may, within six months from the date of the said notification, take appropriate action to obviate the need for making the proposed request.

*(c)* Where the Assembly finds that the request is well founded, it shall decide to terminate, or to limit to certain kinds of microorganisms, the status of international depositary authority of the authority referred to in subparagraph *(a)*. The decision of the Assembly shall require that a majority of two-thirds of the votes cast be in favor of the request.

(2)*(a)* The Contracting State or intergovernmental industrial property organization having made the declaration referred to in Article 7(1)*(a)* may, by a communication addressed to the Director General, withdraw its declaration either entirely or in respect only of certain kinds of microorganisms and in any event shall do so when and to the extent that its assurances are no longer applicable.

*(b)* Such a communication shall, from the date provided for in the Regulations, entail, where it relates to the entire declaration, the termination of the status of international depositary authority or, where it relates only to certain kinds of microorganisms, a corresponding limitation of such status.

(3) The details of the procedure under paragraphs (1) and (2) are provided in the Regulations.

tion under Article 7(1) has led to the acquisition of the status of international depositary authority by a depositary institution shall entail the termination of such status one year after the date on which the Director General has received the notification of withdrawal.

(5) Any declaration referred to in paragraph (1)*(a)*, notification of withdrawal referred to in paragraph (2) or (3), assurances furnished under Article 6(1), second sentence, and included in a declaration made in accordance with Article 7(1)*(a)*, request made under Article 8(1) and communication of withdrawal referred to in Article 8(2) shall require the express previous approval of the supreme governing organ of the intergovernmental industrial property organization whose members are all the States members of the said organization and in which decisions are made by the official representatives of the governments of such States.

## Chapter II

## Administrative Provisions

### ARTICLE 10
### ASSEMBLY

(1)*(a)* The Assembly shall consist of the Contracting States.

*(b)* Each Contracting State shall be represented by one delegate, who may be assisted by alternate delegates, advisors, and experts.

*(c)* Each intergovernmental industrial property organization shall be represented by special observers in the meetings of the Assembly and any committee and working group established by the Assembly.

*(d)* Any State not member of the Union which is a member of the Organization or of the International (Paris) Union for the Protection of Industrial Property and any intergovernmental organization specialized in the field of patents other than an intergovernmental industrial property organization as defined in Article 2(v) may be represented by observers in the meetings of the Assembly and, if the Assembly so decides, in the meetings of any committee or working group established by the Assembly.

(2)*(a)* The Assembly shall:

(i) deal with all matters concerning the maintenance and development of the Union and the implementation of this Treaty;

(ii) exercise such rights and perform such tasks as are specially conferred upon it or assigned to it under this Treaty;

(iii) give directions to the Director General concerning the preparations for revision conferences;

## ARTICLE 11
## INTERNATIONAL BUREAU

(1) The International Burueau shall:

(i) perform the administrative tasks concerning the Union, in particularly such tasks as are specifically assigned to it under this Treaty and the Regulations or by the Assembly;

(ii) provide the secretariat of revision conferences of the Assembly, of committees and working groups established by the Assembly, and of any other meeting convened by the Director General and dealing with matters of concern to the Union.

(2) The Director General shall be the chief executive of the Union and shall represent the Union.

(3) The Director General shall convene all meetings dealing with matters of concern to the Union.

(4)*(a)* The Director General and any staff member designated by him shall participate, without the right to vote, in all meetings of the Assembly, the committees and working groups established by the Assembly, and any other meeting convened by the Director General and dealing with matters of concern to the Union.

*(b)* The Director General, or a staff member designated by him, shall be ex officio secretary of the Assembly, and of the committees, working groups and other meetings referred to in subparagraph *(a)*.

(5)*(a)* The Director General shall, in accordance with the directions of the Assembly, make the preparations for revision conferences.

*(b)* The Director General may consult with intergovernmental and international non-governmental organizations concerning the preparations for revision conferences.

*(c)* The Director General and persons designated by him shall take part, without the right to vote, in the discussions at revision conferences.

*(d)* The Director General, or a staff member designated by him shall be ex officio secretary of any revision conference.

## ARTICLE 12
## REGULATIONS

(1) The Regulations provide rules concerning:

(i) matters in respect of which this Treaty expressly refers to the Regulations or expressly provides that they are or shall be prescribed;

(ii) any administrative requirements, matters or procedures;

(iii) any details useful in the implementation of this Treaty.

cesses, have been received by the Director General from three-fourths of the Contracting States members of the Assembly at the time the Assembly adopted the amendment.

*(b)* Any amendment to the said Articles thus accepted shall bind all the Contracting States which were Contracting States at the time the amendment was adopted by the Assembly, provided that any amendment creating financial obligations for the said Contracting States or increasing such obligations shall bind only those Contracting States which have notified their acceptance of such amendment.

*(c)* Any amendment which has been accepted and which has entered into force in accordance with subparagraph *(a)* shall bind all States which become Contracting States after the date on which the amendment was adopted by the Assembly.

## Chapter IV

## Final Provisions

### ARTICLE 15
### BECOMING PARTY TO THE TREATY

(1) Any State member of the International (Paris) Union for the Protection of Industrial Property may become party to this Treaty by:

(i) signature followed by the deposit of an instrument of ratification, or

(ii) deposit of an instrument of accession.

(2) Instruments of ratification or accession shall be deposited with the Director General.

### ARTICLE 16
### ENTRY INTO FORCE OF THE TREATY

(1) This Treaty shall enter into force, with respect to the first five States which have deposited their instruments of ratification or accession, three months after the date on which the fifth instrument of ratification or accession has been deposited.

(2) This Treaty shall enter into force with respect to any other State three months after the date on which that State has deposited its instrument of ratification or accession unless a later date has been indicated in the instrument of ratification or accession. In the latter case, this Treaty shall enter into force with respect to that State on the date thus indicated.

nizations that may file a declaration under Article 9(1)*(a)* and, on request, to the Government of any other State.

(3) The Director General shall register this Treaty with the Secretariat of the United Nations.

(4) The Director General shall transmit two copies, certified by him, of any amendment to this Treaty and to the Regulations to all Contracting States, to all intergovernmental industrial property organizations and, on request, to the Government of any other State and to any other intergovernmental organization that may file a declaration under Article 9(1)*(a)*.

## ARTICLE 20
## NOTIFICATIONS

The Director General shall notify the Contracting States, the intergovernmental industrial property organizations and those States not members of the Union which are members of the International (Paris) Union for the Protection of Industrial Property of:

(i) signatures under Article 18;

(ii) deposits of instruments of ratification or accession under Article 15(2);

(iii) declarations filed under Article 9(1)*(a)* and notifications of withdrawal under Article 9(2) or (3);

(iv) the date of entry into force of this Treaty under Article 16(1);

(v) the communications under Articles 7 and 8 and the decisions under Article 8;

(vi) acceptance of amendments to this Treaty under Article 14(3);

(vii) any amendment of the Regulations;

(viii) the dates on which amendments to the Treaty or the Regulations enter into force;

(ix) denunciations received under Article 17.

microorganisms, provide for sufficient safety measures to minimize the risk of losing microorganisms deposited with it.

### *2.3 Furnishing of Samples*

The requirements referred to in Article 6(2)(viii) shall include in particular the requirement that any international depositary authority must furnish samples of deposited microorganisms in an expeditious and proper manner.

## RULE 3
## ACQUISITION OF THE STATUS OF INTERNATIONAL DEPOSITARY AUTHORITY

### *3.1 Communication*

*(a)* The communication referred to in Article 7(1) shall be addressed to the Director General, in the case of a Contracting State, through diplomatic channels or, in the case of an intergovernmental industrial property organization, by its chief executive officer.

*(b) The communication shall:*

(i) indicate the name and address of the depositary institution to which the communication relates;

(ii) contain detailed information as to the said institution's capacity to comply with the requirements specified in Article 6(2), including information on its legal status, scientific standing, staff and facilities;

(iii) where the said depositary institution intends to accept for deposit only certain kinds of microorganisms, specify such kinds;

(iv) indicate the amount of any fees that the said institution will, upon acquiring the status of international depositary authority, charge for storage, viability statements and furnishing of samples of microorganisms;

(v) indicate the official language or languages of the said institution;

(vi) where applicable, indicate the date referred to in Article 7(1) *(b)*.

### *3.2 Processing of the Communication*

If the communication complies with Article 7(1) and Rule 3.1, it shall be promptly notified by the Director General to all Contracting States and intergovernmental industrial property organizations and shall be promptly published by the International Bureau.

### *4.2 Communication; Effective Date; Processing of Communication*

*(a)* The communication referred to in Article 8(2)*(a)* shall be addressed to the Director General as provided in Rule 3.1*(a)*.

*(b)* The communication shall:

(i) indicate the name and address of the international depositary authority concerned;

(ii) where it relates only to certain kinds of microorganisms, specify such kinds;

(iii) where the Contracting State or intergovernmental industrial property organization making the communication desires that the effects provided for in Article 8(2)*(b)* take place on a date later than at the expiration of three months from the date of the communication, indicate that later date.

*(c)* Where paragraph *(b)*(iii) applies, the effects provided for in Article 8(2)*(b)* shall take place on the date indicated under that paragraph in the communication; otherwise, they shall take place at the expiration of three months from the date of the communication.

*(d)* The Director General shall promptly notify all Contracting States and intergovernmental industrial property organizations of any communication received under Article 8(2) and of its effective date under paragraph *(c)*. A corresponding notice shall be promptly published by the International Bureau.

### *4.3 Consequences for Deposits*

In the case of a termination or limitation of the status of international depositary authority under Articles 8(1), 8(2), 9(4) or 17(4), Rule 5.1 shall apply, *mutatis mutandis*.

## RULE 5
## DEFAULTS BY THE INTERNATIONAL DEPOSITARY AUTHORITY

### *5.1 Discontinuance of Performance of Functions in Respect of Deposited Microorganisms*

*(a)* If any international depositary authority temporarily or definitively discontinues the performance of any of the tasks it should perform under the Treaty and these Regulations in relation to any microorganisms deposited with it, the Contracting State or intergovernmental industrial property organization which, in respect of that authority, has furnished the assurances under Article 6(1) shall:

### 5.2 *Refusal To Accept Certain Kinds of Microorganisms*

*(a)* If any international depositary authority refuses to accept for deposit any of the kinds of microorganisms which it should accept under the assurances furnished, the Contracting State or intergovernmental industrial property organization which, in respect of that authority, has made the declaration referred to in Article 7(1)*(a)* shall promptly notify the Director General of the relevant facts and the measures which have been taken.

*(b)* The Director General shall promptly notify the other Contracting States and intergovernmental industrial property organizations of the notification received under paragraph *(a)*; the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

## RULE 6
## MAKING THE ORIGINAL DEPOSIT OR NEW DEPOSIT

### 6.1 *Original Deposit*

*(a)* The microorganism transmitted by the depositor to the international depositary authority shall, except where Rule 6.2 applies, be accompanied by a written statement bearing the signature of the depositor and containing:

(i) an indication that the deposit is made under the Treaty;

(ii) the name and address of the depositor;

(iii) details of the conditions necessary for the cultivation of the microorganism, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence;

(iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism;

(v) an indication of the properties of the microorganism which the international depositary authority cannot be expected to foresee but which are dangerous to health or the environment, particularly in the case of new microorganisms.

*(b)* It is strongly recommended that the written statement referred to in paragraph *(a)* should contain the scientific description and/or proposed taxonomic designation of the deposited microorganism.

ferred to it, a receipt in attestation of the fact that it has received and accepted the microorganism.

*7.2 Form; Languages; Signature*

*(a)* Any receipt referred to in Rule 7.1 shall be established on a form called an "international form," a model of which shall be established by the Director General in those languages which the Assembly shall designate.

*(b)* Any words or letters filled in in the receipt in characters other than those of the Latin alphabet shall also appear therein transliterated in characters of the Latin alphabet.

*(c)* The receipt shall bear the signature of the person or persons having the power to represent the international depositary authority or that of any other official of that authority duly authorized by the said person or persons.

*7.3 Contents in the Case of the Original Deposit*

Any receipt referred to in Rule 7.1 and issued in the case of an original deposit shall indicate that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and shall contain at least the following indications:

(i) the name and address of the international depositary authority;

(ii) the name and address of the depositor;

(iii) the date of receipt of the microorganism by the international depositary authority;

(iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;

(v) the accession number given by the international depositary authority to the deposit;

(vi) where the written statement referred to in Rule 6.1*(a)* contains the scientific description and/or proposed taxonomic designation of the microorganism, a reference to that fact.

*7.4 Contents in the Case of the New Deposit*

Any receipt referred to in Rule 7.1 and issued in the case of a new deposit effected under Article 4 shall be accompanied by a copy of the receipt of the original deposit and a copy of the most recent statement concerning the viability of the microorganism originally deposited indicating that the microorganism is viable, and shall at least contain:

(i) the indications referred to in Rule 7.3(i) to (v);

(ii) an indication of the relevant reason and, where applicable, the

(i) the name and address of the depositor;

(ii) the accession number given by the said authority;

(iii) the scientific description and/or proposed taxonomic designation of the microorganism;

(iv) in the case of an amendment, the last preceding scientific description and/or proposed taxonomic designation.

*8.2 Attestation*

The international depositary authority shall, on the request of the depositor having made the communication referred to in Rule 8.1, deliver to him an attestation showing the data referred to in Rule 8.1 *(b)*(i) to (iv) and the date of receipt of such communication.

## RULE 9
## STORAGE OF MICROORGANISMS

*9.1 Duration of the Storage*

Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

*9.2 Secrecy*

No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism under Rule 11 and subject to the same conditions as provided in that Rule.

## RULE 10
## VIABILITY TEST AND STATEMENT

*10.1 Obligation to Test*

The international depositary authority shall test the viability of each microorganism deposited with it:

## RULE 11
## FURNISHING OF SAMPLES

### *11.1 Furnishing of Samples to Interested Industrial Property Offices*

Any international depositary authority shall furnish a sample of any deposited microorganism to the industrial property office of any Contracting State or of any intergovernmental industrial property organization, on the request of such office, provided that the request shall be accompanied by a declaration to the effect that:

(i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;

(ii) such application is pending before the office or has led to the grant of a patent;

(iii) the sample is needed for the purposes of a patent procedure having effect in the said Contracting State or in the said organization or its member States;

(iv) the said sample and any information accompanying or resulting from it will be used only for the purposes of the said patent procedure.

### *11.2 Furnishing of Samples to or with the Authorization of the Depositor*

Any international depositary authority shall furnish a sample of any deposited microorganism:

(i) to the depositor, on his request;

(ii) to any authority, natural person or legal entity (hereinafter referred to as "the authorized party"), on the request of such party, provided that the request is accompanied by a declaration of the depositor authorizing the requested furnishing of a sample.

### *11.3 Furnishing of Samples to Parties Legally Entitled*

*(a)* Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as "the certified party"), on the request of such party, provided that the request is made on a form whose contents are fixed by the Assembly and that on the said form the industrial property office certifies:

(i) that an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that

ty, establish, promptly and free of charge, a certified translation into Russian or Spanish;

(ii) in all other cases, it shall be in English or French, provided that it may be, instead, in the official language or one of the official languages of the international depositary authority.

*(b)* Notwithstanding paragraph *(a)*, where the request referred to in Rule 11.1 is made by an industrial property office whose official language is Russian or Spanish, the said request may be in Russian or Spanish, respectively, and the International Bureau shall establish, promptly and free of charge, a certified translation into English or French, on the request of that office.

*(c)* Any request, declaration, certification or communication referred to in Rules 11.1, 11.2 and 11.3 shall be in writing, shall bear a signature and shall be dated.

*(d)* Any request, declaration or certification referred to in Rules 11.1, 11.2 and 11.3*(a)* shall contain the following indications:

(i) the name and address of the industrial property office making the request, of the authorized party or of the certified party, as the case may be;

(ii) the accession number given to the deposit;

(iii) in the case of Rule 11.1, the date and number of the application or patent referring to the deposit;

(iv) in the case of Rule 11.3*(a)*, the indications referred to in (iii) and the name and address of the industrial property office which has made the certification referred to in the said Rule.

*(e)* Any request referred to in Rule 11.3*(b)* shall contain the following indications:

(i) the name and address of the requesting party;

(ii) the accession number given to the deposit.

*(f)* The container in which the sample furnished is placed shall be marked by the international depositary authority with the accession number given to the deposit and shall be accompanied by a copy of the receipt referred to in Rule 7.

*(g)* The international depositary authority having furnished a sample to any interested party other than the depositor shall promptly notify the depositor in writing of that fact, as well as of the date on which the said sample was furnished and of the name and address of the industrial property office, of the authorized party, of the certified party, or of the requesting party, to whom or to which the sample was furnished. The said notification shall be accompanied by a copy of the pertinent request, of any declarations submitted under Rules 11.1 or 11.2(ii) in connection with the said request, and of any forms

*(c)* Any new fees shall apply as of the date indicated under paragraph *(a)*, provided that, where the change consists of an increase in the amounts of the fees or where no date is so indicated, the new fees shall apply as from the thirtieth day following the publication of the change by the International Bureau.

## RULE 13
## PUBLICATION BY THE INTERNATIONAL BUREAU

### *13.1 Form of Publication*

Any publication by the International Bureau referred to in the Treaty or these Regulations shall be made in the monthly periodical of the International Bureau referred to in the Paris Convention for the Protection of Industrial Property.

### *13.2 Contents*

*(a)* At least in the first issue of each year of the said periodical, an up-to-date list of the international depositary authorities shall be published, indicating in respect of each such authority the kinds of microorganisms that may be deposited with it and the amount of the fees charged by it.

*(b)* Full information on any of the following facts shall be published once, in the first issue of the said periodical published after the occurrence of the fact:

(i) any acquisition, termination or limitation of the status of international depositary authority, and the measures taken in connection with that termination or limitation;

(ii) any extension referred to in Rule 3.3;

(iii) any discontinuance of the functions of an international depositary authority, any refusal to accept certain kinds of microorganisms, and the measures taken in connection with such discontinuance or refusal;

(iv) any change in the fees charged by an international depositary authority;

(v) any requirements communicated in accordance with Rule 6.3 *(b)* and any amendments thereof.

(a) [No change]
(b) [No change]
(c) [No change]
(d) [No change]
(e) In addition to any transfer effected under paragraph (a)(i), the defaulting authority shall, upon request by the depositor, transfer, as far as possible, a sample of any microorganism deposited with it together with copies of all mail or other communications and copies of all files and other relevant information referred to in paragraph (a)(ii) to any international depositary authority indicated by the depositor other than the substitute authority, provided that the depositor pays any expenses to the defaulting authority resulting from the said transfer. The depositor shall pay the fee for the storage of the said sample to the international depositary authority indicated by him.
(f) [No change]

*5.2 [No change]*

## RULE 6

## MAKING THE ORIGINAL DEPOSIT OR NEW DEPOSIT

*6.1 Original Deposit*

(a) [No change in the introductory passage]
(i) an indication that the deposit is made under the Treaty and an undertaking not to withdraw it for the period specified in Rule 9.1;
(ii) [No change]
(iii) [No change]
(iv) [No change]
(v) an indication of the properties of the microorganism which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties.
(b) [No change]

*6.2 New Deposit*

(a) Subject to paragraph (b), in the case of a new deposit made under Article 4, the microorganism transmitted by the depositor to the international depositary authority shall be accompanied by a copy of the receipt of the previous deposit, a copy of the most recent statement concerning the viability of the microorganism which was the subject of the previous deposit indicating that the microorganism

(b) [No change]

*6.4 Acceptance Procedure*

(a) The international depositary authority shall refuse to accept the microorganism and shall immediately notify the depositor in writing of such refusal and of the reasons therefor:

(i) where the microorganism is not of a kind of microorganism to which the assurances furnished under Rule 3.1(b)(iii) or 3.3 extend;

(ii) where the properties of the microorganism are so exceptional that the international depositary authority is technically not in a position to perform the tasks in relation to it that it must perform under the Treaty and these Regulations;

(iii) where the deposit is received in a condition which clearly indicates that the microorganism is missing or which precludes for scientific reasons the acceptance of the microorganism.

(b) Subject to paragraph (a), the international depositary authority shall accept the microorganism when all the requirements of Rule 6.1(a) or 6.2(a) and Rule 6.3(a) are complied with. If any of those requirements are not complied with, the international depositary authority shall immediately notify the depositor in writing of that fact and invite him to comply with those requirements.

(c) When the microorganism has been accepted as an original or new deposit, the date of that original or new deposit, as the case may be, shall be the date on which the microorganism was received by the international depositary authority.

(d) The international depositary authority shall, on the request of the depositor and provided that all the requirements referred to in paragraph (b) are complied with, consider a microorganism, deposited before the acquisition by such authority of the status of international depositary authority, to have been received, for the purposes of the Treaty, on the date on which such status was acquired.

RULE 7
RECEIPT

*7.1 [No change]*

*7.2 [No change]*

*7.3 Contents in the Case of the Original Deposit*

[No change in the introductory passage]

(i) [No change]

(ii) [No change]

(v) the accession number given by the international depositary authority;

(vi) the name and address of the international depositary authority from which the transfer was effected;

(vii) the accession number given by the international depositary authority from which the transfer was effected;

(viii) where the written statement referred to in Rule 6.1(a) or 6.2(a) contained the scientific description and/or proposed taxonomic designation of the microorganism, or where such scientific description and/or proposed taxonomic designation was/were indicated or amended under Rule 8.1 at a later date, a reference to that fact.

### *7.6 Communication of the Scientific Description and/or Proposed Taxonomic Designation*

On request of any party entitled to receive a sample of the deposited microorganism under Rules 11.1, 11.2 or 11.3, the international depositary authority shall communicate to such party the most recent scientific description and/or proposed taxonomic designation referred to in Rules 6.1(b), 6.2(a)(iii) or 8.1(b)(iii).

## RULE 10
## VIABILITY TEST AND STATEMENT

### *10.1 [No change]*

### *10.2 Viability Statement*

(a) [No change]

(b) [No change in the introductory passage]

(i) [No change]

(ii) [No change]

(iii) the date referred to in Rule 7.3(iii) or, where a new deposit or a transfer has been made, the most recent of the dates referred to in Rules 7.4(iii) and 7.5(iii);

(iv) [No change]

(v) [No change]

(vi) [No change]

(c) [No change]

(d) [No change]

(e) [No change]

under the said Treaty or a certification of publication by the industrial property office.

## RULE 12
## FEES

### *12.1 Kinds and Amounts*

(a) [No change in the introductory passage]
(i) [No change]
(ii) [No change]
(iii) [No change]
(iv) subject to Rule 11.4(h), first sentence, for the furnishing of samples;
(v) for the communication of information under Rule 7.6.

### *12.2 [No change]*

## RULE 12BIS
## COMPUTATION OF TIME LIMITS

### *12bis.1 Periods Expressed in Years*

When a period is expressed as one year or a certain number of years, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire in the relevant subsequent year in the month having the same name and on the day having the same number as the month and the day on which the said event occurred, provided that if the relevant subsequent month has no day with the same number the period shall expire on the last day of that month.

### *12bis.2 Periods Expressed in Months*

When a period is expressed as one month or a certain number of months, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire in the relevant subsequent month on the day which has the same number as the day on which the said event occurred, provided that if the relevant subsequent month has no day with the same number the period shall expire on the last day of that month.

### *12bis.3 Periods Expressed in Days*

When a period is expressed as a certain number of days, computation shall start on the day following the day on which the relevant event occurred, and the period shall expire on the day on which the last day of the count has been reached.

## [2] Excerpt from EPC Guidelines for Examination, Chapter II

### *6. Inventions relating to microorganisms*

6.1 Applications relating to microorganisms are subject to the special provisions set out in ER 28. If an invention concerns a microbiological process or the product thereof and involves the use of a microorganism which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art the disclosure is not considered to have satisfied the requirements of E 83 unless the requirements of ER 28(1), (2), first and second sentences, and (3), first sentence, have been met.

6.2 The examiner must form an opinion as to whether or not the microorganism is available to the public. There are several possibilities. Alternatively the microorganism may be known to be readily available to those skilled in the art, e.g. a microorganism such as baker's yeast or *Bacillus natto* which is commercially available; or it may be a standard preserved strain, or other microorganism which the examiner knows to have been preserved in a recognized depository and to be available to the public. Alternatively the applicant

(*Text continued on page App.2-41*)

may have given in the description sufficient information as to the identifying characteristics of the microorganism and as to the prior availability in a depositary institution recognized for the purposes of ER 28(9), to satisfy the examiner. In any of these cases no further action is called for. If however the applicant has given no information, or insufficient information, on public availability, and the microorganism is a particular strain not falling within the known categories such as those already mentioned, then the examiner must assume that the microorganism is not available to the public. He must also examine whether the microorganism could be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art (see in particular C II 4.11; C IV 3.5).

6.3 If the microorganism is not available to the public and if it could not be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the examiner must check

(i) Whether the application as filed gives such relevant information as is available to the applicant on the characteristics of the micro-organism, and
(ii) Whether the identity of the depositary institution and the file number of the deposit have been supplied within the relevant period under ER 23(2)(*a*), (*b*) and (*c*) (cf. A IV 4.1).

In addition, the depositary institution named must be one of the recognized institutions listed in the Official Journal of the European Patent Office. If any of these requirements is not satisfied the application should be refused as not complying with the Convention (E 83, ER 28).

## [3] Excerpt from EPC Guidelines for Examination, Chapter IV

3.4 Also excluded from patentability are *plant or animal varieties or essentially biological processes for the production of plants or animals*. One reason for this exclusion is that, at least for plant varieties, other means of obtaining legal protection are available in most countries. The question whether a process is *essentially biological* is one of degree depending on the extent to which there is technical intervention by man in the process; if such intervention plays a

ed and the file number of the deposit are given in the application.

(2) The information referred to in paragraph 1 (*c*) may be submitted within a period of two months after the filing of the application. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the culture deposited being made available to the public in accordance with this Rule.

(3) The culture deposited shall be available to any person upon request from the date of publication of the application. The request shall be addressed to the culture collection and shall be deemed to have been made only if it contains:

(*a*) The name and address of the person making the request:

(*b*) An undertaking *vis-à-vis* the applicant or proprietor not to make the culture available to any other person:

(*c*) Where the request is made before the date of publication of the mention of the grant of the patent, an undertaking *vis-à-vis* the applicant to use the culture for experimental purposes only.

Prior to the publication of the application the culture deposited shall be available, under the same conditions, upon the request of any person having the right to inspect the file under the provisions of Article 128. paragraph 2.

(4) A copy of the request shall be communicated to the applicant or proprietor.

(5) The undertaking provided for in paragraph 3 (*b*) shall cease if the application is refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, on the expiry of the patent in the designated State in which it last expires.

(6) The undertaking provided for in paragraph 3 (*c*) shall cease if the application is refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, on the date of publication of the mention of the grant of the patent.

(7) The undertaking under paragraph 3(*c*) is not applicable in so far as the person making the request is using the culture under a compulsory license. The term 'compulsory license' shall be construed as including *ex officio* licenses and the right to use patented inventions in the public interest.

(8) The President of the European Patent Office shall publish in the Official Journal of the European Patent Office the culture collections which will be recognized for the purpose of this Rule and shall

person from the date of publication of the European patent application and to any person having the right to inspect the files under the provisions of Article 128, paragraph 2, prior to that date. Subject to the provisions of paragraph 4, such availability shall be effected by the issue of a sample of the microorganism to the person making the request (hereinafter referred to as the 'requester'). Said issue shall be made only if the requester has undertaken *vis-à-vis* the applicant for or proprietor of the patent:

(*a*) Not to make the deposited culture or any culture derived therefrom available to any third party before the application has been refused or withdrawn or is deemed to be withdrawn or, if a patent is granted, before the expiry of the patent in the designated State in which it last expires;

(*b*) To use the deposited culture or any culture derived therefrom for experimental purposes only, until such time as the patent application is refused or withdrawn or is deemed to be withdrawn, or up to the date of publication of the mention of the grant of the European patent. This provision shall not apply insofar as the requester is using the culture under a compulsory license. The term 'compulsory license' shall be construed as including *ex officio* licenses and the right to use patented inventions in the public interest.

(4) Until the date on which the technical preparations for publication of the application are deemed to have been completed, the applicant may inform the European Patent Office that, until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, the availability referred to in paragraph 3 shall be effected only by the issue of a sample to an expert nominated by the requester.

(5) The following may be nominated as an expert:

(*a*) Any natural person provided that the requester furnishes evidence when filing the request, that the nomination has the approval of the applicant;

(*b*) Any natural person recognized as an expert by the President of the European Patent Office. The nomination shall be accompanied by an undertaking from the expert *vis-à-vis* the applicant; paragraph 3 (*a*) and (*b*) shall apply, the requester being regarded as a third party.

within four months from the date of the new deposit stating the number of the application or of the European patent.

(2) In the case provided for in paragraph 1(*a*), the new deposit shall be made with the depositary institution with which the original deposit was made; in the cases provided for in paragraph 1 (*b*), it may be made with another depositary institution recognized for the purposes of Rule 28.

(3) Where the institution with which the original deposit was made ceases to be recognized for the purposes of the application of Rule 28, either entirely or for the kind of microorganism to which the deposited microorganism belongs, or where that institution discontinues, temporarily or definitively, the performance of its functions as regards deposited microorganisms, and the notification referred to in paragraph 1 from the depositary institution is not received within six months from the date of such event, three-month period referred to in paragraph 1 shall begin on the date on which this event is announced in the Official Journal of the European Patent Office.

(4) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited micro-organism is the same as that originally deposited.

(5) If the new deposit provided for in the present Rule has been made under the provisions of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure of 28 April 1977, the provisions of that Treaty shall prevail in case of conflict.

## [7] Information for PCT Applicants Designating EPO under the Pact

### A. Introduction

On 1 January 1981 the new Rule 13bis PCT relating to microbiological inventions entered into force (see OJ 9/1980, p. 315 et seq.). This Rule lays down the particulars to be given in an international application with respect to the deposit of a microorganism where such deposit is required by national law. Where the EPO is a designated or elected Office, Rules 28 and 28a EPC apply.

The requirements mentioned in points 1 and 2 above were published in PCT Gazette No. 26/1980, pp. 2070 and 2071, dated 13 November 1980. They apply therefore to any international application filed on or after 13 January 1981.

## C. Notification Made by the European Patent Office Pursuant to Rule 13bis. 7(b) PCT

The choice of the depositary institution or institutions with which the micro-organism has to be deposited for the purposes of patent procedure before the Offices designated in the international application is determined by the national or regional law of the designated Offices.

Pursuant to Rule 13bis. 7(b) PCT, every national or regional Office whose law provides for the deposit of micro-organisms for the purposes of patent procedure had to notify the International Bureau of WIPO, before entry into force of Rule 13bis PCT, of the depositary institutions for micro-organisms with which such deposits have to be made.

The President of the EPO has consequently sent the following notification to the Director General of WIPO:

> The depositary institutions with which the European Patent Convention permits deposits of micro-organisms to be made for the purposes of patent procedure before the European Patent Office are those having the status of international depositary authority in accordance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and, in addition, those contained in the Annex[11] to this notification.

This notification was also published in PCT Gazette No. 26/1980 of 13 November 1980, pp. 2065 to 2071.

## D. Application of Rule 28, Paragraph 4, EPC, Relating to the Choice of the Expert Solution, to International Applications

Where the person filing an international application, designating States for which the European Patent Office is the designated Office, wishes to benefit from the possibility provided for in Rule 28, paragraph 4, EPC, whereby, until the publication of the mention of the

[11] The depositary institutions for microorganisms listed in the Annex are those given in OJ 8/78, pp. 400 and 401 and in OJ 1/80,pp. 4 and 5.

3. Collection nationale de micro-organismes (CNCM), Institut Pasteur, 128 rue du Docteur Roux, F 75724 Paris (Cedex), France.

4. Deutsche Sammlung von Mikro-Organismen (DSM), Grisebachstrasse 8, 3400 Göttingen, Federal Republic of Germany.

5. Forschungsinstitut Borstel, Institut für experimentelle Biologie und Medizin, 2061 Borstel, Federal Republic of Germany. (Not an IDA.)

6. Fermentation Research Institute (FRI), 1-3, Higashi 1-chome, Yatabe-machi, Tsukuba-gun, Ibaraki-ken 305, Japan.

7. National Collection of Industrial Bacteria, Torry Research Station, P.O. Box 31, 135 Abbey Road, Aberdeen, Scotland, United Kingdom. (Agreement was concluded with the British Minister of Agriculture, Fisheries and Food in his capacity as Minister responsible for this culture collection.)

8. Agricultural Research Culture Collection (NRRL), U.S. Department of Agriculture, Science and Education Administration, Northern Regional Research Centre, 1815 North University Street, Peoria, Illinois, U.S.A.

9. Culture Centre of Algae and Protozoa, 36 Storey's Way, Cambridge CB3 ODT United Kingdom.

10. Culture Collection of the Commonwealth Mycological Institute, Ferry Lane, Kew, Richmond, Surrey TW 3AF United Kingdom.

11. In Vitro International, Inc. (IVI), 7885 Jackson Road, Ann Arbor, Michigan, U.S.A.

12. National Collection of Type Cultures (NCTC), Central Public Health Laboratory, 175 Colindale Avenue, London NW9 5HT United Kingdom.

13. National Collection of Yeast Cultures (NCYC), Food Research Institute, Colney Lane, Norwich, Norfolk NR4 7UA United Kingdom.

14. European Collection of Animal Cell Cultures, formerly National Collection of Animal Cell Cultures (NCACC), Vaccine Research and Production Laboratory, PHLS Centre for Applied Microbiology and Research, Porton Down, Salisbury, Wiltshire SP4 0JG Great Britain.

All of the culture collections have reserved the right to refuse the deposit of microorganisms which they consider dangerous or difficult to preserve.

Source for information on EPO recognition is the Official Journal of the European Patent Office. By collection, see OJ 5/78 at 301-305 (CBS, DSN, ATCC); OJ 4/81 at 104 (CNCM); OJ 7/78 at 351 (FERM); OJ 1/80 at 4-6 (NCIB, NRRL); OJ 8/78 at 400 (Forschenginstitut

APPENDIX 3

# U.S. Patent and Trademark Office: Class 935—Genetic Engineering: Recombinant DNA Technology, Hybrid or Fused Cell Technology and Related Manipulations of Nucleic Acids [February 1984, Amended October 1985]

App.3.01 Index Classification
App.3.02 Patent Classification Definitions

## App.3.01 Index Classification

1 OBTAINING THE DESIRED GENE; DNA, RNA PER SE AND THE MODIFICATION THEREOF OTHER THAN VECTOR MODIFICATION
2 . DNA-RNA hybrid
3 . RNA
4 . . mRNA
5 . . 2-100 nucleotides in length, e.g., t-RNA, etc.
6 . DNA, e.g., regulatory sequences, etc.
7 . . Homopolymeric, e.g., poly d(A) sequence, etc.
8 . . 12-75 nucleotides in length, e.g., primers, etc.
9 . . Structural gene sequence
10 . . . Modified structural gene, e.g., nonnaturally occuring sequence, etc.
11 . . . Polypeptide
12 . . . . Antigenic material
13 . . . . Hormone, e.g., human growth factor, insulin, etc.
14 . . . . Enzyme
15 . . . . Antibody

53 . Microinjection
54 . Microencapsulation, e.g., liposome vesicle etc.
55 . Using vector, e.g., plasmid, etc.
56 . . Plasmid
57 . . Virus
58 . . . Phage, e.g., phage lambda, etc.
59 METHOD OF USE OF GENETICALLY ENGINEERED CELLS, E.G., OIL SPILL CLEANUP, ETC.
60 . To produce an identified chemical product e.g., amino acid, etc.
61 . . Yield optimization
62 . Control of genetic diseases or defects by use of added gene
63 . Use in animal husbandry
64 . Use in agriculature
65 . Vaccine production
66 CELLS CONTAINING A VECTOR AND/OR EXOGENOUS GENE PER SE; PROPAGATION THEREOF; OTHER MEMBRANE ENCAPSULATED. DNA, E.G., PROTOPLASTS, ETC.
67 . Plant cells
68 . Fungal cells
69 . . Yeast cells
70 . Animal cell
71 . . Human cell
72 . Bacteria
73 . . Escherichia
74 . . Bacillus
75 . . Streptomyces
76 ASSAY RELATED TO GENETIC ENGINEERING
77 . Methods of analysis of nucleic acids
78 . . Including hybridization
79 . Methods of selection of recombinant gene containing vector; materials therefore, e.g., replica plating,
80 . . Gene library manipulation
81 . . Antigen-antibody
82 . . Enzyme activity
83 . . Host suicide
84 . . Selection medium
85 GENETIC ENGINEERING APPARATUS
86 . Analytical, e.g., for autoradiography, etc.
87 . . Automated
88 . Synthesis, e.g., peptide or gene synthesizers, etc.

duction of exogenous genetic material or the nonrandom alteration of the genetic contents of a cell. (2) The fusion of cells or the introduction of nuclear material from one cell into another. (3) The introduction of an agent such as a virus into a cell to permit proliferation in long term culture.

B. Methods of producing the means to carry out the methods of A including: (1) Methods of synthesizing, modifying, or isolating specific nucleic acid sequences. (2) Methods of synthesizing, modifying, or isolating vectors or other means of introducing nucleic acids into the protoplasm of a cell. (3) Methods of culture of cells.

C. Methods of use of the cells produced in A including methods of enhancing or diminishing gene expression.

D. Methods of assay involved in any of A to C.

E. Apparatus for any of A to D.

F. Compounds or compositions produced by or used in any of A to E.

## II. Classification Lines with Other Classes

### A. LINES WITH RELATED CLASSES PROVIDING FOR THE USE OF A GENETICALLY ALTERED MICROORGANISM AND THE APPARATUS THEREFORE AND THE COMPOSITION CLASSES PROVIDING FOR THE PRODUCTS OF A GENETICALLY ALTERED MICROORGANISM.

*Search 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 skin or peculiar to making leather.

435, Chemistry, Molecular Biology and Microbiology provides for processes of altering the genetic material of whole plants by use of recombinant DNA technology, cell fusion

127, Sugar, Starch, and Carbohydrates, for process wholly peculiar to processes of extracting or purifying natural starch, natural sucrose, or other natural polysaccharides except cellulose, processes of hydrolyzing polysaccharides, carbohydrates or processes of purifying the products of such hydrolysis. The chemical manufacture or synthesis of sugar or of polysaccharides by process other than that of hydrolysis is not included in Class 127. Molecular rearrangement of one polysaccharide to form another is exluded from Class 127. Such processes are provided for in Class 536.

128 and 604, Surgery provide for methods of treatment of the living body including the use of a Class 424 composition which is more than a single or plural steps of mere applications of one or more 424 compositions, e.g., removal of a body fluid such as milk, adding medicine to the fluid and reinjecting the fluid, surgical implantation, etc. Class 128 will provide for a test which involves contact with a body as well as apparatus used in the inspection and treatment of disease of the bodies of humans and animals which apparatus is provided with means for connection to the living body.

131, Tobacco, for tobacco-containing articles, or composition 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 making the latter articles or compositions for use in the above noted processes.

159, Concentrating, Evaporators, provides for processes peculiar to the concentration of solids held in solution or suspension by evaporation of the liquid containing them and the recovery of the concentrate. If the starting material is a solid or slurrry, placement in Class 34, Dry-

croorganism. Processes directed to the nonmicrobial or nonenzymatic purification of a particular compound or composition (including solutions of either the compound or composition in water), are classified with the particular compound or composition. Microbial or enzymatic purification is provided for in Class 435, subclasses 262-282. Insofar as the treatment of liquid with ion exchange or sorption material (including chromatography) are concerned, the following lines will be maintained: (I) Where water is the only disclosed liquid purified, the patent will be classified in the class 210. (II) Where the disclosure includes water, hydrocarbons 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 water. (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). (III) Purification or separation of liquids by flocculation only is classified in class (210).

Processes wherein all claims are limited to the deposition of specific materials on ion-exchangers or sorbents with subsequent recovery of the specific materials are classified with the materials so operated upon.

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

422, Processes: Disinfecting, Deodorizing, Preserving or Sterilizing and Chemical Apparatus, for apparatus for analysis including means for causing or promoting a chemical

including use of a microorganism or enzyme are in Class 426.

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

435, Molecular Biology and Microbiology is the generic class for all aspects of the production of a genetically engineered microorganism and the means e.g., vectors, restriction enzymes, etc., for carrying out such a process as well as providing for all methods of use of such a microorganism not otherwise provided for.

Class 435 provides for the process of use of the engineered microorganisms, enzymes derived from and used in the process of genetic engineering, microorganisms, and virus and bacteriophages per se.

Class 435 provides for a process of cultivating a microorganism to produce a drug or bio-affecting composition. Class 435 provides for virus culture and attenuation, and for in vitro tests involving a microorganism or an enzyme and antigen antibody tests which involve a living microorganism. Plant cells and animal cells are included in the Class 435 definition of microorganisms. Tissue culture is also provided for in Class 435.

Class 435 is the generic home for subcellular parts of microorganisms such as ribosomes, plasmids, chloroplasts, mitochondria, Golgi bodies and other organelles, as well as DNA and RNA organized into chromosomes, genes, operons, and ribosomal, messenger and transfer RNAs.

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

Disposition of patents to yeast claimed or disclosed (1) as an edible, (2) as a component in an edible, or (3) as a single

## B. Products of Genetically Engineered Cells

| *Product* | *Example* | *Classification* |
|---|---|---|
| Amino Acid | arginine, pheylalanine | see below |
| Antibiotic | penicillin, tetracyclines | Compound 260<br>Composition 424 |
| Biodegradation | | 210/601, 922<br>Digest 32 |
| Enzyme | amylase, DNA polymerase | 435 |
| Genes | | 435 |
| Gene preparations | globin genes,<br>clotting factor genes | 424 |
| Inorganics | ammonia, hydrogen | 423 |
| Mineral Leaching | uranium, transistion metals | 75/1+ |
| Nucleoside | adenosine | 536/27 |
| Nucleotide | 5' IMP, 5' GMP | 536/27 |
| Peptide hormones | ATCH, Insulin,<br>growth hormone | 260/112+ |
| Pesticides | Becillus thuringiensis,<br>aromatic | 424 |
| Proteins and<br>Glycosylated Proteins | interferons, antigens | 260/112R |
| Steroid hormones | corticoids androgens,<br>estrogens | Compound 260,<br>Composition 424 |
| Viral antigens | Foot and mouth disease virus,<br>Epstein Barr virus | Compound 260<br>Composition 424 |
| Monoclonal antibodies | Anti-interferon monoclonal<br>antibody | 260/112R |
| Fused or Hybrid<br>animal cells | | 435 |
| Fused or Hybrid<br>plant cells | | 435 |

| *Amino Acids* | *Classification* |
|---|---|
| Aminio Acids commonly found in proteins | |
| Alanine | 562/575 |
| Arginine | 562/560 |
| Asparagine | 562/561 |
| Aspartic acid | 562/571 |
| Cysteine | 562/557 |
| Glutamine | 562/563 |
| Glutamic acid | 562/573 |
| Glycine | 562/575 |
| Histidine | 548/344 |
| Isoleucine | 526/575 |

| | | | |
|---|---|---|---|
| (7) | Nucelase e.g. | | |
| | Ribonuclease | (3.1.4) | 435/199 |
| | Deoxyribonuclease I (DNase I) | (3.1.21.1) | 435/199 |
| | Exonuclease III | (3.1.11.2) | 435/199 |
| | Exonuclease VII | (3.1.11.6) | 435/199 |
| | Poly (A) Polymerase (RNA terminal riboadenylate transferase) | (2.7.7.19) | 435/194 |
| (8) | Ligase e.g., | | |
| | DNA Ligase | (6.5.1.2) | 435/183 |
| | RNA Ligase | (6.5.1.3) | 435/183 |
| (9) | Terminal Deoxyribonucleotidyl Transferase (terminal transferase) | (2.7.7.31) | 435/194 |

## D. Plant Patents

Asexually propagated plants including cultivated sports, mutants and newly found seedlings other than tuber propagated plants are provided for by the Plant Patents Act, 35 U.S.C. 161-164. See MPEP Chapter 1600 and 37 CFR 1.67-1.167. Ordinarily this section will embrace entire plants, and exclude cell lines, callus cultures, i.e., plant tissues lacking complete organization. However, see Yoden Bros. Inc. v California-Florida Plant Corp., 537 F2d 1347, 193 U.S.P.Q. 264 (5th Cir. 1976). Sexually reproduced plants other than fungi, bacteria or first generation hybrids are provided for by the Plant Variety Protection Act of 1970, 7 U.S.C. 2321-2583 (1976).

"Plant" has been held for purposes of the Plant Patent Act to have been used in its popular sense and not in its scientific sense thus limiting the plant patent act to subject matter of benefit to agriculture and horticulture. See in re Arzberger 46 USPQ 32, 35 (1940). By implication plant cells grown as an undifferentated mass with no claim or showing that the cell mass is grown as a step in a process leading to a differentiated plant would not be within the ambit of the Plant Patent Act's definition of plant and would therefore be provided for under the utility patent act in the manner of a bacteria or fungi. See Diamond v. Chakrabarty 44 U.S. 1028 (1980). That decision intimates that some plants created by genetic engineering methods would fall within 35 U.S.C. 101.

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

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| 429 | II A | |
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| | II B | 57, 59, 60, 65 |
| | II C | 66, 76, 77, 81 |
| | III | 82, 84, 85, 87 |
| | | 89, 106 |
| 436 | II A | 76, 77, 87 |
| | II B | 106 |
| 536 | II A | 1 |
| | II B | |
| 546 | II B | |
| 548 | II B | |
| 562 | II B | |

of performing certain biological functions, such as protein synthesis, when provided with the necessary precursors.

*Cell Fusion.* Formation of a cell hybrid accomplished by fusing two or more cells from different sources. Hybridomas result from the fusion of an antibody-producing cell with a tumor cell.

*Centromere.* A constricted region of a chromosome that includes the site of attachment to the mitotic or meiotic spindle.

*Chromosome* (eukaryotic). A discrete unit of the genome carrying many genes, consisting of proteins and a very long molecule of DNA.

*Clone.* Describes a large number of cells or molecules identical to a single ancestral cell or molecule.

*Codon.* A group of three nucleotides that codes for an amino acid.

*Compatibility group.* A group of plasmids that contains members unable to coexist in the same bacterial cell.

*Concatemer of DNA.* Consists of a series of unit genomes repeated in tandem.

*Concatenated Circles.* Circles of DNA are interlocked like rings in a chain.

*Consensus sequence* is an idealized sequence in which each position represents the base most often found when many actual sequences are compared.

*Constitutive genes.* Genes expressed as a function of the interaction of RNA polymerase with the promotor, without additional regulation; sometimes called household genes in the context of describing functions expressed in all cells at a low level.

*Corepressor.* A small molecule that triggers repression of transcription by bonding to a regulator protein.

*Genetically engineered cell.* Includes cells which are the product of recombinant DNA techniques, hybrid and fused cells and cells which have had genetic elements altered through use of a virus or phage or other technique of introduction of exogenous DNA.

*Genome.* All the genes of an organism or individual.

*Grunstein-Hogness assay.* Colony hybridization procedure for identification of plasmid clones (colony DNAs are transferred to a filter and hybridized with a probe).

*Helper virus.* A virus which provides functions absent from a defective virus, enabling the latter to complete the infective cycle during a mixed infection.

*Heteroduplex.* DNA molecule, the two strands of which come from different individuals so that there may be some base pairs or blocks of base pairs that do not match.

*Hogness box (TATA BOX).* The hypothesized eukaryotic RNA polymerase II promoter analogous to the Pribnow box.

*Housekeeping (constitutive) genes.* Genes theoretically expressed in all cells because they provide basic functions needed for sustenance of all cell types.

*Hybridization (Molecular).* The pairing of complementary RNA and DNA strands to give an RNA-DNA hybrid.

*Hybridoma.* The cell line produced by fusing a myeloma cell with a lymphocyte; it continues indefinitely to express the immunologlobulins of both parents.

*Incompatibility.* The inability of certain bacterial plasmids to coexist in the same cell.

*Inducer.* A small molecule that triggers gene transcription by binding to a regulator protein.

*Induction.* Refers to the ability of bactera (or yeast) to synthesize certain enzymes only when their substrates are present; applied to gene expression, refers to switching on transcrip-

er bond at the site of a single-strand break in duplex DNA; RNA can also act as a substrate to some extent.

*Lysogeny.* Describes the ability of a phage to survive in a bacterium as a stable prophage component of the bacterial genome.

*Microorganism.* For purposes of this class includes bacteria, fungi (including yeast), actinomycetales, unicellular algae, and protoza.

*Monocistronic mRNA.* Messenger RNA that codes for a single polypeptide.

*Nick.* In duplex DNA is the absence of a phosphodiester bond between two adjacent nucleotides on one strand.

*Nick translation.* Describes the ability of E. coli DNA polymerase I to use a nick as a starting point from which one strand of a duplex DNA can be degraded and replaced by resynthesis of new material; is used to introduce radioactively labeled nucleotides into DNA in vitro.

*Nonsense codon.* One of three triplets (UAG, UAA, UGA) that cause termination of protein synthesis. (UAG is known as amber; UAA as ochre.)

*Operator.* A region of DNA that interacts with a repressor protein to control the expression of an adjacent gene or group of genes.

*Operon.* A gene unit consisting of one or more genes that specify a polypeptide and an "operator" that regulates the transcription of the structural gene; the regulator and the coding genes are adjacent on the DNA molecule.

*Palindrome.* Describes a sequence of DNA that is the same when one strand is read left to right or the other is read right to left; consists of adjacent inverted repeats.

*Pelotropic gene.* A gene that affects more than one apparently unrelated characteristic of the phenotype.

accomplished by use of the enzyme reverse transcriptase.

*Selection.* Describes the use of particular conditions to allow survival only of cells with a particular phenotype.

*Shotgun experiment.* The cloning of an entire genome in the form of randomly generated fragments.

*Structural gene.* A gene that codes for an RNA or a protein product other than a regulator.

*Transcription.* Synthesis of RNA on a DNA template.

*Transduction.* The transfer of a bacterial gene from one bacterium to another by a phage; the phage, carrying host genes as well as its own genes, is called a transducing phage; the transfer of information from one cell to another mediated by viruses.

*Transfection of eucaryotic cells.* The acquisition of new genetic markers by incorporation of added DNA. Transfection is the transfer of genetic information to a cell using isolated DNA or RNA.

*Transformation of bacteria.* The acquisition of new genetic material by incorporation of exogenous DNA.

*Transformation of eucaryotic cells.* The conversion of a cell to state of unrestrained growth in culture, resembling or identical with the tumorigenic condition.

*Translation.* Synthesis of protein on a messenger RNA template.

*Vector.* DNA or RNA which can direct its own replication within a host cell, and to which other DNA molecules can be attached and amplified; it serves as a means for introduction of exogenous nucleic acid sequences into a cell.

*Viruses.* Infectious agents which are obligate parasites; they can only replicate and multiply within a host cell; they consist of DNA or RNA sometimes contained in a protein capsid.

and particularly subclass 88+ for production of nucleotides and subclass 91 for production of a polynucleotide such as RNA or DNA; subclass 172.3 for the methods and materials of recombinant DNA technology.

536, Organic Compounds subclass 27 for RNA and DNA compounds per se, methods of chemcial synthesis of RNA and DNA compounds and methods of physical separation or purification of DNA and RNA. Organized forms of DNA and RNA such as operons, ribosomal RNA, messenger RNA, and transfer RNA are provided for in Class 435 and a detailed search for this subject matter is provided for in Class 935.

2. DNA-RNA Hybrid: Subject matter under subclass 1 directed to DNA hydrogen-bonded to RNA and to covalently bonded molecules containing both DNA and RNA.

3. RNA: Subject matter under subclass 1 directed to the synthesis, modification, isolation or purification of ribonucleic acid sequences and the product of such processes.

(1) *Note.* The RNA provided for herein includes messenger RNA (mRNA), transfer RNA (†RNA), ribosomal RNA (rRNA) and heterogeneous nuclear RNA (hnRNA).

4. RNA: Subject matter under subclass 3 in which the ribonucleic acid sequence functions as messenger RNA or is claimed or disclosed as part of a messenger RNA sequence.

5. 2-100 Nucleotides in Length e.g., †RNA, Etc.: Subject matter under subclass 3 in which the ribonucleic acid sequence is from 2 to 100 bases long.

(1) *Note.* This subclass is intended to provide for transfer RNA and methods of isolating it or modifying its structure.

6. DNA, e.g., Regulatory Sequences Etc.: Subject matter under subclass 1 directed to the synthesis, modification or purification

12. Antigenic Material: Subject matter under subclass 11 in which the polypeptide is identified as an antigen.

13. Hormone, e.g., Human Growth Factor, Insulin, Etc.: Subject matter under subclass 11 in which the structural gene codes for the production of a plant or animal hormone.

14. Enzyme: Subject matter under subclass 11 in which the structural gene sequence codes for the production of an enzyme.

15. Antibody: Subject matter under subclass 11 in which the structural gene codes for the production of an antibody.

16. Methods of producing DNA or RNA Other than by Expression Vectors e.g., Culture of Cells High in RNA, Etc.: Subject matter under subclass 1 directed to methods of producing DNA or RNA by the production and use of a cloning vector or by chemical synthesis.

    (1) *Note.* Included herein would be chemical synthesis such as the phoshophodiester method.

17. Cell Free Production: Subject matter under subclass 16 in which nucleotide sequences are produced in the absence of cells.

    (1) *Note.* The use of a cell free transcription system would be provided in this subclass.

18. cDNA Synthesis: Subject matter under subclass 17 in which the nucleotide produced is complementary DNA to a template RNA starting material.

19. Isolation or Purification of DNA or RNA: Subject matter under subclass 1 directed to the isolation or purification of preexisting DNA or RNA by chemical or physical means.

23. Inserting and Gene into a Vector to Form a Recombinant Vector, i.e., Cleavage and Ligation: Subject matter under subclass 22 including the covalent attachment of an exogenous gene sequence to the nucleic acid sequence of modified nucleic acid sequence of a vector.

    (1) *Note.* Typically the patents in this subclass use a restriction endonuclease, an enzyme that recognizes a specific base sequence in a double stranded DNA molecule and cleaves the DNA generating 3′—OH and 5′—P termini. The restriction endonuclease provided for herein are usually type II which cleaves in or close to the recognition site.

24. Vector Utilized, e.g., Episomes, Etc.: Subject matter under subclass 23 including a vector per se, i.e., a nonchromosomal nuclei acid sequence capable of directing its own replication within a host cell and capable of carrying a segment of exogenous nucleic acid.

    *Search This Class, Subclass:*

    55, for methods of introducing the vector into the host cell.

25. Plant Virus: Subject matter under subclass 24 in which the vector is a plant virus.

26. Cosmid: Subject matter under subclass 24 in which the vector is a plasmid carrying the ligated cohesive ends (cos) of bacteriophage which permit in vitro packaging.

27. Plasmid: Subject matter under subclass 24 in which the vector is an extrachromosomal genetic element consisting of a closed circular DNA molecule.

    (1) *Note.* The plasmids provided for herein will usually carry one or more selectable markers to allow identification of transformants and possess a recongnition [*sic*] site for one or more restriction enzymes located in the genes coding for

6 for the use of ss DNA in a hybrid binding test when a microorganism or enzyme is involved in the test.

32. Animal Virus: Subject matter under subclass 24 in which the vector comprises a single or double stranded DNA or RNA animal virus.

*Search Class:*

424, Drug Bio-Affecting and Body Treating Compositions subclass 89 for an antigenic composition containing a virus; subclass 93 for a composition containing a live virus such as a vaccine.

435, Molecular Biology and Microbiology, subclass 235 for virus and bacteriophages; compositions containing the same; culture or purification; inactivation or attenuation and subclass 284 for virus culture apparatus.

33. Methods of Enhancing or Dimishing Expression: Subject matter under the class definition directed to processes of achieving the maximum production of the desired translation product of a genetically engineered cell or minimizing the production of the undesired products of the cell.

*Search Class:*

435, Chemistry, Molecular and Microbiology, subclass 172.3 for the methods and materials of recombinant DNA technology; subclass 68+ for the enzymatic or microbial production of peptides or proteins, particularly subclass 70 for processes of production of polypeptides of known sequence and subclass 106 for the process of production of amino acids.

34. Eucaryotic Cell: Subject matter under subclass 33 in which the cell expressing the genetic information contains a nucleus composed of multiple chromosomes surrounded by a membrane.

39. Transcription: Subject matter under 38 in which the transfer of genetic information from DNA to messenger RNA by DNA-directed RNA polymerase is modified.

40. Operon Selection: Subject matter under subclass 39 in which the structural gene, regulator gene or genes or control elements of the operon are modified to enhance or dimish [*sic*] expression.

    (1) *Note.* This subclass will provide for any process of optimizing the cellular feedback system under the control of an operator gene in which a structural gene transcribes its message in the form of mRNA.

41. Promoter, e.g., Portable Promoters, Etc.: Subject matter under subclass 40 in which the region of DNA involved in binding RNA polymerase to initiate transcription is altered or substituted.

42. Gene Dosage Modification e.g., Copy Number Amplification, Etc.: Subject matter under subclass 38 in which a process is carried out to increase or decrease the number of times a structural gene of interest appears in a cell population.

    (1) *Note.* The most common process is the amplification of exogenous DNA in a cell population by selection for resistance to gradually increasing doses of a toxic reagent resulting in a cell population with an increased copy number of the resistance gene.

43. Inducible, e.g., Temperature Inducible, Etc.: Subject matter under subclass 42 in which the gene dosage modification is brought about by altering the physical or chemical surroundings of the cell carrying the desired gene.

    (1) *Note.* This subclass includes for example the control of plasmid copy number by change in temperature.

44. Translation: Subject matter under subclass 38 in which the syn-

(1) *Note.* The modifications include carboxylation, hydroxylation, acetylation, phosphorylation, methylation, glycosylation, oxydation-reduction, degradation, lysis, peptide bond formation and changes in molecular weight and electrophoretic mobility.

50. Glycosylation: Subject matter under subclass 49 in which the post translational modification is the addition of saccharide moleties.

51. Peptide Bond Clevage: Subject matter under subclass 49 in which the post translational modification is the cleav.ge of a peptide bond.

52. Methods of Introducing a Gene into a Cell, e.g., Transformation, Transfection, Etc.: Subject matter under the class definition for the physical introduction of an exogenous gene into the cytoplasm of a cell.

(1) *Note.* Physical introduction includes such expedients as using a calcium chloride or phosphate solution to cause DNA uptake by cells.

*SEARCH CLASS:*

435, Chemistry, Molecular and Microbiology, subclass 172.3 for the methods and materials of recombinant DNA technology.

53. Microinjection: Subject matter under subclass 52 in which exogenous DNA is introduced into the cytoplasm of a cell by physical piercing of the cell wall and/or nuclear membrane.

54. Microencapsulation e.g., Liposome, Vesicle, Etc.: Subject matter under subclass 52 in which the method of introduction of exogenous DNA into a cell includes enveloping the DNA in a substance which permits or encourages passage of the DNA through the cell wall and nuclear membrane.

virus; subclass 93 for a composition containing a live virus such as a vaccine.

435, Molecular Biology and Microbiology, subclass 235 for virus and bacteriophages; compositions containing the same; culture or purification, inactiviation or attenuation and subclass 284 for virus culture apparatus.

58. Phage, e.g., Phage Lambda Etc.: Subject matter under subclass 58 in which the vector is a single or double stranded DNA bacterial virus or single or double stranded RNA bacterial virus.

*SEARCH THIS CLASS, SUBCLASS:*

26, for a cosmid per se or methods of modifying cosmids.

31, for claims to a phage per se and methods of modifying phages.

59. Method of Use of Genetically Engineered Cells Other than Hybrid or Fused Cells e.g., Oil Spill Cleanup, Etc.: Subject matter under the class definition including a method of use of the recombinant gene containing cell.

(1) *Note.* See section II of the headnotes of this class for a guide to the original classification of the patents found in this and the indented subclasses. This and the indented subclasses will provide for the use of a recombinant cell even absent claims to the gene insertion technique.

*SEARCH THIS CLASS, SUBCLASS:*

106, for methods of use of fused or hybrid cells.

*SEARCH CLASS:*

8, Bleaching and Dyeing; Fluid Treatment and Chemical

directory of the disposition of the products of genetically engineered cells.

*SEARCH CLASS:*

260, Chemistry, Carbon Compounds, subclasses 112+ provides for the peptide or protein products of a genetically engineered microorganism including antibodies per se and the purification of such products by physical or chemical methods.

435, Chemistry: Molecular and Microbiology, subclass 85 for enzymatic or microbial production of an N-Glycoside and particularly subclasses 88+ for production of nucleotides and subclass 91 for production of a polynucleotide such as RNA or DNA, subclasses 68+ for the enzymatic or microbial production of polypeptides of known sequence and subclass 106 for the process of production of amino acids.

61. Yield Optimization: Processes under subclass 60 including a step which results in increased production of a desired chemical product or reduces production of an undesired product.

(1) *Note.* Scale up of processes involving the regulation of cultivation conditions and the modification of cultivation conditions are provided for in this subclass.

62. Control of Genetic Disease or Defects by Use of Added Gene, e.g., Gene Therapy, Etc.: Processes under subclass 59 in which a condition caused by a genetic defect is treated by alteration of the defective gene structure.

*SEARCH THIS CLASS, SUBCLASS:*

128, subclass 1 will provide for a process including application of the techniques of genetic engineering and significant steps of surgery. If the claim is to apparatus for use in or

plant breeding by chromosome multiplication and processes of nucleic acid manipulation that result in a new whole plant or part of thereof. Class 435 provides for the apparatus used in such processes.

71, Chemistry, Fertilizers, for the production of substances having a nutrient or stimulating, inhibiting, or regulating action on plant growth and the product of such processes including methods of utilizing microorganisms to produce a fertilizer, e.g., composting as well as the microorganism containing fertilizer so produced.

65. Vaccine Production: Processes under subclass 59 of use of genetically engineered cells in the production of antigenic compositions for the prevention of disease.

*SEARCH CLASS:*

424, Drug Bio-Affecting and Body Treating Compositions, subclass 89 for an antigenic composition containing a virus; subclass 93 for a composition containing a live virus such as a vaccine.

435, Molecular Biology and Microbiology, subclass 235 for virus and bacteriophages; compositions containing the same; culture or purification; inactivation or attenuation and subclass 284 for virus culture apparatus.

66. Cells Containing a Vector and/or Exogenous Gene Per Se; Propagation Thereof; Other Membrane Encapsulated DNA, e.g., Protoplasts, Etc.: Subject matter under the class definition including microorganisms containing a vector or exogenous gene, compositions containing such microorganisms, processess of propagation of such microorganisms and materials for the propagation of such microorgansims and membrane encapsulated DNA.

(1) *Note.* This subclass provides for DNA encapsulated within

72. Bacteria: Subject matter under subclass 66 including microorganisms containing a vector or exogenous gene, compositions containing such microorganisms, processes of propagation of such microorganisms and materials for the propagation of such microorganisms.

73. Escherichia: Subject matter under subclass 72 including microorganisms containing a vector or exogenous gene, compositions containing such microorganisms, processes of propagation of such microorganisms and materials for the propagation of such microorganisms.

74. Bacillus: Subject matter under subclass 72 including microorganism containing a vector or exogenous gene, compositions containing such microorganisms, processes of propagation of such microorganisms and materials for the propagation of such microorganism.

75. Streptomyces: Subject matter under subclass 72 including microorganisms containing a vector or exogenous gene, compositions containg such microorganisms, processes of propagation of such microorganisms and materials for the propagation of such microorganisms.

76. Assay Related to Genetic Engineering: Processes and materials under the class definition in which there is a direct or indirect qualitative or quantative test or measurement of (1) the materials used in a process of genetic engineering (2) the effect of a process of genetic engineering or (3) the expression product of the genetically engineered microorganism.

(1) *Note.* Material used in a process of genetic engineering include DNA, RNA, vectors, microorganisms, enzymes and substrates or media.

*SEARCH CLASS:*

424, Drug Bio-Affecting and Body Treating Compositions, subclass 9 for an in vivo antigen antibody test.

80. Gene Library Manipulation: Processes materials under subclass 79 for the production of a gene library or the selection of a desired gene from a gene library.

81. Antigen Antibody: Processes and materials under subclass 79 in which an antigen antibody reaction is used to identify the recombinant gene containing vector.

*SEARCH CLASS:*

424, Drug Bio-Affecting and Body Treating Composition, subclass 9 for an in vivo antigen antibody test.

435, Chemistry: Molecular Biology and Microbiology subclass 7 for an antigen antibody assay involving a microorganism or using an enzyme e.g., enzyme immunoassay, etc.

82. Enzyme Activity: Processes and materials under subclass 79 in which the method of selection of the recombinant gene containing vector involves detection of enzyme activity.

*SEARCH CLASS:*

435, Chemistry: Molecular Biology and Microbiology, subclasses 4+ for tests involving detection of enzyme activity.

83. Host Suicide: Processes or materials under subclass 79 in which particular cells in a culture are selected against by their loss of viability.

84. Selection Medium: Subject matter under subclass 79 directed to media which selects for recombinant gene containing cells.

(1) *Note.* Typically the media provided for here will contain an agent which is lethal to cells not containing the desired DNA insert.

88. Synthesis, e.g., Peptide or Gene Synthesizers, Etc.: Apparatus under subclass 85 in which (1) the synthesis of a product of a genetically engineered cell is carried out or (2) one of the materials used in the process of transforming a host cell is synthesized.

*SEARCH THIS CLASS, SUBCLASS:*

66+, for cell line or microorganisms with optimized fusing characteristics.

*Search Class:*

424, Drug Bio-Affecting and Body Treating Compositions, subclasses 89+ for an antigenic composition containing a virus and subclass 93 for a composition containing a live virus; subclass 92 for a bacteria containing antigenic composition and subclass 93 for compositions containing a whole live bacteria; subclasses 180+ for compositions containing DNA or RNA used to alter the genetic structure of the cells of a multicellular organism i.e., gene therapy with compositions containing DNA or RNA.

435, Chemistry, Molecular or Microbiology, subclass 172.2 for methods and materials for the production of hybrid or fused cells.

89. Hybrid or Fused Cell Technology; methods of immortalizing cells e.g., Hybridoma etc.: Subject matter under the class definition for the production, selection or use of cells resulting from (1) the fusion of two cells, (2) the insertion of the nucleus or chromosome of one cell into another or (3) the treatment of a cell with an immortalizing agent which results in a cell which will proliferate in long-term culture.

(1) *Note.* This and the indented subclasses provide for hybridoma technology and methods such as transformation of human B lymphocytes with Epstein-Barr virus (EBV), insertion of an isolated oncogene, or chemical treatment re-

tive selection technique in which the selection technique involves the elimination of cells lacking the desired properties by biocidal or biostatic conditions.

(3) *Note.* The cells may be eliminated by being killed or by failure to grow and multiply.

91. Of Plant Cells, e.g., Protoplasts, Etc.: Processes under subclass 89 in which one of the fusing partners is a plant cell.

92. Using Positive Selection Technique: Processes under subclass 90 in which cells with the desired genotype or phenotype are chosen after formation by a treatment which specifically identifies the cell with the desired properties.

93. Method of Production of Hybrid Cells, e.g., Chromosome or Genome Transfer Techniques, Etc.: Processes under subclass 89 directed to techniques of production of a single cell containing the genetic material from at least two fusing partners.

(1) *Note.* This subclass would provide for electrofusion and immortalizing treatments as well as chemical cell wall treatments to bring about fusion or transfer of genetic material.

(2) *Note.* Immortalizing treatments include morphological transformation by virus, oncogene expression, etc.

*SEARCH THIS CLASS, SUBCLASS:*

53, for use of microinjection and other surgical methods of introducing genetic material into cells.

94. Of Plant Cells: Processes under subclass 93 in which one of the fusing partners is a plant cell.

(1) *Note.* It should be noted that the scientific and legal definitions of plant are not coterminous. See section II, D, supra.

104. B Lymphocyte: Subject matter under subclass 103 in which one of the partners is a B lymphocyte.

105. T Lymphocyte: Subject matter under subclass 103 in which one of the partners is a T lymphocyte.

106. Method of Use of the Fused or Hybrid Cell or the Product Thereof: Processes under subclass 89 for the use of the fused or hybrid cell, or the use of the product produced by the fused or hybrid cell.

(1) *Note.* The most common product produced by fused cell technology is a monoclonal antibody.

(2) *Note.* Included herein is the use of a fused or hybrid cell to perform a function e.g., the biochemical transformation of compounds.

*SEARCH CLASS:*

260, Chemistry, Carbon Compounds, subclasses 112+ provides for the peptide or protein products of a genetically engineered microorganism including antibodies per se and the purification of such products by physical or chemical methods.

424, Drug Bio-Affecting and Body Treating Compositions, subclass 9 for an in vivo antigen antibody test.

435, Chemistry: Molecular Biology and Microbiology, subclasses 41+ for the use of a microorganism, enzyme, tissue or cell culture to produce a chemical product; subclass 262 for processes utilizing a microorganism or enzyme to liberate, separate or purify a preexisting compound or composition. Subclass 262 and the indented subclasses provide a comprehensive listing of related separation technologies.

APPENDIX 4

# United States Plant Variety Protection Act [7 U.S.C.A. §§2321 et seq.]

**AN ACT**

To encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest. (84 Stat. 1542) (7 U.S.C. 2321 et seq.)

**Title 1 - PLANT VARIETY PROTECTION OFFICE**

**Chapter 1.—ORGANIZATION AND PUBLICATIONS**

**Sec. 1. [7 U.S.C.A. § 2321] Establishment.**

There is hereby established in the Department of Agriculture an office to be known as the Plant Variety Protection Office, which shall have the functions set forth in this Act.

**Sec. 2. [7 U.S.C.A. § 2322] Seal.**

The Plant Variety Protection Office shall have a seal with which documents and certificates evidencing plant variety protection shall be authenticated.

**Sec. 3. [7 U.S.C.A. § 2323] Organization.**

The organization of the Plant Variety Protection Office shall, except as provided herein, be determined by the Secretary of Agriculture (hereinafter called the Secretary). The Office shall devote itself substantially exclusively to the administration of this Act.

**Sec. 4. [7 U.S.C.A. § 2324] Restrictions on Employees as to Interest in Plant Variety Protection.**

Employees of the Plant Variety Protection Office shall be ineligi-

**Sec. 9. [7 U.S.C.A. § 2329] Register of Protected Plant Varieties.**

The Secretary shall maintain a register of descriptions of United States protected plant varieties.

**Sec. 10. [7 U.S.C.A. § 2330] Publications.**

(a) The Secretary may publish, or cause to be published, in such format as he shall determine to be suitable, the following:

(1) The descriptions of plant varieties protected, including drawings and photographs.

(2) The Official Journal of the Plant Variety Protection Office, including annual indices.

(3) Pamphlet copies of the plant variety protection laws and rules of practice and circulars or other publications relating to the business of the Office.

(b) The Secretary may (1) establish public facilities for the searching of plant variety protection records and materials, and (2) from time to time, as through an information service, disseminate to the public those portions of the technological and other public information available to or within the Plant Variety Protection Office to encourage innovation and promote the progress of plant breeding.

(c) The Secretary may exchange any of the publications specified for publications desirable for the use of the Plant Variety Protection Office. The Secretary may exchange copies of descriptions, drawings, and photographs of United States protected plant varieties for copies of descriptions, drawings, and photographs of applications and protected plant varieties of foreign countries.

**Sec. 11. [7 U.S.C.A. § 2331] Copies for Public Libraries.**

The Secretary may supply printed copies of descriptions, drawings, and photographs of protected plant varieties to public libraries in the United States which shall maintain such copies for the use of the public.

**Chapter 2.—LEGAL PROVISIONS AS TO THE PLANT VARIETY PROTECTION OFFICE**

**Sec. 21. [7 U.S.C.A. § 2351] Day for Taking Action Falling on Saturday, Sunday, or Holiday.**

When the day, or the last day, for taking any action or paying any fee in the United States Plant Variety Protection Office falls on Saturday, Sunday, a holiday within the District of Columbia, or on any other day the Plant Variety Protection Office is closed for the receipt

**Sec. 25. [7 U.S.C.A. § 2355] Effect of Defective Execution.**

Any document to be filed in the Plant Variety Protection Office and which is required by any law or regulation to be executed in a specified manner may be provisionally accepted by the Secretary despite a defective execution, provided a properly executed document is submitted within such time as may be prescribed.

**Sec. 26. [7 U.S.C.A. § 2356] Regulations for Practice Before the Office.**

The Secretary shall prescribe regulations governing the admission to practice and conduct of persons representing applicants or other parties before the Plant Variety Protection Office. The Secretary may, after notice and opportunity for a hearing, suspend or exclude, either generally or in any particular case, from further practice before the Office of Plant Variety Protection any person shown to be incompetent or disreputable or guilty of gross misconduct.

**Sec. 27. [7 U.S.C.A. § 2357] Unauthorized Practice.**

Anyone who in the United States engages in direct or indirect practice before the Office of Plant Variety Protection while suspended or excluded under section 26, or without being admitted to practice before the Office, shall be liable in a civil action for the return of all money received, and for compensation for damage done by such person and also may be enjoined from such practice. However, there shall be no liability for damage if such person establishes that the work was done competently and without negligence. This section does not apply to anyone who, without a claim of self-sufficiency, works under the supervision of another who stands admitted and is the responsible party; nor to anyone who establishes that he acted only on behalf of any employer by whom he was regularly employed.

**Chapter 3.—PLANT VARIETY PROTECTION FEES**

**Sec. 31. [7 U.S.C.A. § 2371] Plant Variety Protection Fees.**

(a) In general. The Secretary shall, under such regulations as the Secretary may prescribe, charge and collect reasonable fees for services performed under this chapter.

(b) Late payment penalty. On failure to pay such fees, the Secretary shall assess a late payment penalty. Such overdue fees shall accrue interest as required by section 3717 of Title 31.

(c) Disposition of funds. Such fees, late payment penalties, and accrued interest collected shall be credited to the account that incurs

sential and distinctive characteristics with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.

(b) The terms "United States" and "this country" means the United States of America, its territories and possessions, and the Commonwealth of Puerto Rico.

(c) The term "kind" means one or more related species or subspecies singly or collectively known by one common name, for example, soybean, flax, or radish.

(d) The term "date of determination" means the date when there has been at least tentative determination that the variety has been sexually reproduced with recognized characteristics, whether or not the novelty of those characteristics has been determined.

(e) The term "breeder" shall mean the person who—

(1) directs the final breeding creating the novel variety, or

(2) discovers the novel variety, and makes the tentative determination described in subsection (d). Where such actions are conducted by an agent on behalf of his principal, the principal, rather than the agent, shall be considered the breeder. The terms "breed", "develop", "originate", and "discover", and derivatives thereof shall each include the other.

(f) The term "sexually reproduced" shall include any production of a variety by seed.

(g) The term "basic seed" means the seed planted to produce certified or commercial seed.

(h) The term "testing" means testing or experimental use of a variety before any sale thereof. Sale for other than seed purposes of seed or other plant material produced as the result of testing shall not constitute a sale for the purpose of the preceding sentence or the purpose of the following subsection.

(i) The term "public variety" means a variety sold or used in this country, or existing in and publicly known in this country; but use for the purpose of testing, or sale or use as individual plants not known to be sexually reproducible, shall not make the variety a public variety.

(j) A variety described in a publication as specified in section 42(a)(1)(B) is "effectively available to workers in this country" if a source from which it can be purchased is indicated in such publication or readily determinable or if such publication teaches how to produce the variety from source-material effectively available to workers in this country.

**Sec. 42. [7 U.S.C.A. § 2402] Right to Plant Variety Protection; Plant Varieties Protectable.**

in order to insure an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may be reasonably be deemed fair. Such declaration may be, with or without limitation, with or without designation of what the remuneration is to be; and shall be subject to review as under section 71 or 72 (any finding that the price is not reasonable being reviewable), and shall remain in effect not more than two years. In the event litigation is required to collect such remuneration, a higher rate may be allowed by the court.

## Chapter 5.—APPLICATIONS; FORM, WHO MAY FILE, RELATING BACK, CONFIDENTIALITY

### Sec. 51. [7 U.S.C.A. § 2421] Application for Recognition of Plant Variety Rights.

(a) An application for a certificate of Plant Variety Protection may be filed by the owner of the variety sought to be protected. The application shall be made in writing to the Secretary, shall be signed by or on behalf of the applicant, and shall be accompanied by the prescribed fee.

(b) An error as to the naming of the breeder, without deceptive intent, may be corrected at any time, in accordance with regulations established by the Secretary.

### Sec. 52. [7 U.S.C.A. § 2422] Content of Application.

An application for a certificate recognizing plant variety rights shall contain:

(1) The name of the variety except that a temporary designation will suffice until the certificate is to be issued.

(2) A description of the variety setting forth its novelty and a description of the genealogy and breeding procedure, when known. The Secretary may require amplification, including the submission of adequate photographs or drawings or plant specimens, if the description is not adequate or as complete as is reasonably possible, and submission of records or proof of ownership or of allegations made in the application. An applicant may add to or correct the description at any time, before the certificate is issued, upon a showing acceptable to the Secretary that the revised description is retroactively accurate. Courts shall protect others from any injustice which would result. The Secretary may accept records of the breeder and of any official seed certifying agency in this country as evidence of stability where applicable.

first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

(c) A later application shall not by itself establish that a characteristic newly described was in the variety at the time of the earlier application.

**Sec. 56. [7 U.S.C.A. § 2428] Confidential Status of Application.**

Applications for plant variety protection and their contents shall be kept in confidence by the Plant Variety Protection Office, by the Board, and by the office in the Department of Agriculture to which access may be given under regulations. No information concerning the same shall be given without the authority of the owner, unless necessary under special circumstances as may be determined by the Secretary, except that the Secretary may publish the variety names designated in applications, stating the kind to which each applies, the name of the applicant, and whether the applicant specified that the variety is to be sold by variety name only as a class of certified seed.

**Sec. 57. [7 U.S.C.A. § 2427] Publication.**

The Secretary may establish regulations for the publication of any pending application when publication is requested by the owner.

## Chapter 6.—EXAMINATION, RESPONSE TIME, INITIAL APPEALS

**Sec.61. [7 U.S.C.A. § 2441] Examination of Application.**

The Secretary shall cause an examination to be made of the application and if on such examination it is determined that the applicant is entitled to plant variety protection under the law, the Secretary shall issue a notice of allowance of plant variety protection therefor as hereinafter provided.

**Sec. 62. [7 U.S.C.A. § 2442] Notice of Refusal; Reconsideration.**

(a) Whenever an application is refused, or any objection or requirement made by the examiner, the Secretary shall notify the applicant thereof, stating the reasons therefor, together with such information and references as may be useful in judging the propriety of continuing the prosecution of the application, and if after receiving such notice the applicant requests reconsideration, with or without amendment, the application shall be reconsidered.

retary, shall have the right, by notice served within ten days of the notice to him, to elect that any review shall be by civil action. In such suits the record in the Plant Variety Protection Office shall be admitted on motions of any party upon the terms and conditions as to costs, expenses, and the further cross-examination of witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Plant Variety Protection Office when admitted shall have the same effect as if originally taken and produced in the suit.

(b) Such suit may be instituted against the party in interest as shown by the record of the Plant Variety Protection Office at the time of the decision complained of, but any party in interest may become a party to the action. If there be adverse parties residing in a plurality of districts not embraced within the same State, or an adverse party residing in a foreign country, the United States District Court for the District of Columbia, or any United States district court to which it may transfer the case, shall have jurisdiction and may issue summons against the adverse parties directed to the marshal of any district in which any adverse party resides. Summons against adverse parties residing in foreign countries may be served by publication or otherwise as the court directs. The Secretary shall not be made a party but he shall have the right to intervene. Judgment of the court in favor of the right of an applicant to plant variety protection shall authorize the Secretary to issue a certificate of plant variety protection on the filing in the Plant Variety Protection Office of a certified copy of the judgment and on compliance with the requirements of this Act.

## Chapter 8.—CERTIFICATES OF PLANT VARIETY PROTECTION

### Sec. 81. [7 U.S.C.A. § 2481] Plant Variety Protection.

(a) If it appears that a certificate of plant variety protection should be issued on an application, a written notice of allowance shall be given or mailed to the owner. The notice shall specify the sum, constituting the issue fee, which shall be paid within one month thereafter.

(b) Upon timely payment of this sum, and provided that deposit of seed has been made in accordance with section 52(3), the certificate of plant variety protection shall issue.

(c) If any payment required by this section is not timely made, but is submitted with an additional fee prescribed by the Secretary within nine months after the due date or within such further time as the Secretary may allow, it shall be accepted.

curred through the fault of the Plant Variety Protection Office is clearly disclosed by the records of the Office, the Secretary may issue, without charge, a corrected certificate of plant variety protection, stating the fact and nature of such mistake. Such certificate of plant variety protection shall have the same effect and operation in law as if the same had been originally issued in such corrected form.

**Sec. 85. [7 U.S.C.A. § 2485] Correction of Applicant's Mistake.**

Whenever a mistake of a clerical or typographical nature, or of minor character, or in the description of the variety, which was not the fault of the Plant Variety Protection Office, appears in a certificate of plant variety protection and a showing has been made that such mistake occurred in good faith, the Secretary may, upon payment of the required fee, issue a corrected certificate, if the correction could have been made before the certificate issued. Such certificate of plant variety protection shall have the same effect and operation in law as if the same had been originally issued in such corrected form.

**Sec. 86. [7 U.S.C.A. § 2486] Correction of Named Breeder.**

An error as to the naming of a breeder in the application, without deceptive intent, shall not affect validity of plant variety protection and may be corrected at any time by the Secretary in accordance with regulations established by him or upon order of a federal court before which the matter is called in question. Upon such correction the Secretary shall issue a certificate accordingly. Such correction shall not deprive any person of any rights he otherwise would have had.

## Chapter 9.—REEXAMINATION AFTER ISSUE, AND CONTESTED PROCEEDINGS

**Sec. 91. [7 U.S.C.A. § 2501] Reexamination After Issue.**

(a) Any person may, within five years after the issuance of a certificate of plant variety protection, notify the Secretary in writing of facts which may have a bearing on the protectability of the variety, and the Secretary may cause such plant variety protection to be reexamined in the light thereof.

(b) Reexamination of plant variety protection under this section and appeals shall be pursuant to the same procedures and with the same rights as for original examinations. Abandonment of the procedure while subject to a ruling against the retention of the certificate shall result in cancellation of the plant variety certificate thereon and

**Sec. 94. [7 U.S.C.A. § 2504] Interfering Plant Variety Protection.**

The owner of a certificate of plant variety protection may have relief against another owner of a certificate of the same variety by civil action, and the court may adjudge the question of validity of the respective certificates, or the ownership of the certificate. The provisions of section 73(b) of this title shall apply to actions brought under this section.

## TITLE III—PLANT VARIETY PROTECTION AND RIGHTS

### Chapter 10.—OWNERSHIP AND ASSIGNMENT

**Sec. 101. [7 U.S.C.A. § 2531] Ownership and Assignment.**

(a) Subject to the provisions of this title, plant variety protection shall have the attributes of personal property.

(b) Applications for certificates of plant variety protection, or any interest in a variety, shall be assignable by an instrument in writing. The owner may in like manner license or grant and convey an exclusive right to use of the variety in the whole or any specified part of the United States.

(c) A certificate of acknowledgement under the hand and official seal of a person authorized to administer oaths within the United States, or in a foreign country, of a diplomatic or consular officer of the United States or an officer authorized to administer oaths whose authority is proved by a certificate of a diplomatic or consular officer of the United States, shall be prima facie evidence of the execution of an assignment, grant, license, or conveyance of plant variety protection or application for plant variety protection.

(d) An assignment, grant, conveyance or license shall be void as against any subsequent purchaser or mortgagee for a valuable consideration, without notice, unless it, or an acknowledgement thereof by the person giving such encumbrance that there is such encumbrance, is filed for recording in the Plant Variety Protection Office within one month from its date or at least one month prior to the date of such subsequent purchase or mortgage.

**Sec. 102. [7 U.S.C.A. § 2532] Ownership During Testing.**

An owner who, with notice that release is for testing only, releases possession of seed or other sexually reproducible plant material for testing retains ownership with respect thereto; and any diversion from authorized testing, or any unauthorized retention, of such material by anyone who has knowledge that it is under such notice, or

Nothing in this Act shall abridge the right of any person, or his successor in interest, to reproduce or sell a variety developed and produced by such person more than one year prior to the effective filing date of an adverse application for a certificate of plant variety protection.

**Sec. 113. [7 U.S.C.A. § 2543] Right To Save Seed; Crop Exemption.**

Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 111, it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: *Provided,* That without regard to the provisions of section 111(3) it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes, provided such sale is in compliance with such State laws governing the sale of seed as may be applicable. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 127 that his actions constitute an infringement.

**Sec. 114. [7 U.S.C.A. § 2544] Research Exemption.**

The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this Act.

**Sec. 115. [7 U.S.C.A. § 2545] Intermediary Exemption.**

Transportation or delivery by a carrier in the ordinary course of its business as a carrier, or advertising by a person in the advertising business in the ordinary course of that business, shall not constitute an infringement of the protection provided under this Act.

**Chapter 12.—REMEDIES FOR INFRINGEMENT OF PLANT VARIETY PROTECTION, AND OTHER ACTIONS**

the infringer to have established innocent intentions, shall have discretion as to awarding damages.

**Sec. 125. [7 U.S.C.A. § 2565] Attorney Fees.**

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

**Sec. 126. [7 U.S.C.A. § 2566] Time Limitation on Damages.**

(a) No recovery shall be had for that part of any infringement committed more than six years (or known to the owner more than one year) prior to the filing of the complaint or counterclaim for infringement in the action.

(b) In the case of claims against the United States Government for unauthorized use of a protected variety, the period between the date of receipt of written claim for compensation by the department or agency of the Government having authority to settle such claim, and the date of mailing by the Government of a notice to the claimant that his claim has been denied shall not be counted as part of the period referred to in the preceding paragraph.

**Sec. 127. [7 U.S.C.A. § 2567] Limitation of Damages; Marking and Notice.**

Owners may give notice to the public by physically associating with or affixing to the container of seed of a novel variety or by fixing to the novel variety, a label containing either the words "Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" and after the certificate issues, such additional words as "U.S. Protected Variety." In the event the novel variety is distributed by authorization of the owner and is received by the infringer without such marking, no damages shall be recovered against such infringer by the owner in any action for infringement, unless the infringer has actual notice or knowledge that propagation is prohibited or that the variety is a protected variety, in which event damages may be recovered only for infringement occurring after such notice. As to both damages and injunction, a court shall have discretion to be lenient as to disposal of materials acquired in good faith by acts prior to such notice.

**Sec. 128. [7 U.S.C.A. § 2568] False Marking; Cease and Desist Orders.**

(a) Each of the following acts, if performed in connection with the sale, offering for sale, or advertising of sexually reproductible plant material, is prohibited, and the Secretary may, if he determines after

end, so as to afford adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties. Constitutional clauses 3 and 8 of article I, section 8 are both relied upon.

**Sec. 132. [7 U.S.C.A. § 2582] Severability.**

If this Act is held unconstitutional as to some provisions or circumstances, it shall remain in force as to the remaining provisions and other circumstances.

**Chapter 14.—TEMPORARY PROVISION; EXEMPTED PLANTS; MISCELLANEOUS.**

**Sec. 141. Effective Date.**

This Act shall take effect upon enactment. Applications may be filed with the Secretary and held by him until the Office of Plant Variety Protection is organized and is in operation.

**Sec. 145. Short Title.**

This Act may be cited as the "Plant Variety Protection Act".

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an opportunity for hearing that the act is being so performed, issue an order to cease and desist, said order being binding unless appealed under section 71:

(1) Use of the words "U.S. Protected Variety" or any word or number importing that the material is a variety protected under certificate, when it is not.

(2) Use of any wording importing that the material is a variety for which an application for plant variety protection is pending, when it is not.

(3) Use of either the phrase "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or similar phrase without reasonable basis. Any reasonable basis expires one year after the first sale of the variety except as justified thereafter by a pending application or a certificate still in force.

(b) Anyone convicted of violating a binding cease and desist order, or of performing any act prohibited in subsection (a) of this section for the purpose of deceiving the public, shall be fined not more than $10,000 and not less than $500.

(c) Anyone whose business is damaged or is likely to be damaged by an act prohibited in subsection (a) of this section, or is subjected to competition in connection with which such act is performed, may have remedy by civil action.

**Sec. 129. [7 U.S.C.A. § 2569] Nonresident Proprietors; Service and Notice.**

Every owner not residing in the United States may file in the Plant Variety Protection Office a written designation stating the name and address of a person residing within the United States on whom may be served process or notice of proceedings affecting the plant variety protection or rights thereunder. If the person designated cannot be found at the address given in the last designation, or if no person has been designated, the United States District Court for the District of Columbia shall have jurisdiction and summons shall be served by publication or otherwise as the court directs. The court shall have the same jurisdiction to take any action respecting the plant variety protection, or rights thereunder that it would have if the owner were personally within the jurisdiction of the court.

## Chapter 13.—INTENT AND SEVERABILITY

**Sec. 131. [7 U.S.C.A. § 2581] Intent.**

It is the intent of Congress to provide the indicated protection for new varieties by exercise of any constitutional power needed for that

**Sec. 121. [7 U.S.C.A. § 2561] Remedy for Infringement of Plant Variety Protection.**

An owner shall have remedy by civil action for infringement of his plant variety protection under section 111. If a variety is sold under the name of a variety shown in a certificate, there is a prima facie presumption that it is the same variety.

**Sec. 122. [7 U.S.C.A. § 2562] Presumption of Validity; Defenses.**

(a) Certificates of plant variety protection shall be presumed valid. The burden of establishing invalidity of a plant variety protection shall rest on the party asserting invalidity.

(b) The following shall be defenses in any action charging infringement and shall be pleaded: (1) noninfringement, absence of liability for infringement, or unenforceability; (2) invalidity of the plant variety protection in suit on any ground specified in section 42 of this title as a condition for protectability; (3) invalidity of the plant variety protection in suit for failure to comply with any requirement of section 52; (4) that the asserted infringement was performed under an existing certificate adverse to that asserted and prior to notice of the infringement; and (5) any other fact or act made a defense by this Act.

**Sec. 123. [7 U.S.C.A. § 2563] Injunction.**

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right hereunder on such terms as the court deems reasonable.

**Sec. 124. [7 U.S.C.A. § 2564] Damages.**

(a) Upon finding an infringement the court shall award damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the variety by the infringer, together with interest and costs as fixed by the court.

(b) When the damages are not determined by the jury, the court shall determine them. In either event the court may increase the damages up to three times the amount determined.

(c) The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

(d) As to infringement prior to, or resulting from a planting prior to, issuance of a certificate for the infringed variety, a court finding

who is chargeable with notice, is prohibited, and violates the property rights of the owner. Anyone receiving the material tagged or labeled with the notice is chargeable with the notice. The owner is entitled to remedy and redress in a civil action hereunder. No remedy available by State or local law is hereby excluded. No such notice shall be used, or if used be effective, when the owner has made identical sexually reproducible plant material available to the public, as by sale thereof.

## Chapter 11.—INFRINGEMENT OF PLANT VARIETY PROTECTION

### Sec. 111. [7 U.S.C.A. § 2541] Infringement of Plant Variety Protection.

Except as otherwise provided in this title, it shall be an infringement of the rights of the owner of a novel variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a novel plant variety with the notice under section 127:

(1) sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;

(2) import the novel variety into, or export it from, the United States;

(3) sexually multiply the novel variety as a step in marketing (for growing purposes) the variety; or

(4) use the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom; or

(5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progency thereof to propagate the novel variety; or

(6) dispense the novel variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received; or

(7) perform any of the foregoing acts even in instances in which the novel variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or

(8) instigate or actively induce performance of any of the foregoing acts.

### Sec. 112. [7 U.S.C.A. § 2542] Grandfather Clause.

notice thereof shall be endorsed on copies of the description of the protected plant variety thereafter distributed by the Plant Variety Protection Office.

(c) If a person acting under subsection (a) makes a prima facie showing of facts needing proof, the Secretary may direct that the reexamination include such interparty proceedings as he shall establish.

**Sec. 92. [7 U.S.C.A. § 2502] Priority Contest.**

(a) If the Secretary determines that two applications of different applicants may be based on the same variety, he may:

(1) Initiate a priority contest on his own motion whether or not one of the applications may have been certified; or

(2) Issue a certificate on the application having the earliest effective filing date, with notice to all; or

(3) Issue a certificate naming alternative owners, under a single variety name acceptable to both.

(b) On request of any person when a certificate has been issued naming another as an owner or alternative owner, both having applied for protection on the same variety, the Secretary shall institute a priority contest, except that any person shall have forfeited his right to assert priority for the purpose of obtaining plant variety protection when an adverse certificate has issued if he fails to make the request within one year of the mailing of notice specified in part (2) above or if he fails to make the request within the period for taking action after refusal of his application on the basis of the adverse certificate.

**Sec. 93. [7 U.S.C.A. § 2503] Effect of Adverse Final Judgment or of Non Action.**

(a) A final judgment under section 92 adverse to an application from which no appeal or other review had been or can be taken or had shall constitute cancellation of any certificating on that application, and notice thereof shall be endorsed on copies of the description of the protected plant variety thereafter distributed by the Plant Variety Protection Office.

(b) Any person who has not proceeded in accordance with the provision of this chapter shall not be foreclosed or in any way prejudiced with respect to the defense of an infringement suit or affirmative relief under declaratory judgment proceedings.

(c) No person subject to an adverse decision in a proceeding under this chapter shall be foreclosed with respect to asserting comparable grounds in defense of an infringement suit or as a basis for affirmative relief under declaratory judgment proceedings.

**Sec. 82. [7 U.S.C.A. § 2482] How Issued.**

A certificate of plant variety protection shall be issued in the name of the United States of America under the seal of the Plant Variety Protection Office, and shall be signed by the Secretary or have his signature placed thereon, and shall be recorded in the Plant Variety Protection Office.

**Sec. 83. [7 U.S.C.A. § 2483] Contents and Term of Plant Variety Protection.**

(a) Every certificate of plant variety protection shall certify that the breeder (or his successor in interest) his heirs or assignees, has the right, during the term of the plant variety protection, to exclude others from selling the variety, of offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom, to the extent provided by this Act. If the owner so elects, the certificate shall also specify that in the United States, seed of the variety shall be sold by variety name only as a class of certified seed and, if specified, shall also conform to the number of generations designated by the owner. Any rights, or all rights except those elected under the preceding sentence, may be waived; and the certificate shall conform to such waiver. The Secretary may at his discretion permit such election or waiver to be made after certificating and amend the certificate accordingly, without retroactive effect.

(b) The term of plant variety protection shall expire eighteen years from the date of issue of the certificate in the United States. If the certificate is not issued within three years from the effective filing date, the Secretary may shorten the term by the amount of delay in the prosecution of the application attributed by the Secretary to the applicant.

(c) The term of plant variety protection shall also expire if the owner fails to comply with regulations, in force at the time of certificating, relating to replenishing seed in a public repository: *Provided, however,* That this expiration shall not occur unless notice is mailed to the last owner recorded as provided in section 101(d) and he fails, within the time allowed thereafter, not less than three months, to comply with said regulations, paying an additional fee to be prescribed by the Secretary.

**Sec. 84. [7 U.S.C.A. § 2484] Correction of Plant Variety Protection Office Mistake.**

Whenever a mistake in a certificate of plant variety protection in-

(b) For taking appropriate action after the mailing to him of an action other than allowance, an applicant shall be allowed six months, or such other time as the Secretary in exceptional circumstances shall set in the refusal, or such time as he may allow as an extension. Without such extension, action may be taken up to three months late by paying an additional fee to be prescribed by the Secretary.

**Sec. 63. [7 U.S.C.A. § 2443] Initial Appeal.**

When an applicant for plant variety protection has been refused by the Plant Variety Protection Office, the applicant may appeal to the Secretary. The Secretary shall seek the advice of the Plant Variety Protection Board on all appeals, before deciding the appeal.

## Chapter 7.—APPEALS TO COURTS AND OTHER REVIEW

**Sec. 71. [7 U.S.C.A. § 2461] Appeals.**

From the decisions made under sections 44, 63, 91, 92, and 128 appeal may, within sixty days or such further time as the Secretary allows, be taken under the Federal Rules of Appellate Procedure. The United States Court of Appeals for the Federal Circuit shall have jurisdiction of any such appeal.

**Sec. 72. [7 U.S.C.A. § 2462] Civil Action Against Secretary.**

An applicant dissatisfied with a decision under section 63 or 91 of this title, may, as an alternative to appeal, have remedy by civil action against the Secretary in the United States District Court for the District of Columbia. Such action shall be commenced within sixty days after such decision or within such further time as the Secretary allows. The court may in the case of review of a decision by the Secretary refusing plant variety protection, adjudge that such applicant is entitled to receive a certificate of plant variety protection for his variety as specified in his application as the facts of the case may appear, on compliance with the requirements of this Act.

**Sec. 73. [7 U.S.C.A. § 2463] Appeal or Civil Action in Contested Cases.**

(a) A party to a proceeding under section 92 of this title, dissatisfied with the decision, may take an appeal under section 71 or may have remedy by civil action if commenced within sixty days after such decision or within such further time as the Secretary allows. A party contemplating appeal as provided herein shall notify all adverse parties of his intention and any such adverse party, not the Sec-

(3) A declaration that a viable sample of basic seed necessary for propagation of the variety will be deposited and replenished periodically in a public repository in accordance with regulations to be established hereunder.

(4) A statement of the basis of applicant's ownership.

**Sec. 53. [7 U.S.C.A. § 2423] Joint Breeders.**

(a) When two or more persons are the breeders, one (or his successor) may apply naming the other.

(b) The Secretary, after such notice as he may prescribe, may issue a certificate of plant variety protection to the applicant and such of the other breeders (or their successors in interest) as may have subsequently joined in the application.

**Sec. 54. [7 U.S.C.A. § 2424] Death or Incapacity of Breeder.**

Legal representatives of deceased breeders and of those under legal incapacity may make application for plant variety protection upon compliance with the requirements and on the same terms and conditions applicable to the breeder or his successor in interest.

**Sec. 55. [7 U.S.C.A. § 2425] Benefit of Earlier Filing Date.**

(a) An application for a certificate of plant variety protection filed in this country based on the same variety, and on rights derived from the same breeder, on which there has previously been filed an application for plant variety protection in a foreign country which affords similar privileges in the case of applications filed in the United States by nationals of the United States, shall have the same effect as the same application would have if filed in the United States on the date on which the application for plant variety protection for the same variety was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed. No applications shall be entitled to a right of priority under this section, unless the applicant designates the foreign application in his application or by amendment thereto and, if required by the Secretary, furnishes such copy, translation or both, as the Secretary may specify.

(b) An application for a certificate of plant variety protection for the same variety as was the subject of an application previously filed in the United States by or on behalf of the same person, or by his predecessor in title, shall have the same effect as to such variety as though filed on the date of the prior application if filed before the issuance of the certificate or other termination of proceedings on the

(a) The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor, subject to the conditions and requirements of this title unless one of the following bars exists:

(1) Before the date of determination thereof by the breeder, or more than one year before the effective filing date of the application therefor, the variety was (A) a public variety in this country, or (B) effectively available to workers in this country and adequately described by a publication reasonably deemed a part of the public technical knowledge in this country which description must include a disclosure of the principal characteristics by which the variety is distinguished.

(2) An application for protection of the variety based on the same breeder's acts, was filed in a foreign country by the owner or his privies more than one year before the effective filing date of the application filed in the United States.

(3) Another is entitled to an earlier date of determination for the same variety and such other (A) has a certificate of plant variety protection hereunder or (B) has been engaged in a continuing program of development and testing to commercialization, or (C) has within six months after such earlier date of determination adequately described the variety by a publication reasonably deemed a part of the public technical knowledge in this country which description must include a disclosure of the principal characteristics by which the variety is distinguished.

(b) The Secretary may, by regulation, extend for a reasonable period of time the one year time period provided in subsection (a) for filing applications, and may in that event provide for at least commensurate reduction of the term of protection.

**Sec. 43. [7 U.S.C.A. § 2403] Reciprocity Limits.**

Protection under the Act may, by regulation, be limited to nationals of the United States, except where this limitation would violate a treaty and except that nationals of a foreign state in which they are domiciled shall be entitled to so much of the protection here afforded as is afforded by said foreign state to nationals of the United States for the same genus and species.

**Sec. 44. [7 U.S.C.A. § 2404] Public Interest in Wide Usage.**

The Secretary may declare a protected variety open to use on a basis of equitable remuneration to the owner, not less than a reasonable royalty, when he determines that such declaration is necessary

the cost and shall remain available without fiscal year limitation to pay the expenses incurred by the Secretary in carrying out this chapter. Such funds collected (including late payment penalties and any interest earned) may be invested by the Secretary in insured or fully collateralized, interest-bearing accounts or, at the discretion of the Secretary, by the Secretary of the Treasury in United States Government debt instruments.

(d) Actions for nonpayment. The Attorney General may bring an action for the recovery of charges that have not been paid in accordance with this chapter against any person obligated for payment of such charges under this chapter in any United States district court or other United States court for any territory or possession in any jurisdiction in which the person is found, resides, or transacts business. The court shall have jurisdiction to hear and decide the action.

(e) Authorization of appropriations. There are authorized to be appropriated such sums as are necessary to carry out this chapter.

**Sec. 32. [7 U.S.C.A. § 2372] Payment of Plant Variety Protection Fees; Return of Excess Amounts.**

All fees shall be paid to the Secretary, and the Secretary may refund any sum paid by mistake or in excess of the fee required.

## TITLE II—PROTECTABILITY OF PLANT VARIETIES AND CERTIFICATES OF PROTECTION

### Chapter 4.—PROTECTABILITY OF PLANT VARIETIES

**Sec. 41. [7 U.S.C.A. § 2401] Definitions and Rules of Construction.**

The definitions and rules of construction set forth in this section apply for the purposes of this Act.

(a) The term "novel variety" may be represented by, without limitation, seed, transplants, and plants, and is satisfied if there is:

(1) Distinctness in the sense that the variety clearly differs by one or more identifiable morphological, physiological or other characteristics (which may include those evidenced by processing or product characteristics, for example, milling and baking characteristics in the case of wheat) as to which a difference in geneology may contribute evidence, from all prior varieties of public knowledge at the date of determination within the provisions of section 42; and

(2) Uniformity in the sense that any variations are describable, predictable and commercially acceptable; and

(3) Stability in the sense that the variety, when sexually reproduced or reconstituted, will remain unchanged with regard to its es-

of papers, the action may be taken or the fee paid, on the next succeeding business day.

**Sec. 22. [7 U.S.C.A. § 2352] Form of Papers Filed.**

The Secretary may by regulations prescribe the form of papers to be filed in the Plant Variety Protection Office.

**Sec. 23. [7 U.S.C.A. § 2353] Testimony in Plant Variety Protection Office Cases.**

The Secretary may establish regulations for taking affidavits, depositions, and other evidence required in cases before the Plant Variety Protection Office. Any officer authorized by law to take depositions to be used in the courts of the United States, or of the State where he resides, may take such affidavits and depositions, and swear the witnesses. If any person acts as a hearing officer by authority of the Secretary, he shall have like power.

**Sec. 24. [7 U.S.C.A. § 2354] Subpoenas, Witnesses.**

(a)The clerk of any United States court for the district wherein testimony is to be taken in accordance with regulations established by the Secretary for use in any contested case in the Plant Variety Protection Office shall, upon the application of any party thereof, issue a subpoena for any witness residing or being within such district or within one hundred miles of the stated place in such district, commanding him to appear and testify before an officer in such district authorized to take depositions and affidavits, at the time and place stated in the subpoena. The provisions of the Federal Rules of Civil Procedure relating to the attendance of witness and the production of documents and things shall apply to contested cases in the Plant Variety Protection Office insofar as consistent with such regulations.

(b) Every witness subpoenaed or testifying shall be allowed the fees and traveling expenses allowed to witnesses attending the United States district courts.

(c) A judge of a court whose clerk issued a subpoena may enforce obedience to the process or punish disobedience as in other like cases, on proof that a witness, served with such subpoena, neglected or refused to appear or to testify. No witness shall be deemed guilty of contempt for disobeying such subpoena unless his fees and traveling expenses in going to, and returning from, one day's attendance at the place of examination, are paid or tendered him at the time of the service of the subpoena; nor for refusing to disclose any secret matter except upon appropriate order of the court which issued the subpoena or of the Secretary.

ble during the periods of their employment, to apply for plant variety protection and to acquire directly or indirectly, except by inheritance or bequest, any right or interest in any matters before that Office. This section shall not apply to members of the Plant Variety Protection Board who are not otherwise employees of the Plant Variety Protection Office.

**Sec. 5 [repealed]**

**Sec. 6 [7 U.S.C.A. § 2326] Regulations.**

The Secretary may establish regulations, not inconsistent with law, for the conduct of proceedings in the Plant Variety Protection Office after consultations with the Plant Variety Protection Board.

**Sec. 7. [7 U.S.C.A. § 2327] Plant Variety Protection Board.**

(A) APPOINTMENT.—The Secretary shall appoint a Plant Variety Protection Board. The Board shall consist of individuals who are experts in various areas of varietal development covered by this Act. Membership of the Board shall include farmer representation and shall be drawn approximately equally from the private or seed industry sector and from the sector of government or the public. The Secretary or his designee shall act as chairman of the Board without voting rights except in the case of ties.

(B) FUNCTIONS OF BOARD.—The functions of the Plant Variety Protection Board shall include:

(1) Advising the Secretary concerning the adoption of Rules and Regulations to facilitate the proper administration of this Act;

(2) Making advisory decisions on all appeals from the examiner. The Board shall determine whether to act as a full Board or by panels it selects; and whether to review advisory decisions made by a panel. For service on such appeals, the Board may select, as temporary members, experts in the area to which the particular appeal relates; and

(3) Advising the Secretary on all questions under section 44.

(C) COMPENSATION OF BOARD.—The members of the Plant Variety Protection Board shall serve without compensation except for standard government reimbursable expenses.

**Sec. 8. [7 U.S.C.A. § 2328] Library.**

The Secretary shall maintain a library of scientific and other works and periodicals, both foreign and domestic, in the Plant Variety Protection Office to aid the examiners in the discharge of their duties.

436, Chemistry: Analytical and immunological Testing, subclass 94 for a chemical test for nucleic acids; subclass 501 for binding assays other than antibody assays; subclass 516 for a test including a step of immunoelectrophoresis; and subclass 506-548 which provides for antigen antibody assays and, subclass 548 for process of using monoclonal antibodies in a test or analysis.

107. In Vivo Use of Product: Processes under subclass 106 in which the product of the fused or hybrid cell is used in a living organism.

108. In Vivo, e.g., Cell Cultivation Techniques, Affinity Chromatography, Etc.: Processes under subclass 106 in which the fused or hybrid cell is used in culture or the product of a fused or hybrid cell is so used.

109. Production of a Nonantibody Product: Processes under subclass 108 in which the product produced is not an antibody.

(1) *Note.* This subclass would provide for the use of fused or hybrid cells to produce peptides, proteins, hormones, etc.

110. For Use as a Testing Material: Processes under subclass 108 in which the cells or their products are claimed or disclosed as used in a qualitive or quantitative test.

(1) *Note.* This subclass would provide for monoclonal antibodies used in immunoassays.

111. Miscellaneous: Subject matter under the class definition not provided for in any of the preceding subclasses.

When used in the schedule and definitions of this class plant is to be taken in the scientific sense.

95. Fused or Hybrid Cell Per Se: Subject matter under subclass 89 directed to the fused or hybrid cell per se.

96. Inter Species Hybrids: Subject matter under subclass 95 in which at least two partners are cells of different species.

(1) *Note.* This subclass would include hybrid cells from different kingdoms, e.g., plant cell fused with a human cell, etc., as well as mouse-human, mouse-rat cell hybrids.

97. Fungi, e.g., Yeasts, Etc.: Subject matter under subclass 95 in which one of the partners is a fungus cell.

98. Plant Cells: Subject matter under subclass 95 in which one of the partners is a plant cell.

99. Human Cell: Subject matter under subclass 95 in which the partners are human cells.

(1) *Note.* Included in this subclass are cell strains, cell lines and primary cultures as well as fresh isolates.

100. B Lymphocyte: Subject matter under subclass 99 in which one of the fusing partners is a B lymphocyte.

101. T Lymphocyte: Subject matter under subclass 99 in which one of the fusing partners is a T lymphocyte.

102. Animal Cell: Subject matter under subclass 95 in which the fusing partners are obtained from a nonhuman animal.

103. Murine Cell, e.g., Mouse Cell, Etc.: Subject matter under subclass 102 in which the partners are rat or mouse cells.

sulting in a cell line capable of continuous growth in long term culture.

(2) *Note.* Fusing agents per se should be placed in 93+ according to intended utility. Original classification of such patents will be in an appropriate composition class e.g., 424, etc. or compound class e.g., 423, 260, etc.

*SEARCH THIS CLASS, SUBCLASS:*

66+, for cell lines or microorganisms with optimized fusing characteristics.

424, Drug Bio-Affecting and Body Treating Compositions subclasses 89+ for an antigenic composition containing a virus and subclass 93 for a composition containing a live virus; subclass 92 for a bacteria containing antigenic composition and subclass 93 for compositions containing a whole live bacteria; subclasses 180+ for compositions containing DNA or RNA used to alter the genetic structure of the cells of a multicellular organism i.e., gene therapy with compositions containing DNA or RNA.

*SEARCH CLASS:*

435, Chemistry, Molecular or Microbiology, subclass 172.2 for methods and materials for the production of hybrid or fused cells.

90. Method of Selection of the Desired Cell: Processes under subclass 89 directed to the identification of the hybrid or fused cells that possess the desired genetic characteristics.

(1) *Note.* This subclass provides for assaying based on the quantitative production of some desired product of the fused or hybrid cell.

(2) *Note.* This subclass will provide for processes using a nega-

*SEARCH CLASS:*

435, Chemistry: Molecular Biology and Microbiology, subclasses 34+ which provide for the use of selective media in a test involving a microorganism and the media per se; subclasses 240+ for media for culture or maintenance of animal or plant cells; and subclasses 243+ providing for microbial culture media.

85. Genetic Engineering Apparatus: Apparatus under the class definition for use in testing, propagation or use of a genetically engineering microorganism or of the materials used in the production and culture of the genetically engineered microorganisms.

*SEARCH CLASS:*

435, Chemistry: Molecular Biology and Microbiology, subclasses 287+ for apparatus claimed by solely disclosed as for use with a microorganism or enzyme.

86. Analytical e.g., Autoradiography, Etc.: Apparatus under subclass 85 for the quantitative or qualitative analysis of an intermediate or final product of a process of genetic engineering.

87. Automated: Apparatus under subclass 85 in which the qualitative test is performed by a self operated machine.

*SEARCH CLASS:*

435, Chemistry: Molecular Biology and Microbiology, subclasses 288, 289+ and 291 for automated analysis apparatus involving a microorganism or enzyme.

436, Chemistry: Analytical and Immunological Testing, subclasses 42+ for automated chemical analyzers; and subclass 808 for automated analyzers for antigen antibody or protein binding tests.

435, Chemistry, Molecular and Microbiology, subclasses 4+ for measuring or testing processes involving a microorganism or enzyme; subclass 6 for a test for or with a nucleic acid involving a microorganism.

436, Chemistry: Analytical and Immunological Testing, subclass 94 for a chemical test for nucleic acids; subclass 501 for binding assays other than antigen antibody assays; subclass 516 for a test including a step of immunoelectrophoresis; and subclass 506-548 which provide for antigen antibody assays.

77. Method of Analysis of Nucleic Acids: Process under subclass 76 for a qualitative or quantative analysis of nucleic acid by chemical, electrical or physical means.

(1) *Note.* The typical processes provided for here will include hybrid binding and/or electrophoresis.

(2) *Note.* Disposition of tests for nucleic acids. Chemical tests for nucleic acids are provided for by Class 436, subclass 94; hybrid binding tests are provided for by Class 436, subclasses 501+ and antigen antibody tests by Class 436, subclasses 506 to 548; tests involving a microorganism or enzyme would be provided for in Class 435, subclass 6; electrophoretic tests by Class 204, subclass 1 and Class 204, subclass 18; physical tests such as chromatography would be provided for in Class 75, subclass 53; and in vivo test would be provided for in Class 424, subclass 9.

78. Including Hybridization: Processes under subclass 77 in which a step in the analysis involves DNA or RNA complement binding.

79. Methods of Selection of Recombinant Gene Containing Vector; Materials Therefor, e.g., Replica Plating, Etc.: Processes or materials under subclass 76 for the selection or identification of cells which contain the exogenous DNA bearing vector.

phospholipid vesicles (liposomes) as well as within protoplasts.

(2) *Note.* The subject matter of subclass 66 through 75 is left without formal definition in favor of the many standard reference works on cell structure and function which should be considered dispositive of the subject matter.

(3) *Note.* It should be noted that the scientific and legal definitions of plant are not coterminous. See section II, D, supra. When used in the schedule and definitions of this class plant is to be taken in the scientific sense.

67. Plant Cells: Subject matter under subclass 66 including plant cells containing a vector or exogenous gene, compositions containing such cells, processes of propagation of such cells and materials for the progagation of such cells.

68. Fungal Cells: Subject matter under subclass 66 including microorganisms containing a vector or exogenous gene, compositions containing such microorganisms, processes of propagation of such microorganisms and materials for the propagation of such microorganisms and membrane encapsulated DNA.

69. Yeast Cells: Subject matter under subclass 66 including microorganisms containing a vector or exogenous gene, compositions containing such microorganisms, processes of propagation of such microorganisms and materials for the propagation of such microorganisms.

70. Animal Cells: Subject matter under subclass 66 including animal cells containing a vector or exogenous gene, compositions containing such cells, processes of propagation of such cells and materials for the propagation of such cells.

71. Human Cells: Subject matter under subclass 70 including human cells containing a vector or exogenous gene, compositions containg such cells, processes of propagation of such cells and materials for the propagation of such cells.

on the body classification will be on the basis of the device claimed.

*SEARCH CLASS:*

604, Surgery, subclass 55 will provide for a method of embryo transplantation.

63. Use in Animal Husbandry: Processes under subclass 59 of the use of genetically engineered cells or vectors in the breeding or raising of animals.

(1) *Note.* This subclass provides for processes of altering the genetic structure of an animal or for alteration of the genetic structure of the intestinal flora of the animal.

*SEARCH CLASS:*

119, Animal Husbandry, which provides for processes and apparatus for the propagation and care of living multicellular animals.

604, Surgery, subclass 55 will provide for a method of embryo transplantation.

64. Use in Agriculture: Processes under subclass 59 of use of genetically engineered cells or vectors in plant husbandry.

(1) *Note.* This subclass provides for alterations to a plant's genetic structure a well as alteration of the genetic structure of the symbiotic microorganisms associated with plant growth.

*SEARCH CLASS:*

435, Chemistry, Molecular Biology and Microbiology for processes of genetically altering plants, plant cell fusion,

Modification of Textiles and Fibers, for a dyeing process employing a microorganism; subclasses 94.1+ for processes of tanning hides or skins by use of a microorganism 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, subclass 265 for a fermentation process, per se, of treating a hide or skin, e.g., depilating, batting, etc.

75, Metallurgy, subclasses 1+ particularly subclass 5 for a process of beneficiating metal using a microorganism.

106, Wells, appropriate subclasses for processes and apparatus for treating oil or an oil bearing mineral with a microorganism while in the ground.

210, Liquid Purification or Separation, subclasses 601+ for processes of treatment of liquid by a living organism, subclass 635 for a process of gel chromatography, subclasses 656+ for a process of chromatography and cross reference art collection 906 providing for separating of phosphorous containing materials, 905 providing for protein separation and 922 providing for an oil spill cleanup and Digest 32 for biological removal of fluoride.

435, Chemistry: Molecular Biology and Microbiology, subclasses 41+ for the use of a microorganism, enzyme, tissue or cell culture to produce a chemical product; subclass 262 for processes utilizing a microorganism or enzyme to liberate, separate or purify a preexisting compound or composition. Subclasses 262 and the indented subclasses provide a comprehensive listing of related separation technologies.

60. To Produce an Identified Chemical Product, e.g., Amino Acid, Etc.: Process under subclass 59 of use of a genetically engineered cell to produce a product of known chemical structure.

(1) *Note.* See section II of the headnotes of this class for a

55. Using Vector, e.g., Plasmid Etc.: Subject matter under subclass 52 in which exogenous DNA or RNA is introduced into a cell as part of a larger nonchromosomal DNA or RNA sequence capable of directing its own replication within the cell.

(1) *Note.* This subclass is intended to provide for the introduction of plasmids, phages or virus into a cell for either cloning or expression.

*SEARCH THIS CLASS, SUBCLASS:*

24, for methods of construction vectors and for vectors per se.

56. Plasmid: Subject matter under subclass 55 in which the vector is an extra-chromosomal genetic element consisting of a covalently closed circular DNA molecule (cccDNA).

*SEARCH THIS CLASS, SUBCLASS:*

27, for plasmids per se and methods modifying plasmids.

57. Virus: Subject matter under subclass 55 in which the vector is a virus.

*SEARCH THIS CLASS, SUBCLASS:*

25, for a plant virus per se or methods of modifying a plant virus.

32, for an animal virus per se and methods of modifying animal virus.

*SEARCH CLASS:*

424, Drug Bio-Affecting and Body Treating Compositions, subclass 89 for an antigenic composition containing a

thesis of a protein or peptide by a cell on the mRNA template is modified.

(1) *Note.* This subclass would provide for matching the codon frequency of a synthetic gene to the codon frequency of a particular host.

45. Ribosome Binding Site: Subject matter under subclass 44 in which the site of mRNA at which ribosomes initiate protein synthesis is modified or the position of the binding site on the mRNA is changed to optimize expression.

46. Initiation: Subject matter under subclass 44 in which the initiation of peptide or protein synthesis is modified.

(1) *Note.* This subclass will provide for alteration in the physical or chemical surroundings of the cell to initiate peptide or protein synthesis as well as modification involving initiation factors or the formation of an initiation complex by the cell.

47. Fused Peptide or Protein: Subject matter under subclass 33 in which a DNA sequence coding for at least portions of two or more different polypeptides directs expression of a single polypeptide chain.

(1) *Note.* This subclass is intended to provide for the expression of fused genes such as the N terminal portion of the Beta-glactosidase Z gene fused to the somatosatin gene.

48. Signal Peptide, e.g., Secretion, Etc.: Subject matter under subclass 47 in which the fused peptide or protein is a peptide or protein that initiates or permits some cellular activity.

49. Post Translational Modification: Subject matter under subclass 33 which includes addition to, removal of or rearrangement of the peptide or protein products in the cell.

(1) *Note.* Eucaryotic cells include the cells of all higher organisms in both plant and animal kingdoms as well as fungi, protozoa and most algae.

35. Plant Cell: Subject matter under subclass 34 in which expression is modified in a plant cell.

(1) *Note.* The expression may be optimized in a plant cell culture or as a process in a mature plant.

(2) *Note.* For a directory of the disposition of subject matter relating to claiming to plants per se, see section II, D, of the headnotes of this class.

(3) *Note.* It should be noted that the scientific and legal definitions of plant are not coterminous. See section II, D, supra. When used in the schedule and definitions of this class plant is to be taken in the scientific sense.

36. Transcription: Subject matter under subclass 34 in which the transfer of genetic information from DNA to messenger RNA by DNA-directed RNA polymerase is modified.

(1) *Note.* This subclass will provide for patents related to eukaryotic promoters and ribosome binding site modifications.

37. Yeast Cell: Subject matter under subclass 34 in which the cell is a fungus that reproduces by budding and has either short or nonexistent mycella.

38. Procaryotic Cell: Subject matter under subclass 33 in which the cell expressing the genetic information is a simple cell having no nuclear membrane, the cell membrane is usually surrounded by a rigid cell wall and contains only a single chromosome.

(1) *Note.* Procaryotes include bacteria and eubacteria, the blue green algae.

the selectable markers and be capable of introducing exogenous DNA into cells.

28. Yeast: Subject matter under subclass 27 in which the plasmid is capable of replicating in or transforming yeast.

29. Procaryotic: Subject matter under subclass 27 in which the plasmid is one capable of replicating in or transforming a cell having a single chromosome.

30. Plant: Subject matter under subclass 30 in which the plasmid is one capable or replicating in or transforming a plant cell.

(1) *Note.* It should be noted that the scientific and legal definitions of plant are not coterminous. See section II, D, supra. When used in the schedule and definitions of this class, plant is to be taken in the scientific sense.

31. Bacteriophage: Subject matter under subclass 24 in which the vector is a single stranded or double stranded DNA bacterial virus or single or double stranded RNA bacterial virus.

(1) *Note.* The primary example of the subject matter provided for herein is bacteriophage lambda and vectors derived therefrom. Bacteriophage lambda is a double stranded DNA virus with a genome size of approximately 50 kb.

(2) *Note.* A single stranded DNA bacteriophage would be provided for in this subclass. Single-stranded DNA cloning vehicles are currently used chiefly as sources of templates for sequencing by the Sanger dideoxy-sequencing, chain-termination technique and as sources of strand-specific probes for nucleic acid hybridization.

*Search Class:*

436, Chemistry: Analytical and Immunological Testing, subclass 94 for the sequencing of DNA and Class 435, subclass

*Search Class:*

204, Chemistry, Electrical and Wave Energy subclass 18 for a process of gel electrophoresis.

260, Chemistry, Carbon Compounds provides for the liberation and purification by chemical or physical means of compounds and extracts falling within the class definition of Class 260. Generally, the physical processes included are of two types (1) a purification process prior or subsequent to a chemical reaction producing a 260 product (2) a purification process directed to the purification of a 260 compound by a combination of physical separation techniques the classes for which do not provide for or exclude the combination claimed. Chemical purification processes are generally provided for with each product produced.

20. RNA: Subject matter under subclass 19 directed to the isolation or purification of RNA.

21. mRNA: Subject matter under subclass 20 in which the RNA is messenger RNA.

22. Vectors and Methods of Modifying Vectors: Subject matter under the class definition directed to (1) microscopic agents for the introduction of foreign nucleic acid sequences into cells and (2) methods of forming or modifying such agents.

(1) *Note.* This and the indented subclasses include plasmids, cosmids bacteriophages, and virus per se and methods of modifying the same when used to introduce foreign genetic material into a cell.

*Search Class:*

435, Chemistry, Molecular and Microbiology, subclass 172.3 for the methods and materials of recombinant DNA technology; subclass 317 for the subcellular parts of microorganism such as plasmids, mitochondria, and other organelles.

of deoxyribonucleic acid sequences and the product of such processes.

7. Homopolymeric, e.g., Poly d (A) Sequences, Etc.: Subject matter under subclass 6 in which the deoxyribonucleic acid sequence is composed of repeating units of the same nucleotide base.

8. 12-75 Nucleotides in Length, e.g., Primer, Etc.: Subject matter under subclass 6 in which the nucleotide of interest is composed to 12 to 75 bases.

9. Structural Gene Sequence: Subject matter under subclass 6 in which the DNA sequence codes for the production of the amino acid sequence of a polypeptide.

10. Modified Structural Gene, e.g., Nonnaturally Occuring Sequence, Etc: Subject matter under subclass 9 in which the structural gene is not homologous with a gene isolated from a plant, animal or microorganism.

    (1) *Note.* This subclass would provide for genes such as a hybrid polypeptide gene prepared by combining parts of gene sequences coding for all or part of other different polypeptides.

11. Polypeptide: Subject matter under subclass 9 in which the structural gene codes for production of a polypeptide of two or more amino acid residues.

*Search Class:*

260, Chemistry, Carbon Compounds, subclasses 112+ provides for the peptide or protein products of a genetically engineered microoganism including antibodies per se and the purification of such products by physical or chemical methods.

## VII. Subclass Definitions

1. Obtaining the Desired Gene; DNA, RNA per se and the Modification Thereof Other than Vector Modification: Subject matter under the class definition directed to (1) obtaining a desired DNA or RNA sequence by chemical or biochemical and/or physical means and (2) to the chemical or biochemical modification of a DNA or RNA and (3) to the isolation or purification DNA or RNA.

   (1) *Note.* This and the indented subclasses are intended to provide for the synthesis or isolation of gene or gene fragment for insertion into a cloning or expression vector or a cell or protoplast.

   (2) *Note.* The subject matter of this area is restricted to the chemistry of Adenine, Thymine, Guanine, Uracil, Cytosine, or Inosine containing sequences.

   (3) *Note.* This and the indented subclasses provide for double stranded DNA (ds DNA) and single stranded DNA (ss DNA) as well as single and double stranded RNA and DNA-RNA hybrids.

   *Search This Class, Subclass:*

   23, for methods of inserting a gene into a vector and subclass 24 for virus, cosmid and plasmid vectors.

   *Search Class:*

   435, Chemistry Molecular Biology and Microbiology, subclass 91 for processes of biosynthesis of RNA and DNA and subclass 270 for a process of liberating, separating and purifying nucleic acid from an intact or disrupted cell by means of a microorganism or enzyme. Class 435 will provide for organized forms of RNA and DNA such as operons, ribosomal, messenger and transfer RNAs; subclass 85 for enzymatic or microbial production of an N-Glycoside

*Polycistronic.* mRNA that includes coding regions representing more than one gene.

*Plasmid.* An autonomously replicating circular extrachromosomal DNA element. Carries a few genes, among which are resistance to various antibiotics; useful as cloning vehicles.

*Polymerase.* Enzyme that catalyzes the assembly of nucleotides into RNA and of deoxynucleotides into DNA.

*Pribnow box.* The consensus sequence TATAATG centered about 10 bp before the startpoint of bacterial genes. It is a part of the promoter and is important in binding RNA polymerase.

*Primer.* A short sequence (often of RNA) that is paired with one strand of DNA and provides a free 3′ —OH end at which a DNA polymerase starts synthesis of a deoxyribonucleotide chain.

*Promoter.* DNA sequence at which RNA polymerase binds, and then initiates transcription.

*Prophage.* A phage genome covalently integrated as a linear part of the bacterial chromosome.

*Recombination.* A specialized merging of DNA which results in inheritable traits not found in the parental strain of the host cell.

*Regulatory gene.* A gene whose product is involved in the regulation of another gene, such as a repressor gene.

*Replicatable biological units (RBU).* Biological materials that are capable of producing substantially identical copies in the proper conditions. Included are microorganisms, cell lines (including fused or hybrid cell lines), animal virus, bacteriophage and plasmids.

*Repressor.* A protein molecule that binds to an operator to block transcription of a gene.

*Reverse transcription.* Synthesis of DNA on an RNA template

tion as a result of interaction of the inducer with the regulator protein.

*Induction of prophage.* Describes the excision from the host genome and entry into the lytic (infective) cycle as a result of destruction of the lysogenic repressor.

*Initiation codon* (AUG; sometimes GUG). Codes for the first amino acid in protein sequences.

*Insertion sequence (IS).* A small bacterial transposon carrying only the genetic functions involved in transposition.

*Intercistronic region.* The distance between the termination codon of one gene and the initiation condon of the next gene in a polycistronic transcription unit.

*Intron* or *intervening sequence* is a segment of DNA that is transcribed, but is removed from within the transcript by splicing together the sequences (exons) on either side of it; a portion of a gene that is transcribed but does not appear in the final mRNA transcript.

*Inverted repeats.* Two copies of the same sequence of DNA repeated in opposite orientation on the same molecule. Adjacent inverted repeats constitute a palindrome.

*Jumping genes.* Genes associated with transposable elements.

*Kb.* An abbreviation for 1000 base pairs of DNA or 1000 bases of RNA or 1000 bases of single stranded DNA.

*Klenow Fragment.* A fragment of DNA polymerase which still polymerizes nucleotides into DNA, but lacks one of its exonuclease activities.

*Lac operon.* An operon in Escherichia coli that codes for three genes involved in the metabolism of lactose.

*Library.* A collection of cloned fragments of DNA, which together represent an entire genome.

*Ligase.* DNA ligase catalyzes the formation of a phosphodiest-

*Cosmids.* Plasmids into which phage lambda cos sites have been inserted; as a result, the plasmid DNA can be packaged in vitro in the phage coat.

*Crossing-over.* Exchange of genetic material between chromosomes that pair during meiosis (homologous chromosomes).

*Cyclic AMP.* A molecule of AMP in which the phosphate group is joined to both 3′ and 5′ positions of the ribose; its binding activates the CAP, a positive regulator of procaryotic transcription.

*Depressed state.* The equivalent to induced when describing the normal state of a gene; it has the same meaning as constitutive in describing the effect of mutation.

*Endonucleases.* Cleave bonds within a nucleic acid chain; they may be specific for RNA or for single-stranded or double-stranded DNA.

*Episome.* A plasmid able to integrate into bacterial DNA; a circular gene fragment.

*Exon.* Any segment of an interrupted gene that is represented in the mature RNA product.

*Exonucleases.* Cleave nucleotides one of a time from the end of a polynucleotide chain; they may be specific for either the 5′ or 3′ end of DNA or RNA.

*Extranuclear genes.* Genes that reside in organelles such as mitochondria or chloroplasts outside the nucleus.

*Gene (cistron).* The segment of DNA that is involved in producing a polypeptide chain; it includes regions preceding and following the coding region as well as intervening sequences (introns) between individual coding segments (exons).

*Genetic Engineering.* Production of a nonrandom change in a genome by addition, deletion, substitution or manipulation of the genetic material.

## V. GLOSSARY

*Anticodon.* The triplet of nucleotides in a tRNA molecule that associates by complementary base pairing with the codon in the mRNA during translation.

*Antiparallel.* Describes molecules that are parallel but point in opposite direction (the strands of DNA are antiparallel)

*Antisense strand.* DNA that has the same sequence as mRNA.

*Appoinducer.* Protein that binds to DNA to switch on transcription by RNA polymerase.

*AUG.* See initiation condon.

*Bacteriophages.* Viruses that infect bacteria; often abbreviated as phages.

*Base pair (bp).* A hydrogen bonding of A with T or U or of C with G in polynucleotides.

*cap.* The structure found at the 5' end of many eukaryotic mRNAs; it consists of 7' methyl-guanosine-ppX; where X is the first nucleotide encoded in the DNA; it is not present in prokaryotic mRNAs; it is added post-transcriptionally near the TATA (Hogness) box.

*CAP* (not to be confused with cap). CAP is catabolite gene activator protein (sometimes CRP or CGA); it participates in the initiation of transcription in prokaryotes.

*Capsid.* The protein coat of a virion or virus particle.

*cDNA* (complementary DNA). A DNA complementary to an RNA (e.g., mRNA), synthesized from it by in vitro transcription; used for cloning or as a specific probe.

*cDNA clone.* A duplex DNA sequence representing an RNA, carried in cloning vector and derived from mRNA.

*Cell-free Extract.* A fluid derived from broken cells which contains most of the soluble components of the cell. Capable

## III. Search Notes

This class is intended to provide a field of search for processes which produce a change in the genetic material of a cell primarily by use of recombinant DNA techniques or by production and selection of hybrid or fused cells. Other techniques of producing or selecting for genetic changes are provided for in the following classes:

435, provides for mutation and cell fusion techniques of producing whole plants as well as the treatment of plants and seeds with radiation and methods of plant breeding including chromosome multiplication.

119, provides for methods of treating the eggs of fish to cause sterility in the mature fish.

128, and 604, provides for methods of gene therapy involving removal of a body fluid and reintroduction of the fluid into the body e.g., bone marrow transplants of normal or genetically engineered marrow cells.

435, subclass 172.1, provides for processes relating to microorganisms in which mutation is induced or a natural mutant is selected.

435, subclasses 236+, provides for the inactivation or attenuation of a virus or for the production of viral subunits.

435, subclass 245, provides for a process of adaption or attenuation of cells.

| | |
|---|---|
| Leucine | 562/575 |
| Lysine | 562/562 |
| Methionine | 562/559 |
| Phenylalanine | 562/445 |
| Proline | 548/535 |
| Serine | 562/567 |
| Threonine | 562/570 |
| Tryptophan | 548/496 |
| Tyrosine | 562/444 |
| Valine | 526/575 |

| *Nonprotein Amino Acids* | *Classification* |
|---|---|
| Beta Alanine | 562/576 |
| Gamma-Aminobutyric acid | 562/553 |
| Canavanine | 562/560 |
| Citrulline | 562/560 |
| Beta-Cyanoalanine | 260/465.4 |
| Djenkolic acid | 562/557 |
| Homocysteine | 562/556 |
| Homoserine | 562/567 |
| Ornithine | 562/561 |

| *Rare amino acids from proteins* | *Classification* |
|---|---|
| Desmosine | 546/335 |
| 5 Hydroxylysine | 562/564 |
| 5-Hydroxyproline | 548/532 |
| Isodesmosine | 546/335 |
| 3-Methythistidine | 548/335 |
| Epsilon-N-Methyllysine | 562/561 |
| 3-Hydroxyproline | 548/535 |
| 4-Hydroxyproline | 548/535 |

## C. Enzymes used in Molecular Cloning

| *ENZYME TYPE* | *E. C. NUMBER* | *CLASSIFICATION* |
|---|---|---|
| (1) Restriction endonuclease | (3.1.23) | 435/199 |
| (2) Methylase e.g., ECO RI Methylase | (2.1.1) | 435/193 |
| (3) DNA Polymerase I and the Klenow Fragment of E. coli DNA Polymerase | (2.7.7.7) | 435/194 |
| (4) Polynucleotide Kinase | (2.7.1.78) | 435/194 |
| (5) RNA dependent DNA Polymerase (reverse transcriptase) | (2.7.7.-) | 435/194 |
| (6) Alkaline Phosphatase | (3.1.3.1) | 435/196 |

source material for producing protein useful in making an edible. (1) Yeast with a claimed or solely disclosed utility as a foodstuff in the form it is produced by 435 process is classifiable in 426. (2) Yeast claimed or disclosed as a component of an edible is classifiable in 426 if the claim or disclosure is that the yeast is a food supplement and is not medicative (i.e. used to alleviate a disease) in which case placement in 424 is proper. (3) Refined or crude yeast protein is not classifiable in 426 solely on the basis of a 426 utility. Refined yeast protein is classifiable in Class 260. The disposition of crude yeast is usually on the basis of utility.

*Note:* A genetically engineered microorganism, other than yeast, grown as a source of protein would be classified in a similar manner.

*Search Class:*

436, Chemistry: Analytical and immunological Testing provides for methods of chemical measuring and testing and the compositions therefor and nonenzymatic methods of testing utilizing immunological and protein binding interactions and the compositions therefor. Specifically Class 436, subclass 94 would provide for chemical tests for nucleic acids, subclass 501 would provide for binding assays other than antigen antibody assays and subclasses 506-508 provide for antigen antibody assays.

536, Organic Compounds provides for saccharides or polysaccharides per se including RNA and DNA compounds per se as well as methods of chemically synthesizing such compounds. Specifically subclass 27 would provide for RNA compounds and DNA compounds such as polyadenylic acid and claims to the chemical synthesis of such compounds and methods directed at their purification. Organized forms of DNA and RNA such as genes chromosomes, operons; ribosomal, transfer and messenger RNAs are provided for as subcellular parts of microorganisms in Class 435.

reaction of regulating or controlling a chemical reaction. See Class 435, subclasses 287, 289 and 291 for a summary or apparatus classes related to microbiology.

424, Drug, Bio-Affecting and Body Treating Compositions provides for a process of treating the living body with a microorganism and compositions therefore which may contain a live microorganism. Class 424 provides for in vivo antigen-antibody diagnostic tests for antigen antibody compositions. Class 424 provides for the products of microorganisms which are drug or bio-affecting compositions under I.A. and C. of the Class 424 definition and methods of purification of such products. See especially subclasses 85+ for an antibody or interferon composition; subclasses 88+ for an antigen composition; subclasses 86 and 87 for a method of inducing immunity by using virus or bacteria; subclass 93 for a composition including whole live microorganism or virus; Class 424 also provides for treatment of plants by mere application of a 424 composition, Class 424 provides for a process of gene therapy of an animal or plant.

426, Food or Edible Material: Processes, Compositions and Products provides for processes using a microorganism that are solely disclosed or claimed in preparing an edible, and for compositions containing microorganisms 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 7+ and 70+ for alcoholic beverages, or other beverages, milk or other alimentary articles, or compositions, when the beverage or other alimentary articles contains bacteria and processes of making the same which include microorganisms. Processes of autolysis or microbial or enzymatic destruction of yeasts or other living organisms are in Class 435, subclasses 267 or 270, but processes of preparing foods including such autolysis are in Class 426. Processes of making vinegar by methods

ing and Gas Vapor Contact With Solids would indicated. Class 159 will take concentration to the point of crystalization or to dryness, however removal of water of crystalization is considered to be a chemical reaction and placement would not be proper in 159.

162, Paper Making and Fiber Liberation provides for processes and apparatus which use a microorganism when combined with a step peculiar to Class 162 as well as the use of a microorganism as a component of fiber pulp. For an exhaustive listing of fiber treatment classes see the notes immediately following the class definition of Class 162.

166, Wells provides for processes and apparatus for treating oil or an oil bearing mineral with a microorganism or enzyme while in the ground. See Class 435, subclass 281 for a summary of mineral oil treating classes.

204, Chemistry, Electrical or Wave Energy, provides for processes and apparatus involving electrical or wave energy. Class 204 provides for processes and apparatus for measuring and testing by electrolytic action and electrophoretic, electrolytic or electroosmotic separation techniques.

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 the apparatus of such processes, as well as methods of physical separation of microorganism and viruses from liquid media.

Liquid Purification or Separation, includes processes for the separation or purification of a constituent from a flowable liquid mixture by dialysis, sorption, ion exchange, chromatography, liquid extraction, gravitational separation, or filtration, as well as purification of a liquid mixture by destruction or conversion of a constituent by a mi-

and nucleic acid manipulation that results in the production of a whole plant. Class 435 also provides for apparatus used in these processes. See section II, D, for the disposition of plants per se.

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.

71, Chemistry, Fertilizers provides for processes of plant stimulating or eradicating by use of a microorganism as well as the composition containing a microorganism and the apparatus used to carry out the process. Class 71 also provides for process of treating plants with specific chemicals for the purpose of affecting the growth characteristic of the plants other than on the genetic level.

75, Metallurgy provides for processes and compositions containing a microorganism for use in processes of obtaining free metals from metal compounds or ores. Class 75 in particular provides for processes of hydrometalurgy, processes of beneficiating ores, or recovery of elemental metal from waste in which a microorganism is used when the reduction to elemental metal is claimed.

106, Compositions, Coating or Plastic provides for processes in which a microorganism is used to produce a coating or plastic composition.

119, Animal Husbandry provides for inventions applicable to the propagation and care of living animals. Class 119 does not provide for progagation of protozoa but provides for propagation of insects, fish, birds and mammals and other methods of treating fish eggs to change the traits exhibited by mature fish, such as, by heat treating fish eggs to produce sterile fish.

89 HYBRID OR FUSED CELL TECHNOLOGY, E.G., HYBRIDOMA, ETC.
90 . Method of selection of the desired cell
91 . . Of plant cells, e.g., protoplasts, etc.
92 . . Using positive selection technique
93 . Method of production of hybrid or fused cells, e.g., chromosome or genome transfer techniques, etc.
94 . . Of plant cells
95 . Fused or hybrid cell per se
96 . . Interspecies fusion
97 . . Fungi, e.g., yeasts, etc.
98 . . Plant cells
99 . . Human cell
100 . . . B lymphocyte
101 . . . T lymphocyte
102 . . Animal cell
103 . . . Murine cell, e.g., mouse cell, etc.
104 . . . . B lymphocyte
105 . . . . T lymphocyte
106 . Method of use of the fused or hybrid cell or the product thereof
107 . . In vivo use of product
108 . . In vitro, e.g., cell cultivation techniques, affinity chromatography, etc.
109 . . . Production of non-antibody product
110 . . . For use as testing material
111 MISCELLANEOUS

## App.3.02 Patent Classification Definitions

### I. Statement of Class Subject Matter

*Note:* This class consists solely of Cross-Reference art collections of U.S. and Foreign Patents claiming or disclosing the below defined subject matter. For the original placement of the patents of this class see section 11 below.

This class provides a field of search for the following subject matter:

A. Methods of producing a change in the genetic contents or structure or gene expression of a cell by: (1) The intro-

16 . Methods of producing DNA or RNA other than by expression vectors, e.g., culture of cells high in DNA, etc.
17 . . Cell free production
18 . . . cDNA synthesis
19 . Isolation or purification of DNA or RNA
20 . . RNA
21 . . . mRNA
22 VECTORS AND METHODS OF MODIFYING VECTORS
23 . Inserting a gene into a vector to form a recombinant vector, i.e., cleavage and ligation
24 . . Vector utilized, e.g., episomes, etc.
25 . . . Plant virus
26 . . . Cosmid
27 . . . Plasmid
28 . . . . Yeast
29 . . . . Prokaryotic
30 . . . . Plant
31 . . . Bacteriophage
32 . . . Animal virus, e.g., SV40, etc.
33 METHODS OF ENHANCING OR DIMINISHING EXPRESSION
34 . Eukaryotic cell
35 . . Plant cell
36 . . Transcription
37 . . Yeast cell
38 . Prokaryotic cell
39 . . Transcription
40 . . . Operon selection
41 . . . . Promoter, e.g., portable promoters, etc.
42 . . Gene dosage modification, e.g., copy number amplification, etc.
43 . . . Inducible, e.g., temperature inducible, etc.
44 . . Translation
45 . . . Ribosome binding site
46 . . . Initiation
47 . Fused protein or peptide
48 . . Signal peptide, e.g., secretion, etc.
49 . Post translational modification
50 . . Glycosylation
51 . . Peptide bond cleavage
52 METHODS OF INTRODUCING A GENE INTO A HOST CELL, E.G., TRANSFORMATION OR TRANSFECTION, ETC.

Borstel). A preliminary list of fourteen collections with whom EPO hoped to conclude agreements appeared in OJ 1/78 at 34.

Source is Industrial Property, 16 (January 1984); Id., 240 (July/August 1984)(CNCM); Id., 271 (September, 1984)(NCACC).

grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, the availability of the micro-organism referred to in paragraph 3 of that Rule is effected only by the issue of a sample to an expert nominated by the person wishing to have access to the micro-organism (requester), he must duly inform the International Bureau of WIPO before completion of the technical preparations for publication of the international application (see Rule 28, paragraph 4, in conjunction with Article 158, paragraph 1, EPC).

### E. Translation, Pursuant to Articles 22 or 39 PCT, of the Indications Relating to a Deposited Microorganism

Pursuant to Articles 22 or 39 PCT, in conjunction with Article 158, paragraph 2, EPC, where the international application is not published by WIPO in one of the official languages of the EPO, the applicant must supply a translation in one of these languages to the EPO within the time limit referred to in Articles 22 and 39 (see information for PCT applicants, published in OJ 3/1979, p. 110 et seq., point 2, and OJ 11-12/1979, p. 479 et seq., point B.2).

In accordance with Rules 49.3 and 76.3 PCT, as amended with effect from 1 October 1980 (see OJ 9/1980, pp. 328 and 329), any indication relating to a reference to a deposited microorganism and furnished under Rule 13bis. 4 PCT, i.e. after the international application is filed, is considered part of the international application for the purpose of the translation to be filed with the designated or elected Offices.

Where applicable, the translation should also include the information referred to in point D above regarding the expert solution.

Source: OJ 2/81 at 49-51.

## [8] Names and Addresses of Collections Recognized by the European Patent Office and/or Recognized as International Depository Authorities Under the Budapest Treaty

1. American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852, U.S.A.

2a. Centraal Bureau voor Schimmelcultures (CBS), P.O. Box 273, Oosterstraat 1, Baarn, The Netherlands.

2b. CBS Yeast Division, Julianalaan 67 A, Delft, The Netherlands.

## B. Notification Made by the European Patent Office Pursuant to Rule 13bis. 7(a) PCT

Pursuant to the new Rule 13bis and, in particular, Rule 13bis. 3(a) (iv) PCT, a reference to a deposited micro-organism in an international application must, in addition to the particulars referred to in Rule 13bis. 3(a) (i), (ii) and (iii), indicate any additional matter, required by the national (or regional) law, of which the International Bureau of WIPO has been notified pursuant to Rule 13bis. 7(a) (i) PCT.

Furthermore, under Rule 13bis. 7(a) (ii) PCT, any national or regional Office may notify the International Bureau of any requirement of its law that one or more of the indications referred to in Rule 13bis. 3(a) are required to be included in an international application as filed or are required to be furnished at a time specified in the notification which is earlier than 16 months after the filing date or, the priority date, this 16-month period being, in the absence of such notification, the period allowed for the indication to be considered to have been furnished in time (cf. Rule 13bis. 4 PCT).

Lastly, under Rule 13bis. 4 PCT, second sentence, and, without prejudice to the foregoing, in the event that the applicant makes a request for early publication of the international application under Article 21(2) (b) PCT, any designated Office may consider any indication referred to in Rule 13bis. 3(a) which is not furnished by the time such request is made as not having been furnished in time.

Consequently, the President of the EPO, having regard to Rule 28 EPC, has sent a notification to the following effect to the Director General of WIPO, pursuant to Rule 13bis. 7(a) PCT:

1. By way of additional matter pursuant to Rule 13bis. 3(a) (iv), the application must give such relevant information as is available to the applicant on the characteristics of the micro-organism (Rule 28, paragraph 1(b), EPC).
2. Such information on the characteristics of the micro-organism must be included in the application as filed (Rule 28, paragraph 1(b), EPC).
3. In the event that the applicant makes a request for early publication of the international application under Article 21(2) (b) (PCT), the information relating to the deposited micro-organism referred to in Rule 13bis. 3(a)(i) to 13bis. 3(a)(iii) PCT must be given up to the date of submission of the request for early publication (Rule 28, paragraph 2(b), and Article 158, paragraph 1, EPC).

(6) For the purposes of paragraph 3, a derived culture is deemed to be any culture of the microorganism which still exhibits those characteristics of the deposited culture which are essential to carrying out the invention. The undertaking referred to in paragraph 3 shall not impede a deposit of a derived culture, necessary for the purpose of patent procedure.

(7) The request provided for in paragraph 3 shall be submitted to the European Patent Office on a form recognized by that Office. The European Patent Office shall certify on the form that a European patent application referring to the deposit of the microorganism has been filed, and that the requester or the expert nominated by him is entitled to the issue of a sample of the microorganism.

(8) The European Patent Office shall transmit a copy of the request, with the certification provided for in paragraph 7, to the depositary institution as well as to the applicant for or the proprietor of the patent.

(9) The President of the European Patent Office shall publish in the Official Journal of the European Patent Office the list of depositary institutions and experts recognized for the purpose of this Rule.

Author's Note: On recognition of experts, see OJ 9/81 at 35a-78.

### [6] Rule 28a [Effective June 1, 1980]

NEW DEPOSIT OF A MICROORGANISM

(1) If a microorganism deposited in accordance with Rule 28, paragraph 1, ceases to be available from the institution with which it was deposited because:

(*a*) The microorganism is no longer viable, or
(*b*) For any other reason the depositary institution is unable to supply samples.

and if the microorganism has not been transferred to another depositary institution recognized for the purposes of Rule 28, from which it continues to be available, an interruption in availability shall be deemed not to have occurred if a new deposit of the microorganism originally deposited is made within a period of three months from the date on which the depositor was notified of the interruption by the depositary institution and if a copy of the receipt of the deposit issued by the institution is forwarded to the European Patent Office

conclude agreements with them, in particular in respect of the deposit, storage and availability of cultures.

## [5] Amended Rule 28 [Effective June 1, 1980]

### Requirements of European Patent Applications Relating to Microorganisms

(1) If an invention concerns a micro-biological process or the product thereof and involves the use of a microorganism which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in Article 83 if:

(*a*) A culture of the microorganism has been deposited with a recognized depositary institution not later than the date of filing of the application;
(*b*) The application as filed gives such relevant information as is available to the applicant on the characteristics of the microorganism;
(*c*) The depositary institution and the file number of the culture deposit are stated in the application.

(2) The information referred to in paragraph 1 (*c*) may be submitted:

(*a*) Within a period of sixteen months after the date of filing of the application or, if the priority is claimed, after the priority date;
(*b*) Up to the date of submission of a request for early publication of the application;
(*c*) Within one month after the European Patent Office has communicated to the applicant that a right to inspection of the files, pursuant to Article 128, paragraph 2, exists.

The ruling period shall be the one which is the first to expire. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited culture being made available to the public in accordance with this Rule.

(3) The deposited culture shall be available upon request to any

significant part in determining or controlling the result as is desired to achieve, the process would not be excluded. To take some examples, a method of crossing, inter-breeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable. On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth, e.g., a method of pruning a tree, would not be essentially biological since although a biological process is involved, the essence of the invention is technical; the same could apply to a method of treating a plant characterised by the application of a growth-stimulating substance or radiation. The treatment of soil by technical means to suppress or promote the growth of plants is also not excluded from patentability (see also IV, 4.3).

3.5 The exclusion referred to in the preceding paragraph does not apply to microbiological processes or the products thereof. Thus patents may be obtained not only for processes involving micro-organisms, but also for micro-organisms themselves (as well as inanimate products) when produced by a microbiological process. In the case of microbiological processes particular regard should be had to the requirement of repeatability referred to in II. 4.11.

## [4] Original Rule 28

### Requirements of European Patent Applications Relating to Microorganisms

(1) If an invention concerns a microbiological process or the product thereof and involves the use of a microorganism which is not available to the public, the European patent application and the resulting European patent shall only be regarded as disclosing the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art if:

(*a*) A culture of the microorganism has been deposited in a culture collection not later than the date of filing of the application;
(*b*) The application as filed gives such relevant information as is available to the applicant on the characteristics of the microorganism;
(*c*) The culture collection, the date when the culture was deposit-

Author's Note: For "Agreed Interpretations" of the Budapest Treaty, see *Industrial Property*, 4/81 at 122-124.

### [4] Parties to the Budapest Treaty (as of December 1985)

| | |
|---|---|
| Austria | April 26, 1984 |
| Belgium | December 15, 1983 |
| Bulgaria | August 19, 1980 |
| Denmark | April 1, 1985 |
| Finland | June 1, 1985 |
| France | August 19, 1980 |
| Germany (F.R.) | January 20, 1981 |
| Hungary | August 19, 1980 |
| Japan | August 19, 1980 |
| Lichtenstein | August 19, 1981 |
| Norway | October 1, 1985 |
| Philippines | October 21, 1981 |
| Soviet Union | April 22, 1981 |
| Spain | March 19, 1981 |
| Sweden | October 1, 1983 |
| Switzerland | August 19, 1981 |
| United Kingdom | December 29, 1980 |
| United States | August 19, 1980 |
| EUR. PAT. OFF. | November 26, 1980 |

## App.2.02 European Patent Convention Materials

### [1] EPC Article 53, Exceptions to Patentability

European patents shall not be granted in respect of:

*(a)* Inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States:

*(b)* Plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

## RULE 11
## FURNISHING OF SAMPLES

*11.1 [No change]*

*11.2 [No change]*

*11.3 [No change]*

*11.4 Common Rules*

(a) [No change]

(b) Notwithstanding paragraph (a), where the request referred to in Rule 11.1 is made by an industrial property office whose official language is Russian or Spanish, the said request may be in Russian or Spanish, respectively, and the International Bureau shall establish, promptly and free of charge, a certified translation into English or French, on the request of that office or the international depositary authority which received the said request.

(c) [No change]

(d) [No change]

(e) [No change]

(f) The container in which the sample furnished is placed shall be marked by the international depositary authority with the accession number given to the deposit and shall be accompanied by a copy of the receipt referred to in Rule 7, an indication of any properties of the microorganism which are or may be dangerous to health or the environment and, upon request, an indication of the conditions which the international depositary authority employs for the cultivation and storage of the microorganism.

(g) [No change]

(h) [No change]

*11.5 Changes in Rules 11.1 and 11.3 when Applying to International Applications*

Where an application was filed as an international application under the Patent Cooperation Treaty, the reference to the filing of the application with the industrial property office in Rules 11.1(i) and 11.3(a)(i) shall be considered a reference to the designation, in the international application, of the Contracting State for which the industrial property office is the "designated Office" within the meaning of that Treaty, and the certification of publication which is required by Rule 11.3(a)(ii) shall, at the option of the industrial property office, be either a certification of international publication

(iii) the date of the original deposit as defined in Rule 6.4(c);
(iv) [No change]
(v) [No change]
(vi) [No change]

### *7.4 Contents in the Case of the New Deposit*

Any receipt referred to in Rule 7.1 and issued in the case of a new deposit effected under Article 4 shall be accompanied by a copy of the receipt of the previous deposit (within the meaning of Rule 6.2(c)) and a copy of the most recent statement concerning the viability of the microorganism which was the subject of the previous deposit (within the meaning of Rule 6.2(c)) indicating that the microorganism is viable, and shall at least contain:

(i) the name and address of the international depositary authority;
(ii) the name and address of the depositor;
(iii) the date of the new deposit as defined in Rule 6.4(c);
(iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
(v) the accession number given by the international depositary authority to the new deposit;
(vi) an indication of the relevant reason and the relevant date as stated by the depositor in accordance with Rule 6.2(a)(ii);
(vii) where Rule 6.2(a)(iii) applies, a reference to the fact that a scientific description and/or a proposed taxonomic designation has/have been indicated by the depositor;
(viii) the accession number given to the previous deposit (within the meaning of Rule 6.2(c)).

### *7.5 Receipt in the Case of Transfer*

The international depositary authority to which samples of microorganisms are transferred under Rule 5.1(a)(i) shall issue to the depositor, in respect of each deposit in relation with which a sample is transferred, a receipt indicating that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and containing at least:

(i) the name and address of the international depositary authority;
(ii) the name and address of the depositor;
(iii) the date on which the transferred sample was received by the international depositary authority (date of the transfer);
(iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;

is viable and a written statement bearing the signature of the depositor and containing:

(i) the indications referred to in Rule 6.1(a)(i) to (v);

(ii) a declaration stating the reason relevant under Article 4(1)(a) for making the new deposit, a statement alleging that the microorganism which is the subject of the new deposit is the same as that which was the subject of the previous deposit, and an indication of the date on which the depositor received the notification referred to in Article 4(1)(a) or, as the case may be, the date of the publication referred to in Article 4(1)(e);

(iii) where a scientific description and/or proposed taxonomic designation was/were indicated in connection with the previous deposit, the most recent scientific description and/or proposed taxonomic designation as communicated to the international depositary authority with which the previous deposit was made.

(b) Where the new deposit is made with the international depositary authority with which the previous deposit was made, paragraph (a)(i) shall not apply.

(c) For the purposes of paragraphs (a) and (b) and of Rule 7.4, "previous deposit" means,

(i) where the new deposit has been preceded by one or more other new deposits: the most recent of those other new deposits;

(ii) where the new deposit has not been preceded by one or more other new deposits: the original deposit.

### *6.3 Requirements of the International Depositary Authority*

(a) Any international depositary authority may require:

(i) that the microorganism be deposited in the form and quantity necessary for the purposes of the Treaty and these Regulations;

(ii) that a form established by such authority and duly completed by the depositor for the purposes of the administrative procedures of such authority be furnished;

(iii) that the written statement referred to in Rule 6.1(a) or 6.2(a) be drafted in the language, or in any of the languages, specified by such authority it being understood that such specification must at least include the official language or languages indicated under Rule 3.1(b)(v);

(iv) that the fee for storage referred to in Rule 12.1(a)(i) be paid; and

(v) that, to the extent permitted by the applicable law, the depositor enter into a contract with such authority defining the liabilities of the depositor and the said authority.

### RULE 14
### EXPENSES OF DELEGATIONS

*14.1 Coverage of Expenses*

The expenses of each delegation participating in any session of the Assembly and in any committee, working group or other meeting dealing with matters of concern to the Union shall be borne by the State or organization which has appointed it.

### RULE 15
### ABSENCE OF QUORUM IN THE ASSEMBLY

*15.1 Voting by Correspondence*

*(a)* In the case provided for in Article 10(5)*(b)*, the Director General shall communicate any decision of the Assembly (other than decisions relating to the Assembly's own procedure) to the Contracting States which were not represented when the decision was made and shall invite them to express in writing their vote or abstention within a period of three months from the date of the communication.

*(b)* If, at the expiration of the said period, the number of Contracting States having thus expressed their vote of abstention attains the number of Contracting States which was lacking for attaining the quorum when the decision was made, that decision shall take effect provided that at the same time the required majority still obtains.

## [3] Amendments to the Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*

### RULE 5
### DEFAULTS BY THE INTERNATIONAL DEPOSITARY AUTHORITY

*5.1 Discontinuance of Performance of Functions in Respect of Deposited Microorganisms*

* Adopted by the Assembly of the Budapest Union on January 20, 1981, entry into force, January 31, 1981. Source: Annex II of WIPO document BP/A/II/11, reprinted in *Industrial Property* (Supp. II to No. 1, Jan. 1981). Effective Jan. 31, 1981.

or requests bearing the signature of the requesting party in accordance with Rule 11.3.

*(h)* The furnishing of samples referred to in Rule 11.1 shall be free of charge. Where the furnishing of samples is made under Rule 11.2 or 11.3, any fee payable under Rule 12.1*(a)*(iv) shall be chargeable to the depositor, to the authorized party, to the certified party or to the requesting party, as the case may be, and shall be paid before or at the time of making the said request.

## RULE 12
## FEES

### *12.1 Kinds and Amounts*

*(a)* Any international depositary authority may, with respect to the procedure under the Treaty and these Regulations, charge a fee:

(i) for storage;

(ii) for the attestation referred to in Rule 8.2;

(iii) subject to Rule 10.2*(e)*, first sentence, for the issuance of viability statements;

(iv) subject to Rule 11.4*(h)*, first sentence, for the furnishing of samples.

*(b)* The fee for storage shall be for the whole duration of the storage of the microorganism as provided in Rule 9.1.

*(c)* The amount of any fee shall not vary on account of the nationality or residence of the depositor or on account of the nationality or residence of the authority, natural person or legal entity requesting the issuance of a viability statement or furnishing of samples.

### *12.2 Change in the Amounts*

*(a)* Any change in the amount of the fees charged by any international depositary authority shall be notified to the Director General by the Contracting State or intergovernmental industrial property organization which made the declaration referred to in Article 7(1) in respect of that authority. The notification may, subject to paragraph *(c)*, contain an indication of the date from which the new fees will apply.

*(b)* The Director General shall promptly notify all Contracting States and intergovernmental industrial property organizations of any notification received under paragraph *(a)* and of its effective date under paragraph *(c)*; the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

the subject matter of that application involves the said microorganism or the use thereof;

(ii) that, except where the second phrase of (iii) applies, publication for the purposes of patent procedure has been effected by that office;

(iii) *either* that the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled *or* that the certified party has affixed his signature on a form before that office and that, as a consequence of the signature of the said form, the conditions for furnishing a sample to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before that office; where the certified party has the said right under the said law prior to publication for the purposes of patent procedure by the said office and such publication has not yet been effected, the certification shall expressly state so and shall indicate, by citing it in the customary manner, the applicable provision of the said law, including any court decision.

*(b)* In respect of patents granted and published by any industrial property office, such office may from time to time communicate to any international depositary authority lists of the accession numbers given by that authority to the deposits of the microorganisms referred to in the said patents. The international depositary authority shall, on the request of any authority, natural person or legal entity (hereinafter referred to as "the requesting party"), furnish to it a sample of any microorganism where the accession number has been so communicated. In respect of deposited microorganisms whose accession numbers have been so communicated, the said office shall not be required to provide the certification referred to in Rule 11.3 *(a)*.

### *11.4 Common Rules*

*(a)* Any request, declaration, certification or communication referred to in Rules 11.1, 11.2 and 11.3 shall be

(i) in English, French, Russian or Spanish where is it addressed to an international depositary authority whose official language is or whose official languages include English, French, Russian or Spanish, respectively, provided that, where it must be in Russian or Spanish, it may be instead filed in English or French and, if it is so filed, the International Bureau shall, on the request of the interested party referred to in the said Rules or the international depository authori-

(i) promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;

(ii) at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary for technical reasons;

(iii) at any time, on the request of the depositor.

### *10.2 Viability Statement*

(a) The international depositary authority shall issue a statement concerning the viability of the deposited microorganism:

(i) to the depositor, promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;

(ii) to the depositor, on his request, at any time after the deposit or transfer;

(iii) to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were furnished in conformity with Rule 11, on his or its request, together with or at any time after such furnishing of samples.

*(b)* The viability statement shall indicate whether the microorganism is or is no longer viable and shall contain.

(i) the name and address of the international depositary authority issuing it;

(ii) the name and address of the depositor;

(iii) the date of the deposit of the microorganism and of the transfer, if any;

(iv) the accession number given by the said authority;

(v) the date of the test to which it refers;

(vi) information dn the conditions under which the viability test has been performed, provided that the said information has been requested by the party to which the viability statement is issued and that the results of the test were negative.

*(c)* In the cases of paragraph *(a)*(ii) and (iii), the viability statement shall refer to the most recent viability test.

*(d)* As to form, languages and signature, Rule 7.2 shall apply, ***mutatis mutandis,*** to the viability statement.

*(e)* In the case of paragraph *(a)*(i) or where the request is made by an industrial property office, the issuance of the viability statement shall be free of charge. Any fee payable under Rule 12.1*(a)*(iii) in respect of any other viability statement shall be chargeable to the party requesting the statement and shall be paid before or at the time of making the request.

relevant date as stated by the depositor in accordance with Rule 6.2 *(a)*(ii);

(iii) where Rule 6.2*(a)*(iii) applies, a reference to the fact that a scientific description and/or a proposed taxonomic designation has/have been indicated by the depositor;

(iv) the accession number given to the original deposit.

### *7.5 Receipt in the Case of Transfer*

The international depositary authority to which samples of microorganisms are transferred under Rule 5.1*(a)*(1) shall issue to the depositor, in respect of each deposit in relation with which a sample is transferred, a receipt indicating that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and containing at least:

(i) the indications referred to in Rule 7.3(i) to (v);

(ii) the name and address of the international depositary authority from which the transfer was effected;

(iii) the accession number given by the international depositary authority from which the transfer was effected.

### *7.6 Communication of the Scientific Description and/or Proposed Taxonomic Designation*

On request of any party entitled to receive a sample of the deposited microorganism under Rules 11.1; 11.2 or 11.3, the international depositary authority shall communicate to such party the scientific description and/or proposed taxonomic designation referred to in Rules 7.3(vi) or 7.4(iii).

## RULE 8
## LATER INDICATION OR AMENDMENT OF THE SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

### *8.1 Communication*

*(a)* Where, in connection with the deposit of a microorganism, the scientific description and/or taxonomic designation of the microorganism was/were not indicated, the depositor may later indicate or, where already indicated, may amend such description and/or designation.

*(b)* Any such later indication or amendment shall be made in a written communication, bearing the signature of the depositor, addressed to the international depositary authority and containing:

### *6.2 New Deposit*

*(a)* Subject to paragraph *(b)*, in the case of a new deposit made under Article 4, the microorganism transmitted by the depositor to the international depositary authority shall be accompanied by a copy of the receipt of the original deposit, a copy of the most recent statement concerning the viability of the microorganism originally deposited indicating that the microorganism is viable and a written statement bearing the signature of the depositor and containing:

(i) the indications referred to in Rule 6.1*(a)*(i) to (v);

(ii) a declaration stating the reason relevant under Article 4(1)*(a)* for making the new deposit, the statement required under Article 4(1)*(c)*, and, where applicable, an indication of the date relevant under Article 4(1)*(e)*;

(iii) where a scientific description and/or proposed taxonomic designation was/were indicated in connection with the original deposit, the most recent scientifc description and/or proposed taxonomic designation as existing on the date relevant under Article 4(1)*(e)*.

*(b)* Where the new deposit is made with the international depositary authority with which the original deposit was made, paragraph *(a)*(i) shall not apply.

### *6.3 Requirements of the International Depositary Authority*

*(a)* Any international depositary authority may require that the microorganism be deposited in the form and quantity necessary for the purposes of the Treaty and these Regulations and be accompanied by a form established by such authority and duly completed by the depositor for the purpose of the administrative procedures of such authority.

*(b)* Any international depositary authority shall communicate any such requirements and any amendments thereof to the International Bureau.

## RULE 7
## RECEIPT

### *7.1 Issuance of Receipt*

The international depositary authority shall issue to the depositor, in respect of each deposit of microorganism effected with it or trans-

(i) ensure, to the fullest extent possible, that samples of all such microorganisms are transferred promptly and without deterioration or contamination from the said authority ("the defaulting authority") to another international depository authority ("the substitute authority");

(ii) ensure, to the fullest extent possible, that all mail or other communications addressed to the defaulting authority, and all files and other relevant information in the possession of that authority, in respect of the said microorganisms are promptly transferred to the substitute authority;

(iii) ensure, to the fullest extent possible, that the defaulting authority promptly notifies all depositors affected of the discontinuance of the performance of its functions and the transfers effected;

(iv) promptly notify the Director General of the fact and the extent of the discontinuance in question and of the measures which have been taken by the said Contracting State or intergovernmental industrial property organization under (i) to (iii).

*(b)* The Director General shall promptly notify the Contracting States and the intergovernmental industrial property organizations as well as the industrial property offices of the notification received under paragraph *(a)*(iv); the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

*(c)* Under the applicable patent procedure it may be required that the depositor shall, promptly after receiving the receipt referred to in Rule 7.5, notify to any industrial property office with which a patent application was filed with reference to the original deposit the new accession number given to the deposit by the substitute authority.

*(d)* The substitute authority shall retain in an appropriate form the accession number given by the defaulting authority, together with the new accession number.

*(e)* In addition to any transfer effected under paragraph *(a)*(i), the defaulting authority shall, upon request by the depositor, transfer a sample of any microorganism deposited with it to any international depositary authority indicated by the depositor other than the substitute authority, provided that the depositor pays any expenses to the defaulting authority resulting from the transfer of that sample. The depositor shall pay the fee for the storage of the said sample to the international depositary authority indicated by him.

*(f)* On the request of any depositor affected, the defaulting authority shall retain, as far as possible, samples of the microorganisms deposited with it.

### *3.3 Extension of the List of Kinds of Microorganisms Accepted*

The Contracting State or intergovernmental industrial property organization having made the communication referred to in Article 7(1) may, at any time thereafter, notify the Director General that its assurances are extended to specified kinds of microorganisms to which, so far, the assurances have not extended. In such a case, and as far as the additional kinds of microoganisms are concerned, Article 7 and Rules 3.1 and 3.2 shall apply, *mutatis mutandis.*

## RULE 4
## TERMINATION OR LIMITATION OF THE STATUS OF INTERNATIONAL DEPOSITARY AUTHORITY

### *4.1 Request; Processing of Request*

*(a)* The request referred to in Article 8(1)*(a)* shall be addressed to the Director General as provided in Rule 3.1*(a)*.

*(b)* The request shall:

(i) indicate the name and address of the international depositary authority concerned;

(ii) where it relates only to certain kinds of microorganisms, specify such kinds;

(iii) indicate in detail the facts on which it is based.

*(c)* If the request complies with paragraphs *(a)* and *(b)*, it shall be promptly notified by the Director General to all Contracting States and intergovernmental industrial property organizations.

*(d)* Subject to paragraph *(e)*, the Assembly shall consider the request not earlier than six and not later than eight months from the notification of the request.

*(e)* Where, in the opinion of the Director General, respect of the time limit provided for in paragraph *(d)* could endanger the interests of actual or potential depositors, he may convene the Assembly for a date earlier than the date of the expiration of the six-month period provided for in paragraph *(d)*.

*(f)* If the Assembly decides to terminate, or to limit to certain kinds of microorganisms, the status of international depositary authority, the said decision shall become effective three months after the date on which it was made.

## [2] Regulations under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure

### RULE 1
### ABBREVIATED EXPRESSIONS AND INTERPRETATION OF THE WORD "SIGNATURE"

*1.1 "Treaty"*

In these Regulations, the word "Treaty" means the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

*1.2 "Article"*

In these Regulations, the word "Article" refers to the specified Article of the Treaty.

*1.3 "Signature"*

In these Regulations, whenever the word "signature" is used, it shall be understood that, where the law of the State on the territory of which an international depositary authority is located requires the use of a seal instead of a signature, the said word shall mean "seal" for the purposes of that authority.

### RULE 2
### INTERNATIONAL DEPOSITARY AUTHORITIES

*2.1 Legal Status*

Any international depositary authority may be a government agency, including any public institution attached to a public administration other than the central government, or a private entity.

*2.2 Staff and Facilities*

The requirements referred to in Article 6(2)(ii) shall include in particular the following:

(i) the staff and facilities of any international depositary authority must enable the said authority to store the deposited microorganisms in a manner which ensures that they are kept viable and uncontaminated;

(ii) any international depositary authority must, for the storage of

## ARTICLE 17
## DENUNCIATION OF THE TREATY

(1) Any Contracting State may denounce this Treaty by notification addressed to the Director General.

(2) Denunciation shall take effect two years after the day on which the Director General has received the notification.

(3) The right of denunciation provided for in paragraph (1) shall not be exercised by any Contracting State before the expiration of five years from the date on which it becomes party to this Treaty.

(4) The denunciation of this Treaty by a Contracting State that has made a declaration referred to in Article 7(1)*(a)* with respect to a depositary institution which thus acquired the status of international depositary authority shall entail the termination of such status one year after the day on which the Director General received the notification referred to in paragraph (1).

## ARTICLE 18
## SIGNATURE AND LANGUAGES OF THE TREATY

(1)*(a)* This Treaty shall be signed in a single original in the English and French languages, both texts being equally authentic.

*(b)* Official texts of this Treaty shall be established by the Director General, after consultation with the interested Governments and within two months from the date of signature of this Treaty, in the other languages in which the Convention Establishing the World Intellectual Property Organization was signed.

*(c)* Official texts of this Treaty shall be established by the Director General, after consultation with the interested Governments, in the Arabic, German, Italian, Japanese and Portuguese languages, and such other languages as the Assembly may designate.

(2) This Treaty shall remain open for signature at Budapest until December 31, 1977.

## ARTICLE 19
## DEPOSIT OF THE TREATY; TRANSMITTAL OF COPIES; REGISTRATION OF THE TREATY

(1) The original of this Treaty, when no longer open for signature, shall be deposited with the Director General.

(2) The Director General shall transmit two copies, certified by him, of this Treaty and the Regulations to the Governments of all the States referred to in Article 15(1), to the intergovernmental orga-

(2) The Regulations adopted at the same time as this Treaty are annexed to this Treaty.

(3) The Assembly may amend the Regulations.

(4)*(a)* Subject to subparagraph *(b)*, adoption of any amendment of the Regulations shall require two-thirds of the votes cast.

*(b)* Adoption of any amendment concerning the furnishing of samples of deposited microorganisms by the international depositary authorities shall require that no Contracting State vote against the proposed amendment.

(5) In the case of conflict between the provisions of this Treaty and those of the Regulations, the provisions of this Treaty shall prevail.

## Chapter III

## Revision and Amendment

### ARTICLE 13
### REVISION OF THE TREATY

(1) This Treaty may be revised from time to time by conferences of the Contracting States.

(2) The convocation of any revision conference shall be decided by the Assembly.

(3) Articles 10 and 11 may be amended either by a revision conference or according to Article 14.

### ARTICLE 14
### AMENDMENT OF CERTAIN PROVISIONS OF THE TREATY

(1)*(a)* Proposals under this Article for the amendment of Articles 10 and 11 may be initiated by any Contracting State or by the Director General.

*(b)* Such proposals shall be communicated by the Director General to the Contracting States at least six months in advance of their consideration by the Assembly.

(2)*(a)* Amendments to the Articles referred to in paragraph (1) shall be adopted by the Assembly.

*(b)* Adoption of any amendment to Article 10 shall require four-fifths of the votes cast; adoption of any amendment to Article 11 shall require three-fourths of the votes cast.

(3)*(a)* Any amendment to the Articles referred to in paragraph (1) shall enter into force one month after written notifications of acceptance, effected in accordance with their respective constitutional pro-

(iv) review and approve the reports and activities of the Director General concerning the Union, and give him all necessary instructions concerning matters within the competence of the Union;

(v) establish such committees and working groups as it deems appropriate to facilitate the work of the Union;

(vi) determine, subject to paragraph (1)*(d)*, which States other than Contracting States, which intergovernmental organizations other than intergovernmental industrial property organizations as defined in Article 2(v) and which international non-governmental organizations shall be admitted to its meetings as observers and to what extent international depositary authorities shall be admitted to its meetings as observers;

(vii) take any other appropriate action designed to further the objectives of the Union;

(viii) perform such other functions as are appropriate under this Treaty.

*(b)* With respect to matters which are of interest also to other Unions administered by the Organization, the Assembly shall make its decisions after having heard the advice of the Coordination Committee of the Organization.

(3) A delegate may represent, and vote in the name of, one State only.

(4) Each Contracting State shall have one vote.

(5)*(a)* One-half of the Contracting States shall constitute a quorum.

*(b)* In the absence of the quorum, the Assembly may make decisions but, with the exception of decisions concerning its own procedure, all such decisions shall take effect only if the quorum and the required majority are attained through voting by correspondence as provided in the Regulations.

(6)*(a)* Subject to Articles 8(1)*(c)*, 12(4) and 14(2)*(b)*, the decisions of the Assembly shall require a majority of the votes cast.

*(b)* Abstentions shall not be considered as votes.

(7)*(a)* The Assembly shall meet once in every third calendar year in ordinary session upon convocation by the Director General, preferably during the same period and at the same place as the General Assembly of the Organization.

*(b)* The Assembly shall meet in extraordinary session upon convocation by the Director General, either on his own initiative or at the request of one-fourth of the Contracting States.

(8) The Assembly shall adopt its own rules of procedure.

## ARTICLE 9
## INTERGOVERNMENTAL INDUSTRIAL PROPERTY ORGANIZATIONS

(1)*(a)* Any intergovernmental organization to which several States have entrusted the task of granting regional patents and of which all the member States are members of the International (Paris) Union for the Protection of Industrial Property may file with the Director General a declaration that it accepts the obligation of recognition provided for in Article 3(1)*(a)*, the obligation concerning the requirements referred to in Article 3(2) and all the effects of the provisions of this Treaty and the Regulations applicable to intergovernmental industrial property organizations. If filed before the entry into force of this Treaty according to Article 16(1), the declaration referred to in the preceding sentence shall become effective on the date of the said entry into force. If filed after such entry into force, the said declaration shall become effective three months after its filing unless a later date has been indicated in the declaration. In the latter case, the declaration shall take effect on the date thus indicated.

*(b)* The said organization shall have the right provided for in Article 3(1)*(b)*

(2) Where any provision of this Treaty or of the Regulations affecting intergovernmental industrial property organizations is revised or amended, any intergovernmental industrial property organization may withdraw its declaration referred to in paragraph (1) by notification addressed to the Director General. The withdrawal shall take effect:

(i) where the notification has been received before the date on which the revision or amendment enters into force, on that date;

(ii) where the notification has been received after the date referred to in (i), on the date indicated in the notification or, in the absence of such indication, three months after the date on which the notification was received.

(3) In addition to the case referred to in paragraph (2), any intergovernmental industrial property organization may withdraw its declaration referred to in paragraph (1)*(a)* by notification addressed to the Director General. The withdrawal shall take effect two years after the date on which the Director General has received the notification. No notification of withdrawal under this paragraph shall be receivable during a period of five years from the date on which the declaration took effect.

(4) The withdrawal referred to in paragraph (2) or (3) by an intergovernmental industrial property organization whose communica-

conditions and in conformity with the procedure prescribed in the Regulations.

(3) The Regulations shall provide the measure to be taken:

(i) where an international depositary authority discontinues, temporarily or definitively, the performance of its functions in respect of deposited microorganisms or refuses to accept any of the kinds of microorganisms which it should accept under the assurances furnished;

(ii) in case of the termination or limitation of the status of international depositary authority of an international depositary authority.

## ARTICLE 7
## ACQUISITION OF THE STATUS OF INTERNATIONAL DEPOSITARY AUTHORITY

(1)*(a)* A depositary institution shall acquire the status of international depositary authority by virtue of a written communication addressed to the Director General by the Contracting State on the territory of which the depositary institution is located and including a declaration of assurances to the effect that the said institution complies and will continue to comply with the requirements specified in Article 6(2). The said status may be acquired also by virtue of a written communication addressed to the Director General by an intergovernmental industrial property organization and including the said declaration.

*(b)* The communication shall also contain information on the depositary institution as provided in the Regulations and may indicate the date on which the status of international depositary authority should take effect.

(2)*(a)* If the Director General finds that the communication includes the required declaration and that all the required information has been received, the communication shall be promptly published by the International Bureau.

*(b)* The status of international depositary authority shall be acquired as from the date of publication of the communication or, where a date has been indicated under paragraph (1)*(b)* and such date is later than the date of publication of the communication, as from such date.

(3) The details of the procedure under the paragraphs (1) and (2) are provided in the Regulations.

(i) Where such microorganism is no longer viable, or
(ii) Where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions,

that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited.

*(b)* The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that:

(i) it shall be made with another international depositary authority where the institution with which the original deposit was made has ceased to have the status of international depositary authority, either entirely or in respect of the kind of microorganism to which the deposited microorganism belongs, or where the international depositary authority with which the original deposit was made discontinues, temporarily or definitively, the performance of its functions in respect of deposited microorganisms;

(ii) it may be made with another international depositary authority in the case referred to in subparagraph *(a)*(ii).

*(c)* Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited microorganism is the same as that originally deposited. If the allegation of the depositor is contested, the burden of proof shall be governed by the applicable law.

*(d)* Subject to subparagraphs *(a)* to *(c)* and *(e)*, the new deposit shall be treated as if it had been made on the date on which the original deposit was made where all the preceding statements concerning the viability of the originally deposited microorganism indicated that the microorganism was viable and where the new deposit was made within three months after the date on which the depositor received the notification referred to in subparagraph *(a)*.

*(e) Where subparagraph (b)(i)* applies and the depositor does not receive the notification referred to in subparagraph *(a)* within six months after the date on which the termination, limitation or discontinuance referred to in subparagraph *(b)(i)* was published by the International Bureau, the three-month time limit referred to in subparagraph *(d)* shall be counted from the date of the said publication.

(2) The right referred to in paragraph (1)*(a)* shall not exist where the deposited microorganism has been transferred to another inter-

## Introductory Provisions

### ARTICLE 1
### ESTABLISHMENT OF A UNION

The States party to this Treaty (hereinafter called "the Contracting States") constitute a Union for the international recognition of the deposit of microorganisms for the purposes of patent procedure.

### ARTICLE 2
### DEFINITIONS

For the purposes of this Treaty and the Regulations:

(i) References to a "patent" shall be construed as references to patents for inventions, inventors' certificates, utility certificates, utility models, patents or certificates of addition, inventors' certificates of addition, and utility certificates of addition;

(ii) "Deposit of a microorganism" means, according to the context in which these words appear, the following acts effected in accordance with this Treaty and the Regulations; the transmittal of a microorganism to an international depositary authority, which receives and accepts it, or the storage of such a microorganism by the international depositary authority, or both the said transmittal and the said storage;

(iii) "Patent procedure" means any administrative or judicial procedure relating to a patent application or a patent;

(iv) "Publication for the purposes of patent procedure" means the official publication, or the official laying open for public inspection, of a patent application or a patent;

(v) "Intergovernmental industrial property organization" means an organization that has filed a declaration under Article 9(1);

(vi) "Industrial property office" means an authority of a Contracting State or an intergovernmental industrial property organization competent for the grant of patents;

(vii) "Depositary institution" means an institution which provides for the receipt, acceptance and storage of microorganisms and the furnishing of samples thereof;

(viii) "International despositary authority" means a depositary institution which has acquired the status of international depositary authority as provided in Article 7;

(ix) "Depositor" means the natural person or legal entity transmitting a microorganism to an international depositary authority, which

such depository will be designated an international depository authority.

No depository in the United States or elsewhere has yet been nominated or designated to serve as an international depository authority. It is expected, however, that some depositories will shortly be designated both in the United States and other States adhering to the Treaty. Public notice will be provided of the designation of each international depository authority and its requirements for patent deposits.

An application for a patent in any adhering States involving the action of a microorganism, for which a deposit is required, may make the required deposit in any international depository authority. The fact and date of making the deposit will be recognized for all patent purposes in each State adhering to the Treaty. No further deposit will be required for national patent processing or enforcement, provided a deposit is properly made under the provisions of the Treaty.

An application for a United States patent will not be required to proceed under the provisions of the Budapest Treaty, however. Such an applicant may rely instead on a deposit made in any depository meeting the requirements set forth in *In re Argoudelis, et al.*, 168 U.S.P.Q. 99 (CCPA 1970) and reprinted in § 608.01(p). Manual of Patent Examining Procedure.

Questions or information regarding the Budapest Treaty may be directed to the Office of Legislation and International Affairs, at the following address: Box 4, Commissioner of Patents and Trademarks, Washington, D.C. 20231. The telephone number of the Office of Legislation and International Affairs is (703) 557-3065. July 14, 1980 [997 O.G. 10]

notes the date of receipt of the deposit and gives it an accession number (Rule 7.3(iii) and (v)). It issues a receipt to the depositor attesting the receipt and acceptance of the deposit (Rule 7). The model of the international form for the receipt, the use of which will be mandatory, will be established by the Director General of WIPO and communicated to all international depositary authorities.

7. *Viability test.* The international depositary authority promptly tests the viability of the microorganism; it also undertakes viability tests at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary for technical reasons or at the request of the depositor (Rule 10.1)

8. *Viability statement.* The international depositary authority issues a statement concerning the viability of the microorganism to the depositor or to any person receiving a sample of the microorganism (see paragraph 10 below) (Rule 10.2). The model of the international form for the viability statement, the use of which is mandatory, will be established by the Director General of WIPO and communicated to all international depositary authorities.

9. *Storage of the microorganism.* The international depositary authority stores the microorganism for a period of at least 30 years after the date of its deposit, or until five years have elapsed without its having received a request for a sample, the period expiring later being applicable (Rule 9.1). It complies with the requirement of secrecy at all times (see paragraph 5(v) above). Where it cannot furnish samples of the deposited microorganism for any reason, it notifies the depositor of the fact, indicating the reason and informing him that he is entitled to make a new deposit (Article 4).

10. *Furnishing of samples.* The Regulations contain detailed provisions specifying who is entitled to receive samples of the microorganism, and when (Rule 11). The depositor himself is entitled to receive a sample at any time. He may authorize third parties to have samples furnished to them, whereupon the third parties receive a sample on presentation of their authorizations. Any industrial property office to which the Treaty applies may receive a sample on request if it needs the microorganism for the purposes of a patent procedure. Any other person may obtain a sample on request if an industrial property office to which the Treaty applies certifies that, under the applicable law, that person has a right to a sample of the microorganism concerned; the Regulations specify in detail the certification procedure. The use of a form (whose contents will be established by the Assembly and communicated by the International Bureau to all international depositary authorities) is mandatory for the request and certification. There is an alternative procedure

a sample of the microorganism. When protection for the invention is sought in several countries, the complex and costly procedures of the deposit of the microorganism might have to be repeated in each of those countries. The objective of the Budapest Treaty is precisely to obviate such multiple deposits: under the Treaty a single deposit with one "international depositary authority" is sufficient for the purposes of patent procedure before the industrial property offices of all Contracting States, and of inter-governmental organizations granting regional patents which have declared that they recognize the effects of the Treaty (Articles 3(1)(a) and 9(1)(a)).

*General Remarks on International Depositary Authorities*

3. "International depositary authorities" are depositary institutions that have acquired the status of international depositary authorities. To obtain this status, a depositary institution has to be located on the territory of a Contracting State or of a member State of one of the organizations referred to in the preceding paragraph, and has to benefit from "assurances" furnished by that Contracting State or organization to the effect that the institution complies and will continue to comply with the requirements referred to in paragraph 5 below (Article 6(1)). The action for acquiring this status is taken by the State or organization concerned (Article 7 and Rule 3). There is nothing to prevent it from making more than one depositary institution acquire such status: it is therefore possible for there to be several international depositary authorities located on the territory of one and the same State.

4. An international depositary authority can lose its status either entirely (in which case "termination of status" is spoken of) or partly, in other words in respect of certain types of microorganisms only (in which case "limitation of status" is spoken of). Loss of the status occurs if the State or organization whose action brought about the acquisition of the status denounces the Treaty or withdraws the declaration of recognition of the effects of the Treaty (in which case the loss of status can only be total), or if the State or organization withdraws its assurances regarding the international depositary authority, or again by virtue of a decision of the Assembly of Contracting States taken at the request of another Contracting State or another organization (Articles 8, 9(4) and 17(4); Rule 4).

*Requirements Which Have to be Met by International Depositary Authorities*

5. The requirements referred to in paragraph 3 above which a de-

(206 U.S.P.Q. 193) 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 that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability.

Accordingly, the Patent and Trademark Office is now examining patent applications including claims to microorganisms which had been under suspension. Assuming that the products involved were the result of human intervention and were not products of nature, such claims will not be rejected under 35 U.S.C. §101 as directed to unpatentable subject matter. July 29, 1980 [997 O.G. 24]

### [2] Designation of International Depository Authorities Under the Budapest Treaty

The Budapest Treaty and the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure came into force on Aug. 19, 1980 with respect to the United States, Bulgaria, France, Hungary, and Japan. A copy of the Treaty was published in the *Official Gazette* on Aug. 23, 1977 (961 O.G. 21-26).

This Treaty authorizes each State for which the Treaty is in effect to designate a depository on its territory to serve as an international depository authority. More than one depository may be designated. Each such depository will be authorized to receive and store deposits, and dispense samples thereof, in compliance with the Treaty and the patent laws of each State adhering thereto. The Treaty is open for adherence by any member State of the Paris Union for the Protection of Industrial Property.

The Commissioner of Patents and Trademarks hereby solicits requests from private and public depositories located in the United States to serve as international depository authorities. Requests should be addressed to: Sidney A. Diamond, Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Each request must explain and, to the extent practicable, provide evidence of the depository's capacity to meet the obligations of the Treaty. Such request must also include an offer by the depository to assume the cost of transferring deposits made under the Treaty to another international depository authority in the event of default of any of its Treaty obligations. The availability of funds for such transfer, if needed, must be available through a bond, special reserve fund, escrow or other means judged suitable by the Commissioner.

Requests will be promptly evaluated by the Commissioner of Pat-

923 SLEEP AID (Insomnia)
924 TUBERCULOSIS
925 ULCER TREATMENT
926 . Duodenal
927 . Peptic
928 . Topical
929 VASODILATOR
930 VASOCONSTRICTOR (nondecongestant)
931 VENERAL DISEASE
932 . Gonorrhea
933 . Syphilis
934 . Virus
935 UTERINE MOTILITY

**ART COLLECTIONS 936-975 EXCLUDE PRE 1965 PATENTS ISSUED FROM 260 AND 530 SERIES CLASSES.**

**LIQUID CARRIER, DILUENT OR SOLVENT**

**ART COLLECTIONS 936-975 EXCLUDE PRE 1965 PATENTS ISSUED FROM CLASS 260 AND THE CLASS 532-570 SERIES AND CLASS 585**

936 DMSO CONTAINING
937 DISPERSION OR EMULSION
938 . Oil-water type
939 . . Mineral oil-water type
940 . . . Quick break type
941 . . . Polyoxyalkylated compound containing
942 . . . Organic sulfonate, sulfate or sulfite containing
943 . . . Higher fatty acid or derivative containing
944 GEL
945 FOAM
946 PENETRANT OR ABSORBENT (ENHANCES PENETRATION INTO SUBJECT TREATED)
947 . Topical application

SOLID CARRIER OR SOLID DILUENT

948 SOLID CANDY TYPE
949 NATURALLY DERIVED CLAY (*E.G.*, BENTONITE, ETC.)
950 MACROMOLECULAR (OTHER THAN SYNTHETIC RESINS)
951 POWDERS, GRANULES OR PARTICLES OF SPECIFIED MESH OR PARTICLE SIZE
952 . Wettable
953 SHAPED FORMS ADAPTED FOR NONINGESTIBLE USE

837 CHOLERA
838 CIRRHOSIS
839 CONTACT LENS TREATMENT
840 . Chemical sterilizing
841 CONTRACEPTIVE
842 . Non-mammal
843 . Female (mammal)
844 COSMETIC, FACIAL
845 . Liquid make-up
846 . Cleansing cream or lotion
847 . Facial moisturizer
848 . Facial astringent
849 COUGH AND COLD PREPARATION
850 . Antitussive
851 CYSTIC FIBROSIS
852 DANDRUFF
853 DECONGESTANT
854 . Vasoconstrictor
855 . Expectorant
DERMATITIS
858 . Athlete's foot
859 . Acne
860 . Cellulitis
861 . Eczema
862 . Poison (ivy, oak, sumac)
863 . Psoriasis
864 . Seborrhea
865 . Diaper rash
866 DIABETES
867 DIARRHEA
868 DISTEMPER
869 DIURETIC
870 EDEMA
871 . Topical
872 EMESIS (motion sickness-nausea)
873 EMOLLIENT
874 ESTROGENIC AGENT (noncontraceptive)
875 FLEA CONTROL
876 . Collar type
877 GALLSTONE
878 GERIATRICS
879 . Senility
880 HAIR TREATMENT (therapeutic-scalp)

754 . . . . Plural benzene rings
755 . . . Polycyclo ring system
756 . . . . Bicyclo
757 . . Two or more halogenated hydrocarbons
758 . . Chlorine as only halogen
759 . . Fluorine as only halogen
760 . . Bromine and chlorine as only halogens
761 . . Bromine and fluorine as only halogens
762 . Hydrocarbon DOAI
763 . . Carbocyclic
764 . . . Benzene ring containing
765 . . . . Polycyclo ring system
766 . . . Polycyclo ring system
767 . . With phosphorus containing non-DOAI
768 . . With sulfur containing non-DOAI
769 DESIGNATED INORGANIC NONACTIVE INGREDIENT OR ELEMENTAL MATERIAL OTHER THAN WATER
770 . Siliceous or calcareous material (*e.g.*, clay, earth, etc.)
771 . Oxygen gas containing
772 DESIGNATED ORGANIC NONACTIVE INGREDIENT CONTAINING OTHER THAN HYDROCARBON
773 . Peptide containing
774 . . Gelatin or derivative
775 . . Casein (milk protein) or derivative
776 . . Albumin or derivative
777 . Carbohydrate or lignin, or derivative
778 . . Starch or derivative
779 . . Algin or derivative
780 . . Locust bean gum
781 . . Cellulose or derivative
782 . Natural gum or resin
783 . Plant extract or plant material of undetermined constitution
784 . Carboxylic acid or salt thereof
785 . Carboxylic acid ester
786 . . Glyceride
787 . . Beeswax
788 . Nitrogen containing
789 MISCELLANEOUS (*e.g.*, HYDROCARBONS, etc.)

**CROSS-REFERENCE ART COLLECTIONS PERTAINING TO SUBJECT MATTER ONLY IN CLASS 514 (see subclasses 800-975 below)**

**PEPTIDE AND PROTEIN ART COLLECTIONS PERTAINING TO CLASS 514**

680 . . . . Polycyclo ring system
681 . . . . . Bicyclo
682 . . . . . Naphthyl ring system
683 . . . . Alicyclic ring
684 . . . . . Five-membered alicyclic ring
685 . . . . C=O bonded directly to benzene ring
686 . . . . . Two benzene rings bonded directly to the same C=O
687 . . . . . Oxygen single bonded to carbon
688 . . . C=O bonded directly to benzene ring (*e.g.*, acetophenone, etc.)
689 . . . . Oxygen single bonded to carbon
690 . . Alicyclic ring containing
691 . . . Plural alicyclic rings
692 . . . . Camphor or nuclear substituted derivatives thereof
693 . Aldehyde DOAI
694 . . Formaldehyde
695 . . . With polycyclo compound
696 . . . With alcohol
697 . . . With nitrogen containing compound
698 . . With preservative or stabilizer
699 . . Benzene ring containing
700 . . . Polycyclo ring system
701 . . . Acyclic carbon to carbon unsaturation
702 . . Sulfur containing
703 . . Carbon to carbon unsaturation
704 . . Nitrogen containing
705 . . Plural C=O groups
706 . Sulfur, selenium or tellurium compound (*e.g.*, thioalcohols, mercaptans, etc.)
707 . . Persulfide (*e.g.*, R-S-S-R, etc.)
708 . . Oxygen bonded directly to sulfur (*e.g.*, sulfoxides, etc.)
709 . . . Plural oxygens bonded directly to the same sulfur (*e.g.*, sulfones, etc.)
710 . . . . Acyclic carbon to carbon unsaturation
711 . . . . Acyclic
712 . . Thioether
713 . . . Acyclic carbon to carbon unsaturation
714 . Peroxide DOAI
715 . Ether DOAI
716 . . Nitrogen containing
717 . . Benzene ring containing
718 . . . Plural oxygens
719 . . . . Alicyclic ring

621 . . . . C=O in R
622 . . . . C-O- group in R
623 . . . Plural alicyclic rings in R
624 . . . Three-membered ring in R
625 . . . R is acyclic
626 . . . . Nitrogen in R
627 . . . . Carbon to carbon unsaturation in R
628 . . . . Halogen bonded directly to carbon in R
629 . . . . R is hydrogen or a lower saturated alkyl of less than seven carbons
630 . . . . . A ring or polycyclo ring system in a substituent E is attached indirectly to the carboxamide nitrogen or to an amino nitrogen in substituent E by acyclic non-ionic bonding
631 . . Amidines (*i.e.*, N=C-N)
632 . . . Amidino hydrazines or hydrazones (*i.e.*, N-N=C-N or N=C-N-N)
633 . . . Amidoximes (*i.e.*, N-C=N-O)
634 . . . Guanidines (*i.e.*, N=C(-N)-N)
635 . . . . Biguanides (*i.e.*, N=C(-N)-N(N-)C=N)
636 . . . Polyamidines
637 . . . Benzene ring containing
638 . . Nitrogen double bonded directly to carbon
639 . . . Hydrazones (*i.e.*, C=N-N)
640 . . . Oximes (*i.e.*, C=N-O-)
. Nitrogen containing other than solely as a nitrogen in an inorganic ion of an addition salt, a nitro or a nitroso DOAI
. . Nitrogen double bonded directly to carbon
641 . . . Aldimines or ketimines which contain a benzene ring (*i.e.*, RC=N wherein R is C or H)
642 . . Quaternary ammonium containing
643 . . . Benzene ring containing
644 . . Amine oxides
645 . . Nitroxides, oxyamines or hydroxylamines (*i.e.*, N-O or N-OH)
646 . . Benzene ring containing
647 . . . Amino nitrogen and a ring bonded directly to the same ring and any other amino nitrogen in the compound is bonded directly to one of the rings
648 . . . Two aryl rings or aryl ring systems bonded directly to the same acyclic carbon
649 . . . Amino nitrogen attached to aryl ring or aryl ring system by an acyclic carbon or acyclic chain

. . . Nitrogen other than as nitro or nitroso nonionically bonded
. . . . Plural nitrogens nonionically bonded
566 . . . . . Polycarboxylic acid
567 . . . . Benzene ring nonionically bonded
568 . . . Benzene ring nonionically bonded
569 . . . . Polycyclo ring system
570 . . . . Carboxy or salt thereof only attached indirectly to the benzene ring
571 . . . . . Ether oxygen single bonded to carboxylic acid, percarboxylic acid or salt thereof through an acyclic carbon or acyclic carbon chain
572 . . . Cyclic carboxylic acid containing three to five carbons or cyclic percarboxylic acid containing three to five carbons or salt thereof
573 . . . . Cyclopentyl or cyclopentene (*e.g.*, prostaglandins, etc.)
574 . . . Polycarboxylic acid or salt thereof
575 . . Hydroxamic acid or salt thereof
576 . . Benzene ring containing
577 . . . Polycyclo ring system
578 . . Acyclic acid or salt thereof
579 . Nitrogen containing other than solely as a nitrogen in an inorganic ion of an addition salt, a nitro or a nitroso DOAI
580 . . Thioureas (*i.e.*, N-C(=S)-N)
581 . . . Thiocarbazides or thiosemicarbazides (*i.e.*, N-N-C(=S)-N containing)
582 . . . . Thiocarbazones or thiosemicarbazones (*i.e.*, C=N-N-C(=S)-N containing)
583 . . . . . Benzene ring containing
584 . . . C=O, sulfur or cyano attached directly to thiourea nitrogen by nonionic bonding
585 . . . Benzene ring containing
586 . . . . Nitrogen attached indirectly to the -C(=S)-group by nonionic bonding
587 . . . . Oxygen containing
588 . . Ureas (*i.e.*, N-C(=O)-N)
589 . . . Nitro or nitroso bonded directly to amino nitrogen (*e.g.*, nitramine, nitrosamine, nitro-urea, etc.)
590 . . . Carbazides or semicarbazides (*i.e.*, N-N-C(=O)-N containing)
591 . . . Biurets (*i.e.*, N-C(=O)-N-C(=O)-N)
592 . . . Sulfur attached directly to urea nitrogen by nonionic bonding

505 . . Cadmium or chromium
506 . Ester DOAI
507 . . R-C(=X)-N-X-C containing (*e.g.*, hydroxamic acid ester, etc.) (R is C or H and X is chalcogen)
508 . . X-C=N containing (*e.g.*, imidoester, etc.) (X is chalcogen)
509 . . (O=)N(=O)-O-C containing (*e.g.*, nitrate ester, etc.)
510 . . Polycyclo ring system
511 . . . Two of the cyclos share at least three ring members (*i.e.*, bridged)
512 . . X-C(=X)-X containing (*e.g.*, carbonic acid ester, thiocarbonic acid ester, etc.) (X is chalcogen)
513 . . C-C(=X)-X-C containing (X is chalcogen and at least one X is other than oxygen)
514 . . Carbon bonded to -NCX or -XCN (*e.g.*, cyanate, thiocyanate or isothiocyanate, etc.) (X is chalcogen)
515 . . . With an additional active ingredient
516 . . . Containing plural -NCX or -XCN groups or a cyano
517 . . S-X-C containing (e.g., sulfates, etc.) (X is chalcogen)
518 . . . S of S-X-C attached directly to a benzene ring
519 . . . Cyano or isocyano bonded directly to carbon
520 . . . Benzene ring containing
521 . . . . C=O other than as ketone or aldehyde
522 . . . . . The cyano is bonded directly to a benzene ring
523 . . . . Additional nitrogen other than cyano
524 . . . . . The cyano is bonded directly to a benzene ring
525 . . . . Two or more of the cyano groups
526 . . . Acyclic
527 . . . . C=O other than as ketone or aldehyde
528 . . . . . C(=O)N containing
529 . . Z-C(=O)-O-Y wherein Z is hydrogen or an organic radical bonded to the C(=O) by a carbon and Y is an organic radical bonded to the oxygen by a carbon
530 . . . Z contains a cyclopentyl or cyclopentene ring
531 . . . Z contains a cyclopropyl or cyclopropene ring
532 . . . Z-C(=O)-O-Y, wherein Z contains a benzene ring
533 . . . . Compound contains two or more C(=O)O groups indirectly bonded together by only conalent bonds
534 . . . . Z or Y radical contains a nitrogen atom
535 . . . . . The nitrogen of the Z radical is directly bonded to a benzene ring which is directly bonded to the C(=O) group
536 . . . . . With an agent to enhance topical absorption or with a stabilizing agent

438 . . . The hetero ring is five-membered
439 . . . . Plural hetero atoms in the hetero ring
440 . . . . . Only two ring sulfurs in the hetero ring
441 . . . . . Chalcogen bonded directly to ring carbon of the hetero ring
442 . . . . . Nitrogen bonded directly to the hetero ring by nonionic bonding
443 . . . . Polycyclo ring system having the hetero ring as one of the cyclos
444 . . . . Additional hetero ring
445 . . . . Chalcogen bonded directly to ring carbon of the hetero ring
446 . . . . Chalcogen bonded directly to ring sulfur by nonionic bonding
447 . . . . Nitrogen bonded directly to the hetero ring
448 . . . . C=O bonded directly to the hetero ring (X is chalcogen)
449 . . Oxygen containing hetero ring
450 . . . The hetero ring has at least seven members
451 . . . The hetero ring is six-membered
452 . . . . Plural ring oxygens in the hetero ring
453 . . . . Polycyclo ring system having the hetero ring as one of the cyclos
454 . . . . . Tricyclo ring system having the hetero ring as one of the cyclos
455 . . . . . Chalcogen bonded directly to ring carbon of the hetero ring
456 . . . . . Bicyclo ring system having the hetero ring as one of the cyclos (*e.g.*, chromones, etc.)
457 . . . . . Coumarins (including hydrogenated)
458 . . . . . Tocopherols (*e.g.*, vitamin E, etc.)
459 . . . . Nitrogen containing
460 . . . . Chalcogen bonded directly to ring carbon of the hetero ring
461 . . . The hetero ring is five-membered
462 . . . . Spiro ring system
463 . . . . Plural ring oxygens in the hetero ring
464 . . . . . Bicyclo ring system having the hetero ring as one of the cyclos (*e.g.*, methylenedioxyphenyl group, etc.)
465 . . . . . The hetero ring is substituted
466 . . . . . Nitrogen containing
467 . . . . . Only two ring oxygens in the hetero ring which is not a polycyclo ring system (*e.g.*, dioxolane, etc.)
468 . . . . Polycyclo ring system having the hetero ring as one of the cyclos

395 . . . . . Chalcogen or nitrogen bonded directly at 1-, 2- or 3-position of the diazole ring by nonionic bonding
396 . . . . Imidazoles
397 . . . . . Additional hetero ring
398 . . . . . Chalcogen or nitrogen bonded directly to the imidazole ring by nonionic bonding
399 . . . . . Chalcogen or nitrogen bonded indirectly to the imidazole ring by nonionic bonding
400 . . . . . At imidazole ring carbon
401 . . . . 2-imidazolines
402 . . . . . Additional hetero ring
403 . . . 1,2-diazoles
404 . . . . Divalent chalcogen or acyclic nitrogen double bonded directly to ring carbon of the diazole ring, or tautomeric equivalent
405 . . . . . Polycyclo ring system having the diazole ring as one of the cyclos
406 . . . . Pyrazoles
407 . . . . . Chalcogen or nitrogen bonded directly to the pyrazole ring by nonionic bonding
408 . . . The five-membered hetero ring consists of one nitrogen and four carbons
409 . . . . Spiro ring system
410 . . . . Polycyclo ring system having the five-membered hetero ring as one of the cyclos
411 . . . . . Tricyclo ring system having the five-membered hetero ring as one of the cyclos
412 . . . . . Bicyclo ring system having the five-membered hetero ring as one of the cyclos
413 . . . . . Ring nitrogen is shared by the cyclos of the bicyclo ring system
414 . . . . . Additional hetero ring which is not part of the bicyclo ring system

. Heterocyclic carbon compounds containing a hetero ring having chalcogen (*i.e.*, O, S, Se or Te) or nitrogen as the only ring hetero atoms DOAI
. . Five-membered hetero ring containing at least one nitrogen ring atom (*e.g.*, 1,2,3-triazoles, etc.)
. . . The five-membered hetero ring consists of one nitrogen and four carbons
. . . . Polycyclo ring system having the five-membered hetero ring as one of the cyclos
. . . . . Bicyclo ring system having the five-membered hetero ring as one of the cyclos

347 . . . . Chalcogen bonded directly to chalcogen
348 . . . . Chalcogens bonded directly to at least two ring carbons of the six-membered hetero ring
349 . . . . Nitrogen attached directly to the six-membered hetero ring by nonionic bonding
350 . . . . C=O bonded directly to the six-membered hetero ring
351 . . . . Nitrogen attached indirectly to the six-membered hetero ring by nonionic bonding
352 . . . Nitrogen attached directly to the six-membered hetero ring by nonionic bonding
. Heterocyclic carbon compounds containing a hetero ring having chalcogen (*i.e.*, O, S, Se or Te) or nitrogen as the only ring hetero atoms DOAI
. . Hetero ring is six-membered consisting of one nitrogen and five carbon atoms
. . . Nitrogen attached directly to the six-membered hetero ring by nonionic bonding
353 . . . . Plural acyclic nitrogens bonded directly to the same carbon or bonded directly to each other
354 . . . C=O bonded directly to the six-membered hetero ring
355 . . . . . At 3-position
356 . . . . . C=O in a C(=O)O group (*e.g.*, nicotinic acid, etc.)
357 . . . Nitrogen attached indirectly to the six-membered hetero ring by nonionic bonding
358 . . . The ring nitrogen of the six-membered hetero ring is pentavalent (*e.g.*, quaternary pyridinium salt, etc.)
359 . . Five-membered hetero ring containing at least one nitrogen ring atom (*e.g.*, 1,2,3-triazoles, etc.)
360 . . . Plural ring chalcogens in the hetero ring
361 . . . Plural ring nitrogens and a single chalcogen in the hetero ring
362 . . . . 1,2,5-thiadiazoles (including hydrogenated)
363 . . . . 1,3,4-thiadiazoles (including hydrogenated)
364 . . . . Oxadiazoles (including hydrogenated)
365 . . . 1,3-thiazoles (including hydrogenated)
366 . . . . Polycyclo ring system having the thiazole ring as one of the cyclos
367 . . . . . Bicyclo ring system having the thiazole ring as one of the cyclos
368 . . . . . Ring nitrogen is shared by the cyclos of the bicyclo ring system (*e.g.*, tetramisole, etc.)
369 . . . . Chalcogen bonded directly to ring carbon of the thiazole ring

. . Hetero ring is six-membered consisting of one nitrogen and five carbon atoms
. . . Polycyclo ring system having the six-membered hetero ring as one of the cyclos
. . . . Tricyclo ring system having the six-membered hetero ring as one of the cyclos
295 . . . . . Two of the cyclos share at least three ring carbons (*i.e.*, bridged) (*e.g.*, benzomorphans, etc.)
296 . . . . . Ring carbons shared by each of the three cyclos (*e.g.*, 1,8-naphthalimides, etc.)
297 . . . . . Acridines (including hydrogenated)
298 . . . . . Phenanthridines (including hydrogenated)
299 . . . . Bicyclo ring system having the six-membered hetero ring as one of the cyclos
300 . . . . . Plural hetero atoms in the bicyclo ring system
301 . . . . . Ring sulfur in the bicyclo ring system
302 . . . . . Ring oxygen in the bicyclo ring system
303 . . . . . Exactly three ring nitrogens in the bicyclo ring system
304 . . . . . Tropanes (including nor or dehydro form)
305 . . . . . Quinuclidines (including unsaturation)
306 . . . . . Quinolizines (including hydrogenated)
307 . . . . . Isoquinolines (including hydrogenated)
308 . . . . . Plural isoquinoline ring systems attached directly or indirectly to each other by nonionic bonding
309 . . . . . Chalcogen attached directly to the six-membered hetero ring by nonionic bonding
310 . . . . . Nitrogen, other than as nitro or nitroso, attached directly to the isoquinoline ring system by nonionic bonding
311 . . . . . Quinolines (including hydrogenated)
312 . . . . . Chalcogen attached directly to the six-membered hetero ring by nonionic bonding
313 . . . . . Nitrogen, other than as nitro or nitroso, attached directly to the six-membered hetero ring by nonionic bonding
314 . . . . . Additional hetero ring attached directly or indirectly to the quinoline ring system by nonionic bonding
315 . . . Piperidines
316 . . . . Plural piperidine rings
317 . . . . Additional ring containing
318 . . . . . The additional ring is a six-membered hetero ring consisting of one nitrogen and five carbon atoms

242 . . . Asymmetrical (*e.g.*, 1,2,4-triazine, etc.)
243 . . . . Polycyclo ring system having the hetero ring as one of the cyclos
244 . . . Hexamethylenetetramines
245 . . . Nitrogen bonded directly to ring carbon of the hetero ring
246 . . . . Polycyclo ring system having a 1,3,5-triazine as one of the cyclos
247 . . Hetero ring is six-membered consisting of two nitrogens and four carbon atoms (*e.g.*, pyridazines, etc.)
248 . . . Polycyclo ring system having a 1-2- or 1,4-diazine as one of the cyclos
249 . . . . 1,4-diazine as one of the cyclos
250 . . . . . At least three rings in the polycyclo ring system
251 . . . . . Isoalloxazine (*e.g.*, riboflavins, Vitamin B2, etc.)
252 . . . 1,2- or 1,4-diazine compound having two or more hetero rings
253 . . . . Hetero ring other than 1,2- or 1,4-diazine is part of a polycyclo ring system
254 . . . . . Diazine is bonded directly to the polycyclo ring system
255 . . . 1,4-diazines
256 . . . 1,3-diazines (*e.g.*, pyrimidines, etc.)
257 . . . . Polycyclo ring system having 1,3-diazine as one of the cyclos
258 . . . . . Bicyclo ring system having 1,3-diazine as one of the cyclos
259 . . . . . Quinazolines (including hydrogenated)
260 . . . . . Nitrogen bonded directly to the 1,3-diazine at 2-position
261 . . . . . Purines (including hydrogenated)
262 . . . . . Chalcogen bonded directly to a ring carbon of the purine
263 . . . . . At both 2- and 6-positions (*e.g.*, theophilline, etc.)
264 . . . . . With an additional active ingredient or stabilizer
265 . . . . . Additional hetero ring
266 . . . . . Additional hetero ring
267 . . . . . Tricyclo ring system having 1,3-diazine as one of the cyclos
268 . . . . . Perimidine (including hydrogenated)
269 . . . . Pyrimidines with chalcogen bonded directly to a ring carbon of said pyrimidine moiety
270 . . . . . Barbituric acid or derivative (including thioanalogs)

184 . . Heavy metal containing (including salts)
185 . . . Polycyclo ring system
186 . . . . Bicyclo ring system
187 . . . . . Quinolines or isoquinolines (including hydrogenated)
188 . . . Hetero ring is six-membered consisting of one nitrogen and five carbons
189 . . . Tin
190 . . . Mercury
191 . . Aluminum (including salts)
192 . . 1-thia-4-aza-bicyclo (3.2.0) heptane ring containing (including dehydrogenated) (*e.g.*, penicillins, etc.)
193 . . . Spiro or additional polycyclo ring system
194 . . . 6,6-di-substituted
195 . . . 3-position substituent contains -COOC- group
196 . . . 6-position substituent contains hetero ring
197 . . . 6-position substituent contains carbocyclic ring
198 . . . . Ampicillin per se or salt thereof
199 . . . . Penicillin G per se or salt thereof (e.g., procaine penicillin G, etc.)
200 . . 1-thia-5-aza-bicyclo (4.2.0) octane ring containing (including dehydrogenated) (*e.g.*, cephalosporins, etc.)
201 . . . 7,7-di-substituted
202 . . . Additional hetero ring
203 . . . . 3-position substituent contains pyridine ring
204 . . . . 3-position substituent contains sulfur
205 . . . . . The additional hetero ring is part of a polycyclo ring system
206 . . . . . 7-position substituent contains hetero ring
207 . . . . . Alkyl, hydroxyalkyl, alkoxyalkyl, or alkanoyloxyalkyl bonded directly to 3-position
208 . . . Sulfur containing substituent
209 . . . Alkyl, hydroxyalkyl, alkoxyalkyl, or alkanoyloxyakyl bonded directly to 3-position
210 . . Hetero ring is four-membered and includes at least one nitrogen
211 . . Hetero ring is seven-membered and includes at least one nitrogen and at least one hetero atom other than nitrogen
212 . . Hetero ring is seven-membered consisting of one nitrogen and six carbon atoms
213 . . . Polycyclo ring system having the seven-membered hetero ring as one of the cyclos
214 . . . . Ring nitrogen is shared by two or three of the cyclos
215 . . . . Additional hetero atom in the polycyclo ring system

124 . . . C=0, other than as ketone or aldehyde, attached to a benzene ring
125 . . Ketone or aldehyde containing
126 . . Sulfur not bonded directly to phosphorus
127 . . . Thioether, sulfoxide or sulfone
128 . . . . Sulfur bonded directly to a benzene ring
129 . . Oxygen bonded directly to a carbon or hydrogen and wherein the oxygen is not bonded directly to phosphorus
130 . . . The oxygen is bonded directly to a benzene ring
131 . . Nitro group bonded to a carbon
132 . . . Nitro group is directly bonded to a benzene ring which benzene ring is either bonded directly bonded to phosphorus or indirectly bonded to phosphorus through a chalcogen
133 . . . . Two or more such benzene rings
134 . . Acyclic carbon to carbon unsaturation
135 . . . Alkyne
136 . . . Phosphate ester having three ester groups (*e.g.*, DDVP, etc.)
137 . . Nitrogen bonded directly to phosphorus
138 . . . N-P-N or N-N-P containing
139 . . Phosphorus bonded directly to halogen
140 . . (C)(R)P=X(-XC) containing (*i.e.*, Phosphinate (X is chalcogen; R is C or H)
141 . . (CX-) (C)P=X(XH) or (CX-) (R)P=X(XC) containing (*e.g.*, phosphonate, etc.) (X is chalcogen; R is C or H)
142 . . (CX-) (C)P(C), (CX-)(RX-)P(C),(CX-)P(XH)(XH) or (CX-) (CX-)P(-XR) containing (X is chalcogen; R is C or H) (*e.g.*, phosphinite, phosphite, etc.)
143 . . Ester of (HX)P=X(XH)(XH) (X is chalcogen) (*e.g.*, phosphate, etc.)
144 . . . Triester
145 . . . . Three benzene rings bonded directly to chalcogen
146 . . . . Two benzene rings bonded directly to chalcogen
147 . . . . One benzene ring bonded directly to chalcogen
148 . . . Diester
149 . Azoxy DOAI
150 . Acyclic nitrogen double bonded to acyclic nitrogen, acyclic nitrogen triple bonded to acyclic nitrogen or azide DOAI
151 . . Acyclic C-N=N-N containing
152 . 3,10-dihydroxy-2-naphthacene carboxamide or derivative (*e.g.*, tetracycline, etc.) DOAI
153 . . With stabilizer or preservative

58 . . . Dextrin or derivative
59 . . . Dextran or derivative
60 . . . Starch or derivative
61 . . . Tri- or tetrasaccharide
62 . . Glucosamine or derivative
63 . Silicon containing DOAI
64 . Boron containing DOAI
65 . Pyrethrum plant derived material or plant derived rotenone compound containing DOAI
66 . . With heterocyclic compound
67 . . . Methylenedioxyphenyl group containing (*e.g.*, piperonyl butoxide, etc.)
68 . . With carbocyclic acid ester
69 . . With carboxylic acid metal salt
70 . . With organic nitrogen containing compound
71 . . . Sulfur containing organic nitrogen compound
72 . . With organic oxygen containing compound
73 . . . Phosphorus or halogen containing organic oxygen compound
74 . . With hydrocarbon or halohydrocarbon
75 . Phosphorus containing other than solely as part of an inorganic ion in an addition salt DOAI
76 . . Amine addition salt of organic phosphorus containing acid
77 . . Inner salt (*e.g.*, betaine, etc.)
78 . . . Lecithins
79 . . Nitrogen containing hetero ring
80 . . . Polycylo ring system having a ring nitrogen in the system
81 . . . . Nonshared hetero atoms in at least two rings of the polycyclo ring system
82 . . . . Quinolinyl or isoquinolinyl (including hydrogenated)
83 . . . Hetero ring is three-membered consisting of one nitrogen and two carbons
84 . . . Hetero ring is six-membered consisting of three nitrogens and three carbons
85 . . . Hetero ring is six-membered consisting of two nitrogens and four carbons
86 . . . . Nitrogen atoms occupy 1 and 3-positions
87 . . . . . PX- bonded directly to 1,3-diazine at 2- position (X is chalcogen)
88 . . . . . Two or more PX- groups attached to the same 1,3-diazine (X is chalcogen)
89 . . . Hetero ring is six-membered and includes only one ring nitrogen

909 NEPHELOMETRY
910 IRON-BINDING CAPACITY OF BLOOD

## [4] Class 514 Drug, Bio- affecting and Body Treating Compositions (December 1986)

1 DESIGNATED ORGANIC ACTIVE INGREDIENT CONTAINING (DOAI)
2 . Peptide containing (*e.g.*, protein, peptones, fibrinogen, etc.) DOAI
3 . . Insulin or derivative
4 . . . With an additional active ingredient
5 . . Iodine containing
6 . . Heavy metal containing (*e.g.*, hemoglobin, etc.)
7 . . Phosphorus containing
8 . . Glycoprotein (carbohydrate containing)
9 . . Cyclopeptides
10 . . . Bicyclic
11 . . . Monocyclic
12 . . 25 or more peptide repeating units in known peptide chain structure
13 . . 16 to 24 peptide repeating units in known peptide chain
14 . . 12 to 15 peptide repeating units in known peptide chain
15 . . 9 to 11 peptide repeating units in known peptide chain
16 . . 7 or 8 peptide repeating units in known peptide chain
17 . . 5 or 6 peptide repeating units in known peptide chain
18 . . 3 or 4 peptide repeating units in known peptide chain
19 . . 2 peptide repeating units in known peptide chain
20 . . . Guanidine containing
21 . . Produced by or extracted from animal tissue

Note: See subclasses 800-809 for art collections pertaining to subclasses 1-21.

22 . Lignin or derivative DOAI
23 . Carbohydrate (*i.e.*, saccharide radical containing) DOAI
24 . . S-glycoside
25 . . O-glycoside
26 . . . Cyclopentanohydrophenanthrene ring system
27 . . . Oxygen of the saccharide radical bonded directly to a nonsaccharide hetero ring or a polycyclo ring system which contains a nonsaccharide hetero ring
28 . . . . The hetero ring has 8 or more ring carbons

158 . Dividing or separating a sample stream
PYROLYSIS, COMBUSTION, OR ELEVATED TEMPERATURE CONVERSION
159 . With catalyst or accelerator
160 . Combustion with oxygen containing gas
161 INCLUDING CHROMATOGRAPHY
162 . Utilizing paper or thin layer plate
163 INCLUDING TITRATION OR pH DETERMINATION
164 OPTICAL RESULT
165 . With claimed manipulation of container to effect reaction or use of container of claimed optical structure
166 . Including reagent preparation
167 . Including gas absorption in liquid or solid
168 . . Liquid sorbent
169 . With reagent in absorbent or bibulous substrate
170 . . Plural superposed layers
171 . Spectrum analysis (*e.g.*, flame photometry, etc.)
172 . With fluorescence or luminescence
173 NUCLEAR MAGNETIC RESONANCE, ELECTRON SPIN RESONANCE OR OTHER SPIN EFFECTS OR MASS SPECTROMETRY
174 INCLUDING SAMPLE PREPARATION
175 . Digestion or removing interfering materials
176 . Stabilizing or preserving
177 . Liberation or purification of sample or separation of material from a sample (*e.g.*, filtering, centrifuging, etc.)
178 . . Including use of a solid sorbent, semipermeable membrane, or liquid extraction
179 . Dilution
180 . Volumetric liquid transfer
181 . Gaseous sample or with change of physical state
182 ELEMENT OR INORGANIC COMPOUND
183 MISCELLANEOUS

CROSS-REFERENCE ART COLLECTIONS RELATING TO ANTIGEN-ANTIBODY OR BINDING PROTEIN TESTS

800 FLUORESCENT DYES (E.G., RHODAMINE, ETC.)
801 ELECTRON DENSE COMPOUNDS (E.G., FERRITIN, ETC.)
802 PROTEIN-BACTERIOPHAGE CONGUGATES
803 STABLE FREE RADICALS (E.G., SPIN LABELED IMMUNOASSAY, ETC.)
804 RADIOISOTOPE (E.G., RADIOIMMUNOASSAY, ETC.)
805 OPTICAL PROPERTY

85 SYNTHETIC OR NATURAL RESIN
86 PEPTIDE, PROTEIN OR AMINO ACID
87 . Glycoproteins (*e.g.*, hormone, etc.)
88 . . Albumin
89 . Amino acid or sequencing procedure
90 . . Alpha or beta amino acid
91 HETEROCYCLIC CARBON COMPOUND (*I.E.*, O, S, N, Se, Te, AS ONLY RING HETERO ATOM, ETC.)
92 . Diverse hetero atoms in same or different rings (*e.g.*, alkaloids, opiates, etc.)
93 . Hetero-O (*e.g.*, ascorbic acid, etc.)
94 . . Saccharide (*e.g.*, DNA, etc.)
95 . . . Glucose
96 . Hetero-N
97 . . Bile pigment
98 . . Plural nitrogen in the same ring (*e.g.*, barbituates, creatinine, etc.)
99 . . . Uric acid
100 INORGANIC ACID OR BASE (*E.G.*, HCL, SULFURIC ACID, ETC.)
101 . Halogen containing
102 . Sulfur containing
103 PHOSPHORUS CONTAINING
104 . Organic (*e.g.*, chemical warfare agents, insecticides, etc.)
105 . Of inorganic phosphorus compound in body fluid
106 NITROGEN CONTAINING
107 . N-Nitroso containing (*e.g.*, nitrosamine, etc.)
108 . Urea or blood urea nitrogen
109 . Cyanide or isocyanide
110 . Nitrite or nitrate
111 . Amine and quartenary ammonium
112 . . Tertiary amine
113 . . Ammonia
114 . Total nitrogen determined
115 . . As part of an elemental analysis
116 . Oxides of nitrogen
117 . . Only nitrogen dioxide
118 . . Both nitrogen oxide and dioxide
119 SULFUR CONTAINING
120 . Organic or sulfhydryl containing (*e.g.*, mercaptan, hydrogen, sulfide, etc.)
121 . . Only hydrogen sulfide
122 . Sulfur dioxide

14 . Glucose, ketone, nitrate standard or control
15 . Protein or peptide standard or control (*e.g.*, hemoglobin, etc.)
16 . Blood serum or blood plasma standard or control
17 . Preparation composition (*e.g.*, lysing or precipitation, etc.)
18 . Preservative, buffer, anticoagulant or diluent
19 . Inorganic standards or controls
20 FOOD OR DAIRY PRODUCTS
21 . Meat or eggs
22 . Dairy product
23 . . Milk or butter fat
24 . Wine or alcoholic beverages
25 GEOCHEMICAL, GEOLOGICAL, OR GEOTHERMAL EXPLORATION
26 . For metallic ores
27 . Using chemical tracers
28 . In situ testing
29 . For petroleum oils or carbonaceous minerals
30 . . Removing and testing drilling mud or fluid
31 . . Removing and testing solid samples
32 . . . Analyzing evolved gas
33 . . . . Evolving gas by acidification
34 RATE OF REACTION DETERMINATION
35 USING ACTIVATED SPECIE
36 WITH USE OF CONDENSATION NUCLEI
37 TESTING OF CATALYST
38 PURITY OF STEAM OR CHEMICALLY INERT GAS
39 DETERMINATION OF WATER
40 . In petroleum oil, hydrocarbon oil or organic fluid
41 . By use of cobalt, copper or nickel containing reagent
42 . By use of Karl Fischer Reagent
43 AUTOMATED CHEMICAL ANALYSIS
44 . Utilizing a moving indicator strip or tape
45 . Utilizing a centrifuge or compartmented rotor
46 . With sample on test slide
47 . With conveyance of sample along a test line in a container or rack
48 . . With step of insertion or removal from test line
49 . . With treatment or replacement of aspirator element (*e.g.*, cleaning, etc.)
50 . Condition or time responsive
51 . . With automated titrator
AUTOMATED CHEMICAL ANALYSIS
52 . With a continuously flowing sample or carrier stream

## [3] Class 436 Chemistry: Analytical and Immunological Testing (December 1982)

500 THYROID HORMONE TESTS (*E.G.*, T3, T4, TBG, TBH, ETC.)
501 BIOSPECIFIC LIGAND BINDING ASSAY
502 . Limulus lysate
503 . Utilizing isolate of tissue or organ as binding agent
504 . . Radioactive label
505 . . . B12 or folate
506 FOR PREEXISTING IMMUNE COMPLEX OR AUTOIMMUNE DISEASE
507 . Immune complex
508 . Antinuclear (*e.g.*, DNA, etc.)
509 . Rheumatoid factors
510 VENEREAL DISEASE, PREGNANCY, OR CHROMOSOME DETERMINATION
511 . Syphilis, gonorrhea, herpes
512 INVOLVING ANTIBODY FRAGMENTS
513 INVOLVING IgA, IgD, IgE, or IgM
514 INVOLVING DIFFUSION OR MIGRATION OF ANTIGEN OR ANTIBODY
515 . Through a gel (*e.g.*, Ouchterlony technique, etc.)
516 . . Immunoelectrophoresis
517 INVOLVING KINETIC MEASUREMENT OF ANTIGEN-ANTIBODY REACTION
518 INVOLVING AN INSOLUBLE CARRIER FOR IMMOBILIZING IMMUNOCHEMICALS
519 . Carrier is a biological cell or cell fragment
520 . . Red blood cell
521 . . . Fixation or stabilization of red blood cells
522 . . . Lysis of red blood cell membrane
523 . Carrier is particulate and the particles are of intentionally different sizes or impregnated differently with the immunochemicals
524 . Carrier is inorganic
525 . .Metal or metal coated
526 . . . Magnetic
527 . .Glass or silica
528 . Carrier is organic
529 . .Polysaccharide, carrier (*e.g.*, dextran, etc.)
530 . . . Cellulose or derivative
531 . . Carrier is synthetic resin

CLASSIFICATION DEFINITIONS

ADDENDA NO. 2 - ORDER NO. 741

JULY 21, 1980

D. CHANGES TO THE DEFINITIONS (Project No. X 2842)

CLASS 435 - CHEMISTRY: MOLECULAR BIOLOGY AND MICROBIOLOGY

*Reference Updates* to Definitions or to Search Class Notes in Existing Subclasses*

| *In Subclass* | *Change reference from Class* | *Subclasses* | *To Class* | *Subclasses* |
|---|---|---|---|---|
| 68 and 174 - SEARCH CLASS | 428 | 474+ | 428 | 474.4+ |

*Place these class and/or subclass updates in numerical sequence.

Determinative Bacteriology, Eighth Edition" which is to be considered dispositive of the subject matter.

803. *Physical Recovery Methods, e.g., Chromatography, Grinding:*
Subject matter in which a microorganism or microbial product other than an enzyme is recovered or purified by physical means alone.

804. *Single Cell Protein:*
Subject matter in which the suitability of a microorganism to supply palatable protein is disclosed.

805. *Test Papers:*
Subject matter in which a test material is carried on a bibulous material which may be cellulosic or noncellulosic.

806. *Fertility Test:*
Subject matter in which fecundity or pregnancy is determined.

807. *Gas Detection Apparatus:*
Subject matter in which means is provided to detect the presence of gas in a qualitative or quantitative manner.

808. *Optical Sensing Apparatus:*
Subject matter in which means senses the production or absorbtion of light by a sample or otherwise optically examines a specimen.

809. *Incubators or Racks or Holders for Culture Plates or Containers:*
Subject matter including heating means for culture containers or means to support such containers.

810. *Packaged Device or Kit:*
Subject matter in which a measuring or testing device or sampler or plurality of such is in a container or package.

811. *Interferon:*
Subject matter in which the antiviral agent interferon is isolated or treated.

812. *Foam Control:*

purification apparatus; and subclass 231 for gas introduction means in a chemical reactor of general utility.

314. With Draft Tube:
Apparatus under subclass 313 including a cylindrical element extending from a lower to a higher level in a vessel to provide for internal recycle.

*Search Class:*

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclasses 230+ for similar chemical reaction apparatus of general utility.

315. With Agitator:
Apparatus under subclass 313 including mixing means.

*Search Class:*

366, appropriate subclasses for agitators consisting of a receptacle and stirrer.

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclass 131 for agitation means in a polymerization reactor; subclass 224 for agitation means in a chemical reactor of general utility; subclasses 173+ for a waste gas purifier with a reaction chamber heat exchanger; and subclasses 198+ for a chemical reactor of general utility with an associated heat exchange means.

316. With Agitator or Heat Exchanger:
Apparatus under subclass 287 including mixing means or means for the addition or removal of heat.

317. Miscellaneous:
Subject matter under the class definition not otherwise provided for.

309. With Multilevel Gas Introduction Means:
Apparatus under subclass 302 with means providing for gas entry at different depths below the surface of the material treated.

310. With Means Providing Thin Layer or With Multilevel Trays:
Apparatus under subclass 287 including surface extending means which typically cause liquid to be disposed such that the exposed surface is large relative to the depth, or causes liquid to flow across trays set at different heights the liquid falling from one level to the next lower.

(1) Note. This subclass provides for surface extending means such as, raschig rings although the more common structure provided for here is a plate for flow of a liquid or fluid in a thin layer or a cascade of trays.

(2) Note. This subclass provides for culture devices which provide for growth in a thin layer to facilitate optical observation, e.g., a microscope slide adapted for microorganism growth.

*Search Class:*

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, subclass 211 for chemical reactors of general utility with surface extending means.

311. With Sterilizer or Filtration Means:
Apparatus under subclass 287 including means for killing undesired organisms or porous means effective to remove particulate material by trapping particles greater than a desired size.

*Search Class:*

210, Liquid Purification or Separation, various subclasses for processes and apparatus including filters for liquid purification.

(1) **Note.** Solid media is to be interpreted as including all media that is not liquid or if solid is not fluent.

(2) **Note.** Examples of solid media are pH indicators or antibiotics per se without conventional growth media.

(3) **Note.** Media as used in this and the indented subclasses includes culture media which sustains growth, media which kill or inhibit certain microorganisms, and media which sustain microorganisms.

*Search Class:*

215, Bottles and Jars, for bottles and jars of general utility and for closures for bottles and jars.

300. Multiple Field or Compartment:
Apparatus under subclass 299 including two or more separate media areas or areas adapted to contain or which contain the same or different media.

301. Horizontal, Planar Field:
Apparatus under subclass 300 in which the multiple areas or means to contain the solid media in a multiplicity of areas are arranged in a single orientable plane.

302. Malting or Mashing Apparatus:
Apparatus under subclass 287 with means to effect the sprouting of grain by heat and humidity.

303. Rotary Drum:
Apparatus under subclass 302 which includes a cylindrical vessel and means for rotating the vessel about its axis.

*Search Class:*

422, Process Disinfecting, Deodorizing, Preserving or Steriliz-

346, Recorders, for recording apparatus per se.

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, for apparatus for (a) determining qualitatively or quantitatively the presence of one or more chemical constituents of a material which involve a chemical reaction, and (b) combinations of a test or measurement and means for regulating a chemical reaction.

292. Innoculator Streaker or Sampler:
Apparatus under subclass 287 including means for effecting physical contact between a sample and a media or means for physically removing a portion of a larger mass of material as a sample.

293. Multifield or Continuous:
Apparatus under subclass 292 wherein means provide physical contact between a sample, a sample with two or more separate media areas or areas adapted to contain media simultaneously or sequentially or with a single large area in a continuous manner.

(1) **Note.** This subclass would include moving belts of media, etc., which are moved past a dispensing means as well as devices in which a dispensing means waves over a large media field.

(2) **Note.** This subclass is not intended to include "one shot" samplers.

294. Sampler or Innoculator Is Part of Container:
Apparatus under subclass 292 in which the means for effecting physical contact with something to be investigated forms part of a culture media containing receptacle when the receptacle is closed.

(1) **Note.** Typically the innoculator or sampler is a rod, brush,

note particularly subclass 93 in which the control is in response to a sensing of a chemical property.

196, Mineral Oils: Apparatus, subclasses 132 and 141 for combinations of apparatus for making a test or measurement and means for controlling a reaction provided for in that class.

204, Chemistry, Electrical and Wave Energy, subclass 195 for apparatus specialized for the determination of hydrogen ion concentration of solutions.

324, Electricity, Measuring and Testing, appropriate subclasses for apparatus for testing an 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.

346, Recorders, for recording apparatus per se.

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

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, for apparatus for (a) determining qualitatively or quantitatively the presence of one or more chemical constituents of a material which involve a chemical reaction, and (b) combinations of a test or measurement and means for regulating a chemical reaction.

290. Temperature Responsive Control:
Apparatus under subclass 289 with means to effect control responsive to temperature.

53, Package Making, various subclasses for processes of packaging and package making.

71, Chemistry, Fertilizers, for apparatus for using a microorganism or enzyme to produce a fertilizer.

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

99, Foods and Beverages: Apparatus, subclasses 275+ for apparatus adapted for the preparation of a beverage or beverage intermediate by carrying out primary ethyl alcoholic fermentations and apparatus for aging, refining, and purifying alcoholic beverages.

128, Surgery, for methods of treatment of the living body and apparatus used in the inspection and treatment of diseases, of the bodies of humans and lower animals which apparatus is provided with means for connection to the living body.

206, Special Receptacle or Package, subclass 223 for a test kit of general utility similar in structure to a culture test kit.

215, Bottles and Jars, for bottles and jars of general utility and the closures therefor.

241, Solid Material Comminution or Disintergration, particularly subclass 2 for methods and apparatus of and for the combination of microorganisms or tissues.

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, for apparatus for analysis including means for causing or promoting a chemical reaction or regulating or controlling a chemical reaction.

288. For Use of Free or Immobilized Enzyme: Apparatus under subclass 287 for the use of free or immobilized enzymes.

3, Artificial Body Members, for artificial body members.

62, Refrigeration, subclasses 440+ for process of and apparatus for organ preservation by cooling which may involve chemical treatment to minimize cellular freezing effects.

128, Surgery, subclass 214 for oxygenators connected to or with means for connection to a living human body.

137, Fluid Handling, subclass 560 for systems including pulsating pumps useful for forcing perfusate through organs.

210, Liquid Purification or Separation, subclass 321 for dialysis devices adapted for gas and mass transfer, e.g., artificial kidney which oxygenates blood.

261, Gas and Liquid Contact Apparatus, for gas liquid contact means of general utility.

422, Process Disinfecting, Deodorizing, Preserving or Sterilizing, and Chemical Apparatus, for blood oxygenating devices and other blood treatment devices.

284. Tissue, Animal or Plant Cell, or Virus Culture Apparatus: Apparatus under the class definition adapted for growth of animal or plant tissue, differentiated or undifferentiated animal, or plant cell or a virus including bacteriophage.

*Search This Class, Subclass:*

1, for processes of maintaining tissue or an organ in a viable state.

2, for processes of maintaining blood or sperm in a physiologically active state.

treated to liberate an optically active mixture or compound or a mixture is otherwise purified by a microorganism or enzyme to obtain a specified organic compound.

(1) **Note.** It should be noted that biological, i.e., microbial or enzymatic reactions are generally steriospecific so that a search, to be complete, should also include a search of the synthesis subclass, i.e., subclasses 41+ of this class which provides for the transformation of the "contaminant" if it is chemically identifiable.

281. Petroleum Oil or Shale Oil Treating:
Processes under subclass 262 wherein the preexisting material which is liberated or purified is petroleum or shale oil.

*Search This Class, Subclass:*

9, for processes of prospecting for minerals including petroleum oils.

*Search Class:*

75, Metallurgy, subclass 14, particularly subclass 5 for a process of beneficiating metal ore using a microorganism or enzyme.

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

196, Mineral Oils: Apparatus, for apparatus for treating, refining, or recovering mineral oils such as petroleum, tar, pitch asphalt, or related products not otherwise provided for.

204, Chemistry, Electrical and Wave Energy, appropriate subclass for apparatus for treating mineral oils involving

273. Collagen or Gelatin:
Processes under the subclass 272 wherein the preexisting material is collagen or gelatin.

274. Carbohydrate Material Recovered or Purified:
Processes under subclass 267 wherein the preexisting material is a carbohydrate.

*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 provides for 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.

260, Chemistry, Carbon 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.

275. Pectin or Starch:
Processes under subclass 274 wherein the preexisting material is a pectin or a starch.

276. Sugar, e.g., Molasses Treatment, etc.:
Processes under subclass 274 wherein the preexisting material is a monosaccharide or a polysaccharide which has predominately alpha-1, 4 linkages between the glucose units.

277. Cellulose, e.g., Plant Fibers, etc.:
Processes under subclass 274 wherein the preexisting material is a polysaccharide which has predominately beta-1,4 linkages between the glucose units.

*Search Class:*

2, for processes of treating blood cells in vitro to alter some cellular property while maintaining cell viability.

*Search Class:*

424, Drug, Bio-Affecting and Body Treating Compositions, for a process of radioactive labeling of blood cells for radiopharmaceutical use such as visualization of internal organs and the composition of such use.

270. Removing Nucleic Acid from Intact or Disrupted Cell:
Processes under subclass 267 wherein an intact or disrupted cell's nucleic acid content is reduced by the use of an enzyme or microorganism.

*Search Class:*

71, Chemistry, Fertilizers, for the production of substances having a nutrient or stimulating, inhibiting, or regulating action on plant growth and the product of such processes including methods of utilizing microorganisms to produce a fertilizer, e.g., composting as well as the microorganism containing fertilizer so produced.

271. Glyceridic Oil, Fat, Ester-Type Wax or Higher Fatty Acid Recovered or Purified:
Processes under subclass 267 wherein the preexisting material is a fat, ester-type wax, higher fatty acid, or glyceride oil.

(1) **Note.** Fats and fatty oils are the glycerides of higher fatty acids, including naturally occurring mixtures thereof present in a single oil or fat.

(2) **Note.** Ester-type waxes are waxes which are essentially esters in chemical structure, e.g., beeswax, montan wax, carnauba wax, and spermaceti.

(3) **Note.** Higher fatty acid is a monocarboxylic acid containing

process per se of treating a hide or skin, e.g., depilating, bating, etc.

71, Chemistry, Fertilizers, subclass 18 for compositions of matter including hides, skins, feathers, or animal tissues such as compost.

266. Treating Gas, Emulsion, or Foam:
Processes under subclass 262 wherein the preexisting material is a gas or is initially a component of an emulsion or foam.

*Search Class:*

55, Gas Separation, subclass 36, for a process of removing gas from a liquid and see (1) Note, "Search This Class, Subclass" and "Search Class" thereunder for related fields of search. Subclass 87 for a gas separation process including the step of breaking foam; and subclass 178 for apparatus in which the mixture is a substantially stable aggregation of gas or vapor bubbles dispersed in a liquid phase (foam) and comprising means to destroy or remove the aggregation and see "Search This Class, Subclass," and "Search Class" thereunder for related fields of search.

137, Fluid Handling, subclasses 107+ for apparatus for controlling the degree of foaming in a gas charged liquid.

201, Distillation: Processes, Thermolytic, subclass 9 for a process of surface treating the solid particles of the charge to inhibit, reduce, or prevent foaming during distillation.

202, Distillation: Apparatus, subclass 264 for distillation apparatus intended to break foam or inhibit foaming.

203, Distillation: Processes, Separatory, subclass 20 for processes of defoaming or inhibition of the formation of foam combined with distillation.

per se, generally disclosed or claimed as fluid separation, or if the disclosure or a claim is restricted to liquid separation.

260, Chemistry, Carbon Compounds, provides for the liberation and purification by chemical or physical means of compounds and extracts falling within the class definition of Class 260. Generally, the physical processes included are of two types (a) a purification process prior or subsequent to a chemical reaction producing a Class 260 product, (b) a purification process directed to the purification of a Class 260 compound by a combination of physical separation techniques the classes for which do not provide for or exclude the combination claimed. Chemical purification processes are generally provided for with each product produced.

263. Textile Treating:
Processes under subclass 262 wherein the preexisting material is an organic fiber material per se or the fiber is spun or woven into fabric.

*Search Class:*

8, Bleaching and Dyeing; Fluid Treatment and Chemical Modification of Textiles and Fibers, for chemical modification and fluid treatment of fibers and textiles, not otherwise provided for; and subclass 138 for nonenzymatic removal of natural sericin or other naturally occurring gum or wax or an artificially applied size or gum from textile fibers.

19, Textiles, Fiber Preparation, for the mechanical treatment of fibers to put them in condition for use.

162, Paper Making and Fiber Liberation, particularly subclass 2 for the freeing of silk from a cocoon.

264. Cleaning Using a Microorganism or Enzyme:
Processes under subclass 262 wherein the preexisting material is a solid macroscopic material not obtained from a natural

iar to the concentration of solids held in solution or suspension by evaporation of the liquid containing them and the recovery of the concentrate. If the starting material is a solid or slurry placement in Class 34, Drying and Gas or Vapor Contact with Solids, would be indicated. Class 159 will take concentration to the point of crystallization or to dryness, however, removal of water of crystallization is considered to be a chemical reaction and placement would not be proper in Class 159. Evaporating with subsequent vapor condensation is excluded from Class 159 and in such case, placement in Class 203, Distillation: Processes, Separatory, would be proper.

201, Distillation: Processes, Thermolytic, provides for processes of thermolytic distillation wherein a solid carbonaceous material is heated to vaporize a volatile portion and to cause chemical decomposition of the heated material to form different chemical substances at least some of which are volatile and leave behind a solid carbonaceous material.

203, Distillation: Processes, Separatory, provides for processes for separating a liquid mixture by vaporizing and condensing a portion thereof to isolate in the condensed liquid or the unvaporized portion a relatively pure compound which was present in the original mixture. The original mixture may be in a solid form so long as it melts to form a liquid before it vaporizes. A solid original mixture which undergoes chemical decomposition leaving a carbonaceous residue would be classifiable in Class 201, Distillation: Processes, Thermolytic, which is superior to Class 203. Processes including a chemical reaction and a separatory distillation operation are classified in Class 203 only when the chemical reaction merely facilitates the isolation by the separatory distillation operation of a preexisting substance in the distilland. See Class 260, Chemistry, Carbon Compounds, or Class 423, Chemistry, Inorganic, for a process of preparing a compound and isolating it by a separatory distillation process.

210, Liquid Purification or Separation, includes processes for

Processes under subclass 243 where a microorganism is recovered from culture media.

262. Process of Utilizing an Enzyme or Microorganism to Liberate, Separate, or Purify a Preexisting Compound or Composition therefore; Cleaning Objects or Textiles:
Processes under the class definition wherein a preexisting material or compound present in a composition or material containing a preexisting material is contacted with an enzyme or immobilized enzyme or microorganism or plant or animal cells to isolate or recover the preexisting material which is chemically unchanged by the process.

(1) **Note.** Liberation or purification of a preexisting substance is usually accomplished by breaking down or otherwise physically or chemically altering the substance regarded as a contaminant by means of an enzyme or microorganism.

(2) **Note.** The amount of the preexisting compound or material is not increased by the microbial or enzymatic treatment.

(3) **Note.** Resolution of optical isomers or their salts is considered purification or separation of a preexisting compound.

(4) **Note.** Composition includes oil shale deposits, oil, hides, etc.

(5) **Note.** The hydrolysis of starch or proteins to liberate glucose or amino acids, respectively, is not included in this subclass.

*Search This Class, Subclass:*

69, for the hydrolysis of proteins.

94, for the hydrolysis of starch.

*Search Class:*

(c) Refined or crude yeast protein is not classifiable in 426 solely on the basis of a 426 utility. Refined yeast protein is classifiable in Class 260. Crude yeast is usually disposed of on basis of utility.

*Search Class:*

426, Food or Edible Material: Processes, Compositions and Products, appropriate subclasses, particularly subelasses 7+, 61+, 531+, 656+, 800+, for edible compositions containing yeast and their non-propagative methods of preparation.

256. Bakers or Brewers Yeast:
Subject matter under subclass 255 wherein the yeast is Baker's yeast or Brewer's yeast.

(1) Note. Included herein are saccharomyces cerevisiae, compressed yeast, pressed yeast, etc.

257. Unicellular Algae; Media Therefor:
Subject matter under subclass 243 wherein the microorganism propagated or treated is a unicellular algae or the media useful for the propagation of unicellular algae, or a composition containing unicellular algae or methods of preparing the composition or the media.

(1) Note. Edible compositions containing unicellular algae are excluded herefrom.

(2) Note. Multicellular algae are excluded herefrom. Algae are presumed to be multicellular in the absence of a clear showing to the contrary.

*Search Class:*

47, Plant Husbandry, subclass 1.1 for multicellular algae per se; and appropriate subclasses for processes including

282, for processes in which microorganisms are grown in a petroleum oil to remove sulfur.

*Search Class:*

426, Foods or Edible Material: Processes, Compositions and Products, subclass 62 for growing yeast on a hydrocarbon feed-stock which is claimed as edible yeast.

249. Aliphatic:
Subject matter under subclass 248 wherein the hydrocarbon is aliphatic.

250. Having Five or Less Carbon Atoms:
Subject matter under subclass 249 wherein the aliphatic hydrocarbon contains five or less carbon atoms.

251. Utilizing Media Containing Waste Sulphite Liquor:
Subject matter under subclass 243 wherein the media contains waste liquor from the sulfurous acid treatment of cellulose containing material, e.g., paper pulp, etc.

252. Utilizing Media Containing Cellulose or Hydrolysates Thereof:
Subject matter under subclass 243 wherein the microorganism is propagated on a media which contains cellulose or cellulose hydrolysates or the media per se.

(1) Note. Media containing only glucose prepared by the hydrolysis of cellulose are excluded herefrom.

*Search This Class, Subclass:*

253, 254+, and 257 for a media for bacteria or yeast, or fungi, or protozoa or unicellular algae which contains glucose.

253. Bacteria; Media Therefor:
Subject matter under subclass 243 wherein the microorganism

173, for the use of magnetic or wave energy to enhance microbial growth or product production.

287+, for apparatus used in the cultivation, propagation, or innoculation of microorganisms.

*Search Class:*

71, Chemistry, Fertilizers, appropriate subclasses and in particular subclasses 6+ for a fertilizer containing a microorganism.

424, Drug, Bio-Affecting and Body Treating Compositions, appropriate subclasses for a composition of that class and in particular, subclass 93 which may contain a microorganism.

426, Food or Edible Material: Processes, Compositions and Products, appropriate subclasses for a product containing a microorganism and in particular subclasses 7+, 61+, 531+, 656, and 800+.

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: Subject matter under subclass 243 wherein the growth rate of a microorganism or its metabolic activity is stimulated or enhanced by the addition or removal of a particular element or compound which is not required for the microorganism's growth or the control of the pH of the propagation media.

*Search This Class, Subclass:*

41+, for processes in which the synthesis of compounds is enhanced by methods including the addition of stimulants, etc., to the culture media.

*Search Class:*

424, Drug, Bio-Affecting and Body Treating Compositions, subclass 90 for immunologic compositions prepared by the irradiation of a virus.

237. By Serial Passage of Virus:
Subject matter under subclass 236 which involves attenuation of a virus by serial passage by transferring a virus containing body fluid through a series of animals or transfer of supernatant culture fluid through a series of cultures.

238. By Chemical Treatment:
Subject matter under subclass 236 which involves attenuation of a virus by chemical means.

239. Recovery or Purification:
Subject matter under subclass 235 which involves the purification or recovery of a virus in a purified or uncontaminated state.

240. Undifferentiated Animal or Plant Cell, e.g., Cell Lines, etc.; Tissues; Cultivation or Maintenance Thereof; Media Therefor:
Compositions, processes, and media under the class definition for the maintenance or in vitro propagation of plant or animal cells or groups of cells that are not organized tissues.

(1) Note. Where the tissue is first cultured and then destroyed by subsequent extraction for example to extract a compound, or composition from the tissue, the process is not included in this subclass. Such subject matter is provided for in subclasses 41+.

241. Propagation of Single Cells or Cells in Suspension; Maintenance Thereof; Media Therefor:
Subject matter under subclass 240 wherein the plant or animal cells are maintained or propagated in a discrete suspended state.

242. Spore Forming or Isolating Process:

(1) **Note.** Decarboxylases, aldolases, deaminases are examples of subject matter included in this subclass.

233. Isomerases (5. ):
Subject matter under subclass 183 wherein the enzyme catalyzes an isomerization reaction, e.g., AB⟷BA.

(1) **Note.** This subclass includes racemases, epimerases, cis-trans isomerases, intra-molecular oxide reductases, intramolecular transferases, etc.

234. Glucose Isomerase:
Subject matter under subclass 233 wherein the enzyme catalyzes the conversion of xylose to xylulose or glucose to fructose or glucose -6- phosphate to fructose -6- phosphate.

235. Viruses; Bacteriophage; Composition thereof; Preparation or Purification thereof Producing Viral Subunits:
Subject matter under the class definition including a microorganism that (a) contains either ribonucleic acid or deoxyribonucleic acid, (b) is capable of independently entering a host microorganism, and (c) requires a host microorganism having both ribonucleic acid and deoxyribonucleic acid to replicate, processes of propagating, media for propagating and processes of purifying the microorganism and nontherapeutic compositions under the class definition thereof.

(1) **Note.** Propagation is limited to processes concerned with the multiplication of viruses and not with processes concerned with the artificial alteration of genetic material involving changes in the genotype of the virus.

(2) **Note.** This subclass provides for plant viruses such as Tobacco Mosaic virus.

(3) **Note.** This subclass and the indented subclasses are intended to take only a process in which a propagation step takes place, thus, a process involving the mere killing of a living virus is excluded from these subclasses.

dopeptidase activity is involved), enzyme activity within the meaning of this subclass is presumed.

(3) **Note.** Exopeptidase and enzymes having both exo- and endo-peptidase activity are to be found in subclass 212.

220. Derived from Bacteria:
Subject matter under subclass 219 wherein the source of the enzyme is a bacteria.

221. Bacteria ls Bacillus:
Subject matter under the subclass 220 wherein the bacteria is a species of bacillus.

222. Bacillus Subtilus or Bacillus Lichenoformis:
Subject matter under subclass 221 wherein the species of bacillus is Bacillus subtilus or Bacillus lichenofomis.

223. Derived from Fungi:
Subject matter under subclass 219 wherein the source of the enzyme is fungi.

224. From Yeast:
Subject matter under subclass 223 wherein the source of the enzyme is yeast.

225. From Aspergillus:
Subject matter under subclass 223 wherein the fungi is a species of aspergillus.

226. Derived from Animal Tissue, e.g., Rennin, etc.:
Subject matter under subclass 219 wherein the source of the enzyme is animal tissue, glands, etc.

227. Acting on Carbon to Nitrogen Bond Other than Peptide Bond (3.5):
Subject matter under subclass 195 wherein the enzyme catalyzes the hydrolysis of a carbon-nitrogen bond.

lyzes the hydrolysis of an alpha-1, 6-glucosidic bonds of a polysaccharide.

(1) **Note.** Dextranase and isoamylase are examples of enzymes appropriate for this subclass.

211. Dextranase (3.2.1.11):
Subject matter under subclass 210 wherein the enzyme is alpha-1, 6-glucan-6-glucanohydrolase.

(1) **Note.** Alpha-1, 6-glucan-6-glucanohydrolase is defined as an enzyme which hydrolizes dextran to oligosaccharides of various lengths and upon complete hydrolysis of dextran yields isomaltose and trace amounts of glucose.

212. Acting on Peptide Bond, e.g., Thromboplastin, Leucine Amino-Peptidase, etc. (3.4):
Subject matter under subclass 195 wherein the enzyme catalyzes the hydrolysis of amide bonds in proteins or peptides.

(1) **Note.** Exopeptidases (peptidases which hydrolyze single amino acids from the terminus of peptide chains) and enzymes having both exo- and endo-peptidase-activities are examples of enzymes for this subclass.

(2) **Note.** Where the peptide hydrolase activity is unclear or undisclosed and not ascertainable the activity is presumptively that of an endopeptidase.

*Search This Class, Subclass:*

227, for enzymes which hydrolyze the amide bond in compounds other than proteins or peptides.

213. Trypsin; Chymotrypsin:
Subject matter under subclass 212 wherein the enzyme catalyzes the hydrolysis of the amide bond connecting the carboxyl

(2) **Note.** In the absence of a clear showing to the contrary the recitation of "amylase" is presumed to mean alpha-amylase.

202. Alpha-Amylase, Microbial Source:
Subject matter under subclass 201 wherein the source of alpha-1, 4-glucano-4-glucanohydrolase obtained is a microorganism.

(1) **Note.** In the absence of a clear showing to the contrary, a recitation of "amylase" is presumptively alpha-amylase.

203. Fungal Source:
Subject matter under subclass 202 wherein the source of alpha-1, 4-glucan-4-glucanohydrolase is a fungi.

(1) **Note.** Takadiastase, koji, and taka-koji are classifiable in this subclass.

204. Alpha-Amylase, Plant Source (3.2.1.1):
Subject matter under subclass 201 wherein the source of alpha-1, 4-glucan-4-glucanohydrolase is a nonmicrobial plant.

(1) **Note.** An alpha-1, 4-glucan-4-glucohydrolase is an enzyme that catalyzes in a random fashion the hydrolysis of the alpha-1, 4-glucan bonds in carbohydrates that contain three or more alpha-1, 4-linked-D-glucose units and does not hydrolyze alpha-1, 6- bonds connecting D-glucose units.

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

205. Glucoamylase (3.2.1.3):
Subject matter under subclass 201 wherein the enzyme obtained is an alpha-1, 4-glucanglucohydrolase.

(1) **Note.** Alpha-1, 4-glucanglucohydrolase for the purpose of

transfer phosphate from a nucleoside di- or triphosphate to an acceptor are examples of transferases.

(4) **Note.** Ribonuclease is excluded herefrom.

(5) **Note.** A transferase which catalyzes the cleavage of a functional group from one part of a molecule and its transfer to another part of the same molecule, i.e., an intramolecular transferase, is considered an isomerase and is excluded herefrom.

*Search This Class, Subclass:*

199, for ribonuclease.

233, for transferases which catalyze the cleavage of a functional group from one part of a molecule and the transfer to another part of the same molecule.

194. Transferring Phosphorus Containing Group, e.g., Kineases, etc. (2.7):
Subject matter under subclass 193 wherein the functional group transferred contains phosphorus.

195. Hydrolase (3.):
Subject matter under subclass 183 wherein the enzyme catalyzes the following reaction; $AB + H_2O \rightleftharpoons AOH + BH$

(1) **Note.** The compounds hydrolyzed are usually carboxylic esters, thiolesters, phosphoric esters, sulfuric esters, glycosides, ethers, peptides, amides, amidines, nitriles, acid anhydrides, organic halides, etc.

(2) **Note.** Peptidases, esterases, glycosidases, and phosphatases are examples of hydrolases.

196. Acting on Ester Bond (3.1):

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+.

189. Oxidoreductases (1. ), e.g., Luciferase:
Subject matter under subclass 183 wherein the enzyme catalyzes an oxidation-reduction reaction between a donor and acceptor, e.g., $AH_2 + B = A + BH_2$, etc.

(1) Note. An oxidation-reduction reaction for the purposes of this classification involves the transfer of oxygen, hydrogen, or electrons from a donor to an acceptor.

(2) Note. A water molecule is not considered to be an acceptor or a donor.

(3) Note. Oxidoreductases which catalyze a reaction between a donor and acceptor are different portions of the same molecule, i.e., an intramolecular oxidoreductase, are considered to be isomerases and are excluded herefrom.

*Search This Class, Subclass:*

233+, for isomerases which are oxidoreducatases which catalyze a reaction between a donor and acceptor on the same molecule.

for enhancing enzyme activity, processes for forming granular or free-flowing enzyme compositions.

(6) **Note.** Proenzymes or precursors of enzymes are classified with the related enzyme.

(7) **Note.** The bracketed numerals following the titles in this and the indented subclasses refer to the nomenclature system recommended by the Commission on Biochemical Nomenclature on the Nomenclature and Classification of Enzymes. The titles include the enzymes defined by the bracketed numerals but are not limited to the enzymes so classified.

184. Enzyme Inactivation by Chemical Treatment:
Processes under subclass 183 wherein the enzyme is contacted with an element or chemical compound to reduce its catalytic activity.

(1) **Note.** Processes such as the treatment of an enzyme containing a sulfhydryl group in the active site with mercuric salts, etc., are included herein.

(2) **Note.** Selective inactivation by chemical treatment to obtain a greater proportion of certain enzymes is found in this subclass.

185. Malt:
Subject matter under subclass 183 wherein the enzyme containing composition is green, partially dried, dried, kilned malt, or malt extract.

(1) **Note.** This subclass is intended to provided for documents which germinate grain to produce a mixture containing enzymes, i.e., malt rather than the use of grain as a substrate for microorganism growth, e.g., ergot on rye grain, etc. If the crude mixture is subjected to further refinement to obtain a specific enzyme, placement should be on the basis of the enzyme obtained.

tized polysaccharides are carbohydrates within the meaning of this subclass.

179. Carbohydrate Is Cellulose or Derivative Thereof:
Subject matter under subclass 178 wherein the carbohydrate is cellulose or a substituted cellulose.

(1) **Note.** Examples of substituted cellulose are DEAE cellulose, etc.

180. Carrier is Synthetic Polymer:
Subject matter under subclass 177 wherein the support material is a linear or cross-linked polymer which is not naturally occurring.

181. Attached to the Carrier Via a Bridging Agent:
Subject matter under subclass 180 wherein the enzyme or microbial cell is bonded to the polymeric carrier through an intermediate compound which attaches to both the enzyme and the carrier.

(1) **Note.** The formation of the immobilized enzyme or cell may be in a stagewise manner with a reaction between the carrier and bridging agent being completed before the enzyme is added or in a process in which the carrier, bridging agent, and enzyme are present simultaneously in which case some care should be exercised in distinguishing the process of this subclass from mere entrapment. In general, if three separate entities, i.e., enzyme and two different chemical species are present simultaneously bonding through a bridging agent should be presumed.

(2) **Note.** A product or process classifiable in this subclass combines a polymeric carrier with a bridging agent to provide functional groups for enzyme attachment. It should be noted that similar functional groups can be provided by formation of a polymeric carrier by copolymerization of monomers one or more of which contain the desired functional group for enzyme attachment and that such would be provided for in subclass 180.