BIOTECHNOLOGY & LAW Final Examination Exam No. _____
Prof. Jepson

Instructions:

There are TWO Sections: (1) 50 multiple-choice questions worth 50 points; (2) Very Short Answer questions where you choose questions adding up to 50 points. You may divide your time any way you like.

Check right now that you have **26** consecutively numbered pages, including three pages of attachments.

Put your Examination number on this booklet and on the Scantron™ answer sheet. Turn in BOTH.

CLOSED BOOK EXAMINATION: You may NOT use course materials, notes, outlines, or anything else. YOU MAY NOT USE A COMPUTER. You may use your own handheld dictionary.

Multiple Choice

Your score will be the number correct.

Using a No. 2 pencil, fill in the bubbles on the SCANTRON™ sheet. Fill in completely the bubble that you believe corresponds to the BEST choice of the five responses. Make no stray marks. If you erase, erase completely. This portion of the Exam is machine scored and there will be no manual recount. THIS IS YOUR RESPONSIBILITY.

If you wish to explain an answer, do so in this booklet.

VERY Short Answer

Pick any combination of questions for a total of 50 points. Answer each question you choose in the space immediately following the chosen question. I will read only your responses to the first fifty points worth of questions NOT your best fifty. I will read no word beyond the word limit.

Good Luck and have fun!

1. To be admissible in Federal Court, biological scientific evidence must be:
   a) Relevant and reliable
   b) Reliable and valid
   c) Relevant and valid
   d) Scientific and knowledge
   e) Generally accepted

2. To be admissible in California State Courts, scientific evidence must be:
   a) Relevant and generally accepted
   b) Relevant and reliable
   c) Reliable and valid
   d) Relevant and valid
   e) Scientific and knowledge

3. The applicable tests in (1) Washington State court and (2) Federal court are from:
   a) (1) *Frye* and (2) *Daubert*
   b) (1) *Daubert* and (2) *Frye*
   c) (1) FRE and (2) *Daubert*
   d) (1) FRE and (2) *Frye*
   e) (1) *Frye* and (2) *Dilbert*

4. The "Natural Rights" justification for the private ownership of the commons originated with:
   a) Richard Dawkins
   b) John Locke
   c) Adam Smith
   d) Garrett Hardin
   e) Jane Radin

5. The private incentive to improve and market new and undeveloped biological ideas will be less than the social value of such efforts unless:
   a) The idea owner is given exclusive control of the idea.
   b) The prospective purchaser knows what he is buying.
   c) The idea is unburdened by potential liability claims.
   d) The idea can be brought to market.
   e) There are few disputes over ownership.

6. In the *Moore v. U. of Calif.* (the hairy-cell leukemia case) the greatest influence on the decision of the majority NOT to extend liability for conversion was:
   a) Public policy
   b) Caselaw
   c) Statutory law
   d) Local precedent
   e) Moore's unclean hands (equity)

7. In *Moore v. U. of Calif.*, the plaintiff settled his informed consent claim for $50,000. To succeed on his conversion theory, he would have had to show:
   a) Ownership of his property was permanently interfered with by defendant(s).
   b) Living cells can be personal property.
   c) The hairy-cell leukemia cells belonged to him.
   d) The lymphokines produced by the Mo cell line were unique and identifiable.
   e) Science is advanced by rewarding the patient more than it is advanced by rewarding the physician.

8. In *Moore v. U. of Calif.*, the holding was
   a) Physicians must disclose personal interests unrelated to a patient's health, research or economic, that may affect the physician's professional judgment; and failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent.
   b) Ownership of Moore's property was permanently interfered with by Dr. Golde.
   c) Removal of hairy cell leukemia cells from a patient does not terminate the patient's possessory interests.
   d) Biotechnology is advanced by rewarding science and industry more than it is advanced by rewarding patients .
   e) Living cells can be personal property.

9. The *Moore v. U. of Calif.* decision that I assigned you to read was decided by:
   a) The Supreme Court of the United States of America.
   b) The United States Court of Appeals for the Federal Circuit.
   c) The United States Court of Appeals for the Ninth Circuit.
   d) The California Supreme Court.
   e) Learned Hand.

10. The failure or inability to recognize private property rights in certain types of goods often leads to a variety of adverse effects, including
   a) Arrow's Paradox
   b) The Tragedy of the Commons
   c) The Free Rider Problem
   d) All the above
   e) Just "b" and "c"

11. To avoid inefficiencies, United States law generally favors the establishment of property rights in new technology because:
    a) Giving innovators the exclusive right to reap the benefits of their efforts compensates them for the costs of innovation, the risk of failure, and the potential liability that can arise if the product proves defective.
    b) If successful entrepreneurs are denied exclusive rights, they will be less likely to invest the necessary time, money, and energy into innovation.
    c) Denying free access to innovation impoverishes society, therefore society wants to strike a balance through positive law between giving access and restricting access.
    d) All the above.
    e) None of the above.

12. Federal law preempts enforcement of a State law right if
    a) Congress has explicitly preempted the state law.
    b) A federal scheme occupies a given field.
    c) Compliance with both state and federal law is impossible.
    d) Operation of the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.
    e) Any of the above.

13. The fumes from drying house paint are a(n) ___1___ but if the home owner attempted to buy the right to put vapors in his neighbors' air, the home owner would likely face the ____2___ problem.
    a) (1) external problem; (2) black box.
    b) (1) negative externality; (2) holdout.
    c) (1) transaction cost; (2) freerider.
    d) (1) positive externality; (2) Coarse.
    e) (1) transaction cost; (2) holdover.

14. Genentech's discharge into San Franciso bay does $100,000 damage every year to the Oyster Farmers. It would cost Genentech $80,000 a year to run cleanup equipment to eliminate the damage. Oyster Farmers would make $50,000 a year less if they converted the oyster beds to storage uses. Who benefits from the externality and by how much?
    a) The Oyster farmers by $30,000.
    b) The Oyster farmers by $50,000.
    c) Genentech's customers by $100,000.
    d) Genentech's customers by $80,000.
    e) Genentech's customers by $30,000.

15. Genentech's discharge into San Franciso bay does $100,000 damage every year to the oyster farmers. It would cost Genentech $80,000 a year to run cleanup equipment to eliminate the damage. The Oyster Farmers would make $50,000 a year less if they converted the oyster beds to storage uses. If the Oyster Farmer's go to court and get an injunction, and there are no transaction costs.
    a) Genentech will continue discharging, but the farmers will receive something more than $50,000 but less than $100,000.
    b) Genentech will continue discharging, but the farmers will receive something more than $50,000 but less than $80,000.
    c) Genentech will continue discharging, but the farmers will receive something more than $30,000 but less than $50,000.
    d) Genentech will stop discharging.
    e) Genentech will relocate.

16. Genentech's discharge into San Franciso bay does $100,000 damage every year to Oyster Farmers. It would cost Genentech $20,000 a year to run cleanup equipment to eliminate the damage. Oyster Farmers would make $50,000 a year less if they converted the oyster beds to storage uses. If Oyster Farmers go to court to get an injunction, but the court rules that Genentech is not doing anything wrong, and there are no transaction costs.
    a) Genentech will continue discharging, and the Oyster Farmers will continue osytering.
    b) Genentech will continue discharging, and Oyster Farmers will go into the storage business.
    c) Genentech will continue discharging, but Oyster Farmers will receive something more than $30,000 but less than $50,000.
    d) Genentech will stop discharging, and will get money from Oyster Farmers.
    e) Genentech will stop discharging, and will get money from the ex-Oyster Farmers now in the boat storage business.

17. Ms. Dawkins made three arguments. First, that current biotechnology laws allow "patents on life", which is immoral. Second, current biotechnology laws increase the cost of medical research by non-patent-holders. Third, genetic engineering is inherently dangerous.
    a) The First argument is well-taken, except that patents on life are not immoral.
    b) The First argument is well-taken, except that whether or not patents on life are immoral is a value judgment.
    c) The First argument is well-taken.
    d) The First argument is well-taken, except that moral issues are not for the PTO to decide).
    e) The First argument is not well-taken because life is an abstraction, hard to define, impossible to patent.

18. Ms. Dawkins argued that current biotechnology laws increase the cost of medical research by non-patent-holders.
    a) The argument is well-taken because firms patent simple discoveries, such as gene sequences that they happened to have stumbled across.
    b) The argument is well-taken because the owner of an asthma gene might try to charge others for the privilege of experimenting with it.
    c) The argument is well-taken because, in practice, companies always enforce their patents against research uses, especially when that research may produce profitable products down the road.
    d) The argument is not well-taken because the absence of patent protection would make firms keep information secret and will decrease the amount of research.
    e) The argument is well-taken because without proper patent protection, biotech firms are unlikely to spend the huge sums needed to invent a drug in the first place, as Europe and Brazil shows.

19. Dawkin's third argument—that genetic engineering is dangerous—cannot be disproved, but
    a) That is a reason for keeping clinical trials strict; it does not justify a patent regime that hampers biotechnology itself.
    b) All the evidence is that biotechnology is perfectly safe.
    c) The best hope for curing many diseases – and the only hope of beating genetic disorders – should be outlawed.
    d) If nature can produce smallpox, the AIDS virus, and malarial mosquitoes, then there is no reason why a scientist could not make something equally nasty.
    e) All the above

20. State law may not "give protection of a kind that clashes with the objectives of the federal patent laws." In ***Moore*** v. ***U. of Calif.***, would federal patent law preempt a holding that Moore has any property rights under state law in the Regents' patent, including the patented cell line.
    a) No, because Moore's rights under state property law are different from and do not interfere with the rights protected by the patent laws.
    b) Yes, if Moore would, in essence, have rights as a joint inventor.
    c) Yes, because Moore could not enforce a state property right without invalidating the patent.
    d) Yes, because Moore could not enforce a state property right without asserting a federal ownership interest in the patent.
    e) Yes, because Moore could not enforce a state property right without preventing Golde from getting the patent.

21. Could the University of California and Dr. Golde have a patent on John Moore's blood containing his hair-cell leukemia lymphocytes?
    a) Yes, and they did!
    b) No, only the individual, Dr. Golde, could file for the application for that patent, which he did, and then he assigned the application and patent to the University.
    c) No.
    d) Yes, but the court declared Moore a co-inventor.
    e) Yes, but the court declared Moore a joint inventor.

22. In *Moore v. U. of Calif.,* the viewpoint of the majority was __1__ because it focused on the need to create the resource; while the viewpoint of Justice Mosk in dissent was ___2___, because it took the resource as a given and asked what would be a fair division.
    a) (1) Ex ante; (2) Ex post
    b) (1) Ex post; (2) Ex ante
    c) (1) Unfair; (2) Equitable
    d) (1) Coasian; (2) Lockean
    e) (1) divisive; (2) remedial

23. All the profitable pure biotech firms are in America. Our laboratories have poured out a glass of blessings upon the world, providing limitless supplies of insulin, iagra, novel treatments for cancer, and crops that resist pests or do not rot. As yet, no European biotech firm has brought a single notable pill to market. According to the 1997 *The Economist* article from your readings (from which I took the above) why are European biotechnology firms so feeble?
    a) Europeans are as thick as two planks.
    b) Shortages of money and of managers, and an excess of militant greens.
    c) Dolly, the cloned sheep, created a back-lash.
    d) The European Parliament voted to harmonize Europe's rag-bag of national patent laws.
    e) You cannot patent life.

Questions 24 through 26 are from ***Commonwealth*** v. ***Lanigan*** (the population structure DNA forensics case).

24. The Commonwealth followed the __1__ test in deciding whether to admit the __2__ offered by the Commonwealth.
    a) (1) Frye test; (2) scientific data
    b) (1) Frye test; (2) opinion
    c) (1) Daubert test; (2) scientific data
    d) (1) Daubert test; (2) opinion
    e) (1) Frye test; (2) population studies

25. Evidence of a match between the DNA on the victim's clothes and the suspect's DNA:
    a) Buys suspect a ticket to jail.
    b) Is admissible if the match is random.
    c) Is meaningless without evidence indicating the significance of the match.
    d) Is not admissible in the Commonwealth of Mass., if the proponent based his testimony on the product rule.
    e) Is not admissible in the Commonwealth of Mass., if the proponent based his testimony on the ceiling rule.

26. This proposition: "Whether the community of biologists involved generally accepts as valid and sound the genetics-based theory that was the basis of a geneticist's testimony" — could be referred to as the:
    a) Frye Test
    b) Daubert Test
    c) PCR test
    d) RFLP test
    e) Lanigan test

27. Why was Dr. Unger allowed to tell the jury about the amount of the breakdown products of succinyl acetylchloride he found in Ms. Coppolino's thigh?
    a) Inventors can normally testify about their inventions.
    b) The test had gained general acceptability.
    c) The court applied the Daubert test, and Dr. Unger's methods were scientifically valid and reliable.
    d) While Dr. Unger's test did not meet the requirements under Frye, that fact only went to the weight not the admissibility.
    e) There was no objection.

28. The most likely obstacle to the admissibility of Dr. Unger's testimony would have been issues regarding:
    a) The Reading on the instrument.
    b) The correctness of the Laboratory Procedures.
    c) The adherence to good, accepted Laboratory Protocols.
    d) The scientific validity of the Underlying Theory.
    e) The general acceptance of the Toxicity Level of succinyl acetylchloride.

29. The appropriate group to look to in determining the admissibility of Dr. Halprins' testimony, would have been:
    a) Pathologists.
    b) Biochemistry Professors.
    c) People situated similarly to Marge Farber.
    d) Grave Diggers.
    e) Medical Doctors in Family Medicine.

30. Celera's whole genome approach has __ stages:
    a) Three: Sequencing; Assembly; and Analysis.
    b) Three: Chopping; Tagging; and Running a gel.
    c) Four: DNA; RNA; Ribosome; and Protein.
    d) Four: Isolate; Amplify; Select; and Identify.
    e) Five: Identify; Isolate; Replicate; Patent; and Sell.

31. At which stage(s), if any (speaking potentially and hypothetically, but realistically), could value be added to Celera by a knowledgeable intellectual property advisor:
    a) Every stage
    b) No stage
    c) Stages 1, 3, & 4
    d) Stages 1 & 3
    e) Stage 3

32. If in a jurisdiction, 327 appellate court rulings have upheld the admissibility of DNA evidence from RFLP tests, then in that jurisdiction
    a) The admissibility of DNA evidence cannot be challenged.
    b) A judge will likely take judicial notice of the validity of RFLP.
    c) A judge will likely take judicial notice of the admissibility of DNA evidence.
    d) The request for admissibility in the 328th case must be accepted.
    e) Dr. Coppolino's medical license would be restored.

33. This document, __1__, resulted from __2__ and is the vehicle by which the principles underlying DNA forensic evidence usually gets admitted in court proceedings.
    a) (1) The TWGDAM; (2) corroboration between the FBI and the forensic DNA industry.
    b) (1) The NRC II; (2) the Human Genome Project.
    c) (1) The TWGDAM; (2) the Human Genome Project.
    d) (1) The NRC II; (2) thousands of invalid DNA test.
    e) (1) The NRC II; (2) the California Department of Corrections DNA Database.

34. Merrill Dow removed Benedictine from the market because:
    a) Too many birth defects.
    b) Too many law suits.
    c) Too much good science.
    d) Too much criticism from ObGyns.
    e) Too much morning sickness.

35. A large percentage of the people who are good at knitting are not good at cleaning a rifle. The explanation could be:
    a) The genes are linked
    b) The genes are not linked
    c) The genes are sex linked
    d) The alleles are not independent
    e) The allelic frequency depends upon sub-populations

36. According to the article from <u>The Economist</u> that I distributed the day we watched the twelve-fingered guy play the piano, what percent of our genome appears to be parasitic?
    a) 2
    b) 20
    c) 45
    d) 80
    e) 90

37. According to the article from The Economist that I distributed the day we watched the twelve-fingered guy play the piano, of the __1__ genes Celera reports to be in the human genome, __2__ of those genes are NOT found in the mouse?
   a) (1) 130,000; (2) none
   b) (1) 26,588; (2) 300
   c) (1) 100,000; (2) 15,000
   d) (1) 130,000; (2) 300
   e) (1) 30,000; (2) 3,000

38. SNPs are
   a) Places where the genomes of individuals differ by a single genetic letter.
   b) Important because they can be used as signposts because each SNP is likely to have an independent evolutionary origin, therefore, if two people share one , the chances are they will share the same versions of the genes that are near that SNP.
   c) Important because they act as markers for particular versions of genes.
   d) Important because they are among the causes of different versions of a gene.
   e) All the above and more.

39. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991) (the "Double Lumen Catheter" case) was an appeal from a decision by __1__ on the issue of ___2___.
   a) (1) Judge Dillin sitting in the USDC in Indiana; (2) was the addition of the second lumen obvious.
   b) (1) Judge Dillin sitting in the De Paw county Superior Court; (2) who owned the technology.
   c) (1) Judge Easterbrook sitting in the Northern District of Illinois; (2) can a drawing satisfy the written description requirement.
   d) (1) Judge Rich; (2) was the addition of a lumen an obvious variation.
   e) (1) Judge Rich; (2) can a drawing satisfy the written description requirement.

40. The following paragraph about _____ is from ***Evans*** v ***Eaton*** (1822) (Story, J.):

> * * * to put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is, therefore, for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

a) The written description requirement
b) The best mode requirement
c) The novelty requirement
d) The nonobviousness requirement
e) The enablement requirement

41. This year it took Myriad three months to sequence a grain of rice. Yet, in the not to distant future Uma had Ethan sequenced in under an hour. The difference ___1 ___ be explained rationally because ___2___:

a) (1) Can largely; (2) It is largely only necessary to look for predictable variations from the expected.
b) (1) Cannot; (2) It is largely only necessary to look for predictable variations from the expected.
c) (1) Can largely; (2) Sequencing can be computerized.
d) (1) Cannot; (2) It will always be necessary to amplify prior to sequencing.
e) (1) Cannot; (2) It is unethical and therefore will not happen.

42. An innovative biotech firm selling only unique and well-protected products is likely to have an "Average Cost Curve" that is U-shaped because:
   a) At first costs are low; then later decreasing economies-of-scale are balanced by decreasing transaction costs.
   b) Average variable costs are initially high, then drop with increasing economies-of-scale, and then rise when production costs increase due to the transaction cost of the need to pay premiums.
   c) Average variable costs are straight, but fixed costs are U-shaped.
   d) Marginal cost is flat, but actual costs always rise.
   e) Ex ante, monopolists never prosper.

43. ***Yamanouchi*** v. ***Danbury*** (the Pepcid AC case):
   a) Was a matter of first impression before the Federal Circuit.
   b) Presented issues related to obviousness.
   c) Dealt specifically with patent term restoration.
   d) A and B.
   e) All of the above.

44. The best argument that generic companies should be able to certify a Big Pharma patent under 21 U S C § 355(j)(2)(A)(viii)(IV) without fear of having attorneys' fees accessed is:
   a) Big Pharma probably does frivolous R&D
   b) Title 21 allows such certification
   c) In the long run, there will be more drugs at lower cost
   d) In the short run, there will be more drugs at lower cost
   e) Title 35 provides an exemption

45. Mr. Abhishek Malhotra proposed that we need to define "Genetic Information" because:
    a) As a predictive tool genetic information is not very accurate.
    b) Management of genetic information depends upon how it is defined.
    c) Genetic information is different from other medical information.
    d) The activities of Insurance Companies should not be unduely impeded.
    e) All of the above.

Questions 46-50 are from the presentation by Mr. Sampath Kumar Karai-Pattabiram and the decision in ***International Dairy Foods Ass'n*** v. ***Amestoy***, 92 F.3d 67 (2d Cir. 1996) (the blue dot milk case).

46. Who was Jeffrey Amestoy?
    a) A Holstein milk cow dairy association representative
    b) Counsel for Ben & Jerry
    c) Attorney General of Vermont
    d) Owner of Greenfield Diaries
    e) The owner of a country store that sold blue dot milk

47. All other considerations aside, under the ***Amestoy*** ruling, would Chicken Ranchers be allowed to decide as an industry that the term "Free Range" meant "20 minutes of exercise a day" and thereafter label birds so treated as "100% Free Range."
    a) No, because the FDA has not sanctioned that label.
    b) No, unless the FDA certifies the so labeled birds.
    c) No, unless the FDA approves after Notice & Comment.
    d) No, because its inherently misleading.
    e) Yes!

48. The FDA __1__ generally characterized transgenes and other bioengineered substances such as proteins, carbohydrates, fats, or oils as ___2___, because they are ubiquitous in living organisms and comparable to substances in foods already on the market and are therefore ___3___.
   a) (1) has; (2) food additives; (3) GRAS
   b) (1) has not; (2) food additives; (3) GRAS
   c) (1) has; (2) adulterative; (3) GRAS
   d) (1) has; (2) food additives; (3) safe
   e) (1) has not; (2) adulterative; (3) safe

49. The position of the Government of India is more like that of the United States and less like that of European countries on the topic of GM foods because
   a) GM foods are completely safe and risk-free.
   b) Europeans have extensive experience with poisonous foods.
   c) India has a burgeoning biotechnology industry.
   d) Europe has ruled that the treatment of cows is a "material fact" that should be disclosed.
   e) What people "think" they need to know is irrelevant.

50. In ***Stauber*** v. ***Shalala***, consumer advocates unsuccessfully tried to force the FDA to require labeling of milk produced with the use of recombinant bovine somatotropin, because the milk is compositionally indistinguishable from milk produced without the hormone. Thus, the district court concluded in effect that
   a) A labeling requirement based solely on consumer demand to know the method of manufacture would violate the FFDCA.
   b) The Method of Manufacture was not a material fact.
   c) The Composition of the Product was a material fact.
   d) A labeling requirement based solely on consumer demand to know the method of manufacture would violate the First Amendment rights of the Milk producers.
   e) All the above.

51. Mr. Miguel Tachna Felix, spokesman for Agricultural Association of Rio Fuerte, Mexico, says United States Pat. No. 5,894,079 – also known as the "Enola bean" patent – "has caused great economic hardship for farmers in northern Mexico * * * we welcome attempts to overturn it!" Mr. Felix must be:
   a) Arguing the '079 patent keeps Mexican imports out of the United States.
   b) Mistaken.
   c) Under the misconception that patents are transnational.
   d) Proposing that plants cannot be protected by utility patents.
   e) Elevating superstitious nonsense over scientific fact.

52. Mr. Felix asserts that the American patent holder spirited the yellow bean out of Mexico after misappropriating it from a village deep in the heart of the Mayacocaba valley where the natives have grown and consumed it for centuries. If Mr. Felix' assertions are true:
   a) The '079 patent is invalid for anticipation.
   b) The '079 patent is invalid for theft.
   c) The '079 patent is invalid for obviousness.
   d) The '079 patent could be invalidated during reexamination based on the facts regarding Mexico.
   e) The '079 patent would not be invalidated during reexamination based on the facts regarding Mexico.

53. Good argument(s) for not giving Patent Term Extensions include
   a) The patentee has not really lost anything, and certainly nothing that is the fault of the patent system.
   b) There is no check to be sure Big Pharma is not doing frivolous R&D.
   c) The PTO needs no incentive to work briskly.
   d) Extensions are available only really for drugs that are enormously profitable.
   e) It makes more sense to extend the term of FDA exclusivity.

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Pick any combination of questions for a total of 50 points. Answer each question you choose in the space immediately following the chosen question. I will read only your responses to the first fifty points worth of questions NOT your best fifty. I will read no word beyond the word limit.

Questions 1-3 are based upon United States Patent No. 6,174,724 B1 (the cover sheet, one page of drawings, and the claims of which are attached) and the facts stated in this paragraph:

> 3.5 Trillion GM plants have been harvested and consumed in the United States, Canada, and Argentina. In those countries, it is almost impossible for humans to avoid consuming GM foods, or farm animals that have consumed GM foods. Two genetically engineered traits — herbicide tolerance and B.t. insect resistance were included in almost all of the 44 million hectares of GM crops last year.

1. (10 points) State in short, declarative phrases (totaling 35 words or fewer cumulatively), as counsel for Monsanto, in the space provided immediately below, a rebuttal to the following quote from the 27 April 2001 Rural Agricultural Foundation Report:

> "This raises very sharply the question of what we should do about patented research tools," remarks IP specialist John Barton of Stanford Law.

2. (5 points) State in short, declarative phrases (totaling 25 words or fewer cumulatively), as counsel for Monsanto, by way of material for a Press

Release, describe what Monsanto is going to do for the world with respect to this patent (without of course compromising any of Monsanto's rights).

3. (5 points) In two words or fewer, what is this sort of patent derogatorily referred to as?

4. (10 points) Describe in 35 words or fewer what is illustrated in FIG. 6 of the patent. (This question not available to anyone who would have been able to answer it before taking this class. I will resolve all my doubts in favor of denying you any credit.)

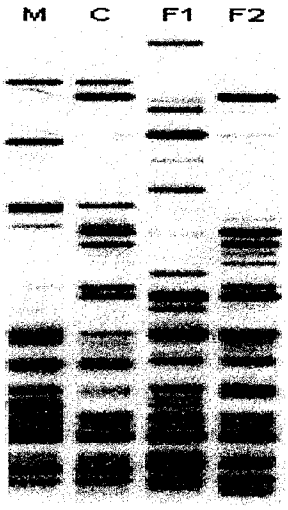
5. (10 points) In 35 words or fewer, in the space provided immediately below, explain, citing authority and using terms of art, whether or not the following quote is a sufficient statement of utility of a biotechnology invention in a specification of a patent application.

> "Our in vitro tests, as described below, illustrate the cytotoxicity of the claimed compounds against human tumor cells; we conclude the compounds have a good action."

6. (5 pts) In two words, in the space provided immediately below, what was the form of the Scientific Evidence that Daubert's parents sought to have admitted on the Motion for Summary Judgment?

7. (10 points) In 35 words or fewer, in the space provided immediately below, explain, citing authority and using terms of art, what this most cited ***Daubert*** quote means: "the focus of the trial court's inquiry must be solely on the principles and methodology, not on the conclusions they generate."

8. (20 points) In 75 words or fewer, in the space provided immediately below, explain and using terms of art, who is the father, how you know, the name of the test, who invented it, how it is performed, and what is the "Prosecution Fallacy".



9. Fill in the blanks in the following from *B. Braun Medical Inc.*, v. *Abbott Laboratories*, 124 F.3d 1419 (Fed. Cir. 1997) (the SafSite Valve case). (10 points)

Abbott asserted the equitable defenses of _____ _____ , _____ and _____ _____ . The jury found no infringement because it construed the fifth element of the claims as requiring a traverse cross bar, or its equivalent, which it found lacking in the accused products. The court, relying on the _____ _____ of the patent, _____ the jury's interpretation of the claim. The trial court told the jury: "[A] patent holder is not allowed to place restrictions on customers which prohibit resale of the patented product, or allow the customer to resell the patented product only in connection with certain products. * * * If you find, by _____, that Braun placed such restrictions on its customers, including Abbott, you must find that Braun is guilty of _____."

The theory behind this rule is that in such a transaction, the patentee has bargained for, and received, an amount equal to the full value of the goods. This _____ doctrine, however, does not apply to an expressly _____ sale or license.

Assume Braun sells the SafSite value in a shrink wrapped package labeled "One Use Only: Do Not Clean and Reuse" under an agreement having such terms. If Abbott sells replacement part to hospitals that use to refurbish used SafSite valves, Abbott may be liable for _____ if the hospitals are liable for _____.

GIVE ME YOUR OPINION PLEASE -- Grade the following presentations based on Quality and Value (ignore showmanship and confidence to the extent you can):

Mr. Abhishek Malhotra– Privacy of Genentic information __
Mr. Chang Hong – Affymetrix v. Incyte, ___
Dr. Matt Leff – Danbury v. Yamanouchi, FDA paragraph 4 Certification __
Ms. Kaji Reiko – Rebuttal to Fair use of Drug Patents ___
Mr. Mike Frodsham – Economics of Biotechnology research and Obviousness ___
Mr. Paul Kroon – Utility Standard for Biotechnology Patents __
Mr. Sumeet Malik – Protection of Indigenous Medicine from Western IP ___
Mr. Sampath Kumar Karai-Pattabiram – Frankenfood, should GM food be FDA approved _____
Mr. Aaron Young-- Array technology _____

US006174724B1

(12) **United States Patent**
Rogers et al.

(10) **Patent No.: US 6,174,724 B1**
(45) **Date of Patent: *Jan. 16, 2001**

(54) **CHIMERIC GENES SUITABLE FOR EXPRESSION IN PLANT CELLS**

(75) Inventors: **Stephen G. Rogers**, Webster Groves; **Robert T. Fraley**, Glendale, both of MO (US)

(73) Assignee: **Monsanto Company**, St. Louis, MO (US)

(*) Notice: Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **08/435,951**

(22) Filed: **May 4, 1995**

Related U.S. Application Data

(62) Division of application No. 08/127,100, filed on Sep. 24, 1993, which is a continuation of application No. 07/732,974, filed on Jul. 19, 1991, now abandoned, which is a continuation of application No. 07/333,802, filed on Apr. 5, 1989, now Pat. No. 5,034,322, which is a continuation of application No. 06/793,488, filed on Oct. 30, 1985, now abandoned, which is a continuation of application No. 06/458,414, filed on Jan. 17, 1983, now abandoned.

(51) **Int. Cl.**[7] **C12N 15/82**; C12N 15/84; C12N 5/04; C12N 15/31

(52) **U.S. Cl.** **435/419**; 435/69.1; 435/70.1; 435/252.2; 435/252.3; 435/252.33; 435/418; 435/469; 536/23.2; 536/23.7; 536/24.1; 536/23.6; 800/288; 800/294

(58) **Field of Search** 536/23.2, 23.7, 536/24.1, 23.6; 435/69.1, 70.1, 172.3, 240.4, 252.2, 252.3, 252.33, 419, 418, 469; 800/205, 294, 288

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Primary Examiner—David T. Fox
(74) *Attorney, Agent, or Firm*—Lawrence M. Lavin, Jr.; Howrey Simon Arnold & White, L.L.P.

(57) **ABSTRACT**

This invention relates to chimeric genes which are capable of being expressed in plant cells. Such genes contain (a) a promoter region derived a gene which is expressed in plant cells, such as the nopaline synthase gene; (b) a coding or structural sequence which is heterologous with respect to the promoter region; and (c) an appropriate 3' non-translated region. Such genes have been used to create antibiotic-resistant plant cells; they are also useful for creating herbicide-resistant plants, and plants which contain mammalian polypeptides.

23 Claims, 27 Drawing Sheets

24

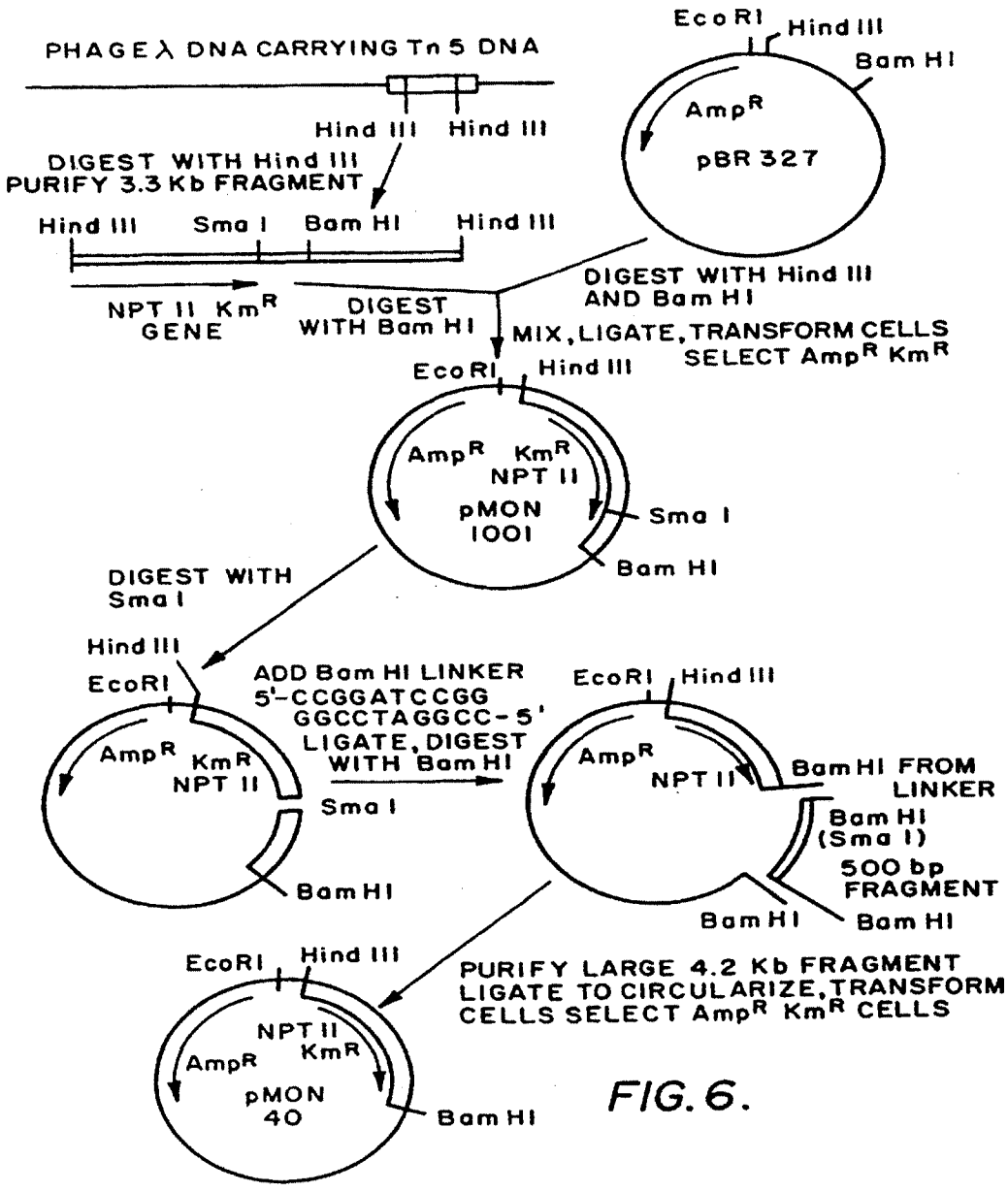

PHAGE λ DNA CARRYING Tn 5 DNA
Hind III
Hind III
DIGEST WITH Hind III
PURIFY 3.3 Kb FRAGMENT
Hind III
Sma I
Bam HI
Hind III
NPT II Km^R GENE
DIGEST WITH Bam HI
EcoRI
Hind III
Amp^R
pBR 327
DIGEST WITH Hind III AND Bam HI
MIX, LIGATE, TRANSFORM CELLS SELECT Amp^R Km^R
EcoRI
Hind III
Amp^R
Km^R NPT II
pMON 1001
Sma I
Bam HI
DIGEST WITH Sma I
Hind III
EcoRI
Amp^R
Km^R NPT II
Sma I
Bam HI
ADD Bam HI LINKER
5'-CCGGATCCGG
GGCCTAGGCC-5'
LIGATE, DIGEST WITH Bam HI
EcoRI
Hind III
Amp^R
NPT II
Bam HI FROM LINKER
Bam HI (Sma I)
500 bp FRAGMENT
Bam HI
Bam HI
EcoRI
Hind III
Amp^R
Km^R NPT II
pMON 40
Bam HI
PURIFY LARGE 4.2 Kb FRAGMENT
LIGATE TO CIRCULARIZE, TRANSFORM
CELLS SELECT Amp^R Km^R CELLS

FIG. 6.

85

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What is claimed is:

1. A chimeric plant-expressible gene, said gene comprising in the 5' to 3' direction:

(a) a promoter region derived from a gene that is naturally expressed in a plant cell and that is capable of effecting mRNA transcription in the selected plant cell to be transfonned, operably linked to

(b) a structural DNA sequence encoding a polypeptide that permits the selection of transformed plant cells containing said chimeric gene by rendering said transformed plant cells resistant to an amount of an antibiotic that would be toxic to non-transformed plant cells, operably linked to

(c) a non-translated region of a gene naturally expressed in plant cells, said region encoding a signal sequence for polyadenylation of mRNA.

2. The gene of claim **1** in which the polypeptide renders transformed plant cells resistant to an amount of an aminoglycoside antibiotic that would be toxic to non-transformed plant cells.

3. The gene of claim **2** in which the polypeptide is a neomycin phosphotransferase polypeptide.

4. The gene of claim **1** in which the non-translated region is selected from a gene from the group consisting of the genes of the T-DNA region of *Agrobacterium tumefaciens*.

5. The gene of claim **4** in which the non-translated region is from the nopaline synthase gene of *Agrobacterium tumefaciens*.

6. The gene of claim **3** wherein said polypeptide is a neomycin phosphotransferase I polypeptide.

7. The gene of claim **3** wherein said polypeptide is a neomycin phosphotransferase II polypeptide.

8. A chimeric gene capable of expressing a polypeptide in plant cells comprising in sequence

(a) a promoter region from a gene which is naturally expressed in plant cells;

(b) a 5' non-translated region;

(c) a structural coding sequence encoding a neomycin phosphotransferase polypeptide; and

(d) a 3' non-translated region of a gene naturally expressed in plant cells, said region encoding a signal sequence for polyadenylation of mRNA.

9. The gene of claim **8** in which the 3' non-translated region is selected from a gene from the group consisting of the genes of the T-DNA region of *Agrobacterium tumefaciens*.

10. The gene of claim **9** in which the non-translated region is from the nopaline synthase gene of *Agrobacterium tumefaciens*.

11. The gene of claim **8** wherein said polypeptide is a neomycin phosphotransferase I polypeptide.

12. The gene of claim **8** wherein said polypeptide is a neomycin phosphotransferase II polypeptide.

13. A microorganism containing a chimeric gene of claim **1**.

14. A microorganism containing a chimeric gene of claim **8**.

15. A culture of microorganisms of claim **13**.

16. A culture of microorganisms of claim **14**.

17. The culture of claim **15** in which the microorganism is *E. coli*.

18. The culture of claim **15** in which the microorganism is *Agrobacterium tumefaciens*.

19. A plant cell susceptible to infection with *Agrobacterium tumefaciens* which contains and expresses a chimeric gene of claim **1**.

20. A plant cell susceptible to infection with *Agrobacterium tumefaciens* which contains and expresses a chimeric gene of claim **8**.

21. Plant tissue comprising plant cells susceptible to infection with *Agrobacierieim tumefaciens* which contain and express a chimeric gene of claim **1**.

22. Plant tissue comprising plant cells susceptible to infection with *Agrobacterium tumefaciens* which contain and express a chimeric gene of claim **8**.

23. Plant tissue as in either claim **21** or **22** wherein said tissue comprises undifferentiated tissue.

* * * * *

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