



## **Seeds of Dissension:**

A Case Study in Patenting Genetic Material

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Soybean oil is used in products ranging from breast implants to biodegradable printing inks for newspapers to edible birthday candles. ExOil, Inc. has patented a line of soybeans that produce high levels of oleic acids. One step in oil production is from oleic acid to linoleic acid. When the enzyme that catalyzes this step is missing because the gene encoding the enzyme has a mutation, the soybeans will have high levels of oleic acid. Higher levels of oleic acids in cooking oils increase the shelf life and allow for frying at higher temperatures. This high oleic acid soybean oil is in testing for use to replace chemically hydrogenated vegetable oils for frying French fries at McDonalds. The market for this modified oil could be huge--in the millions of dollars in sales every year.

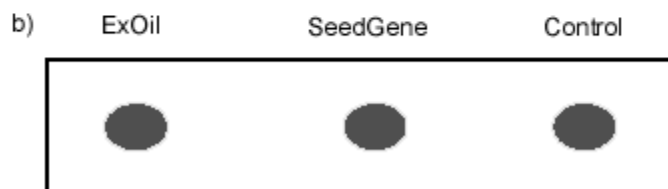
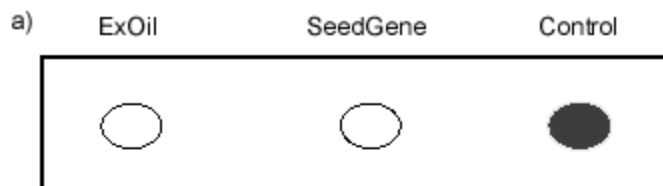
Roger Wezel worked at ExOil developing soybean seeds that are high in oleic acid. Last year, he was fired after a dispute with his boss, and ExOil has just discovered that he is now working at SeedGene, Inc. ExOil has also discovered that SeedGene is now advertising high-oil soybean seeds. ExOil naturally suspects that Roger stole their seeds and gave them to SeedGene, to produce their own high oleic acid variety. ExOil obtained some of the seeds being sold by SeedGene and they want to test them to see if they are the same strain, to support the accusation that SeedGene is violating their patent. Some relevant excerpts from the US Patent Office rules are given below:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. S 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. S 121 and 37 CFR 1.141 et seq.

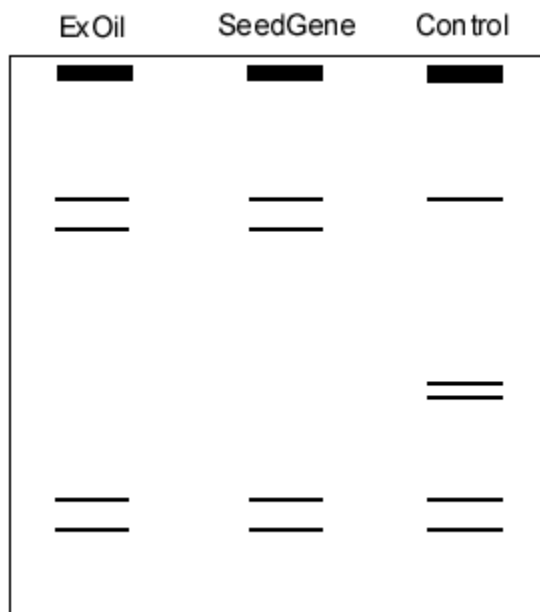
... In addition to the specifically selected sequences, those sequences, which are patentably indistinct from the selected sequences, will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

The following are results of tests that were performed on the two seed varieties. Assume all testing was done by an independent company and, thus, are not in themselves suspect.

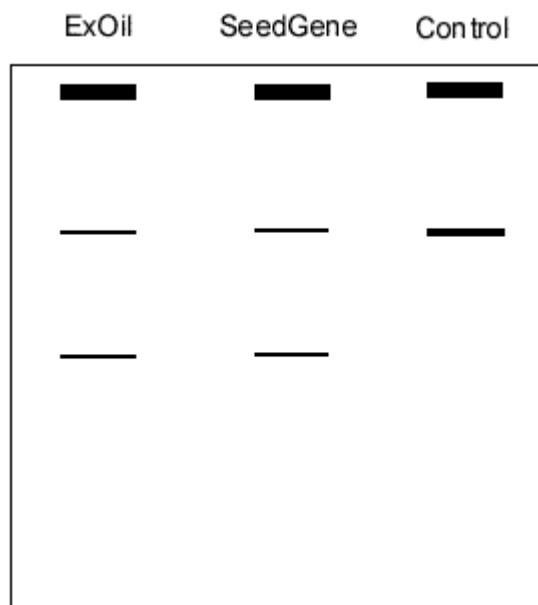
1. **Protein Tests:** Proteins were isolated from ExOil seeds, SeedGene seeds and a commercially available, normal oil yielding seed, that was used as a control. Protein extracts were placed on nitrocellulose paper and tested for the presence of
  - a. enzyme activity responsible for converting oleic acid to linoleic acid
  - b. general proteins



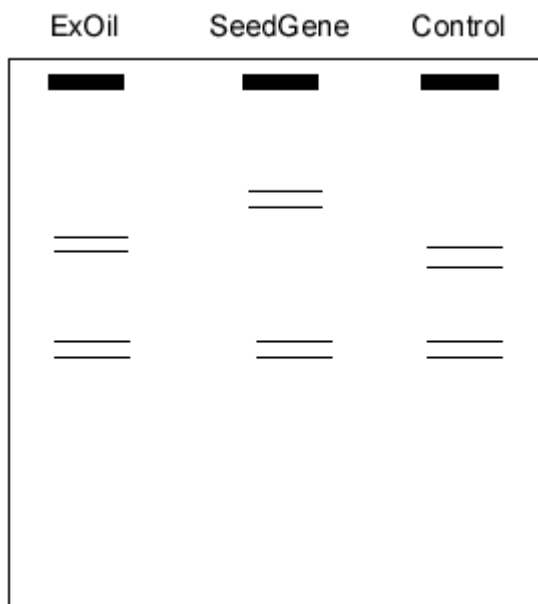
2. **Restriction Fragment Length Polymorphism (RFLP):** ExOil and SeedGene both provided samples of their genes, isolated from the cloning vector originally used. The unmodified gene was also isolated and used as a control. All DNA samples have been digested with HindIII restriction enzyme and loaded on a 1% agarose electrophoresis gel.



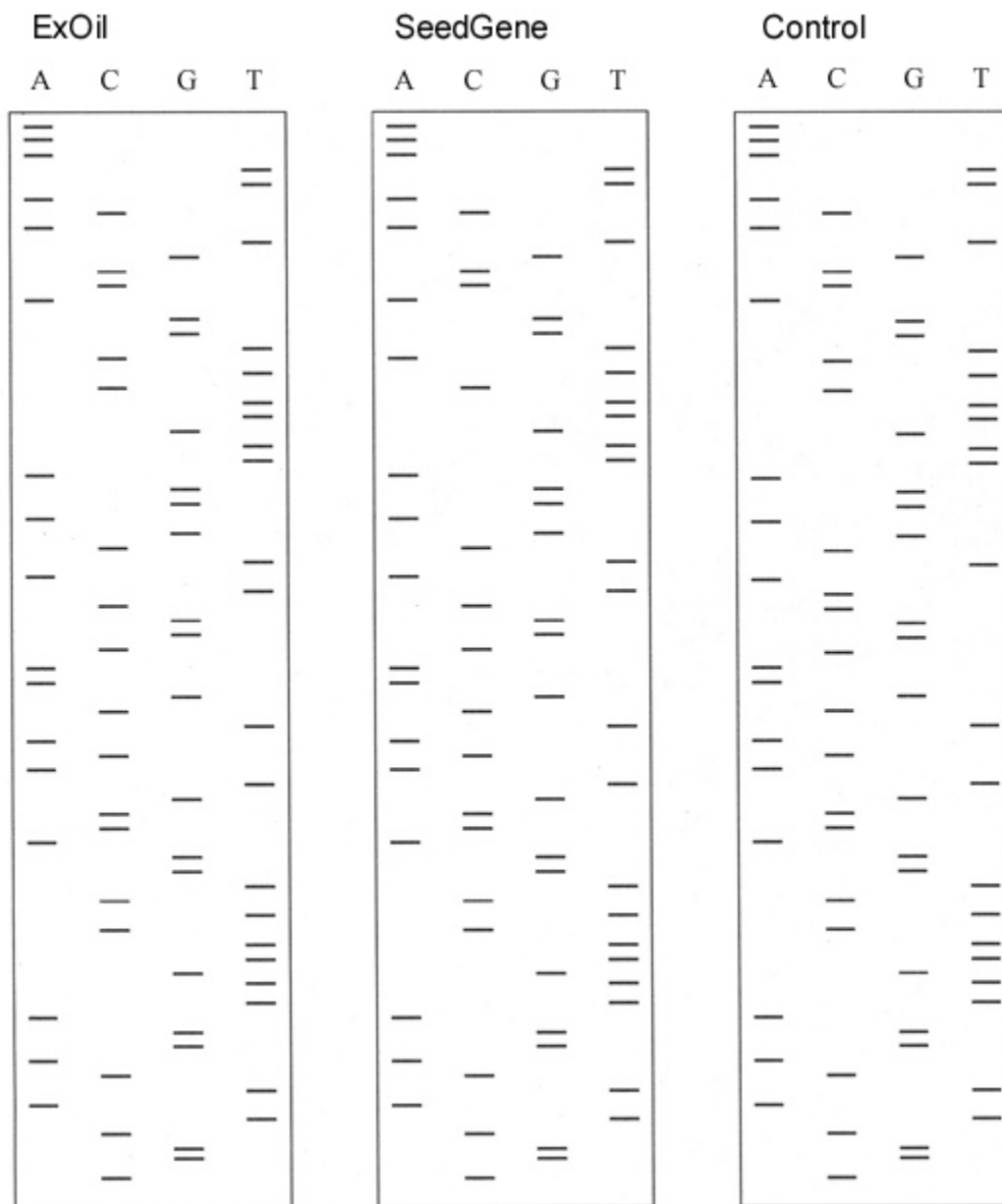
3. **Polymerase Chain Reaction (PCR):** ExOil provided the gene specific primers that are used by ExOil to identify their high oil yielding variety. DNA has been isolated from both ExOil and SeedGene varieties and a commercially available, low oil yielding stock used as a control. Classic PCR reactions were run on ExOil, SeedGene and control soybean DNA and loaded on a 1% agarose electrophoresis gel.



4. **Single Strand Conformational Polymorphism:** Performed with the same PCR reaction done in #3. Sensitive enough to detect a single base difference.



5. **DNA Sequencing Gel:** Run on polyacrylamide and exposed to X-ray film.



## Student Instructions

1. You will be divided into three groups.
2. Within each group there must be an "expert witness" for the following techniques:
  - a. Enzyme/Protein Assay
  - b. Gel Electrophoresis
  - c. Restriction Enzyme Digest
  - d. PCR
  - e. SSCP
  - f. DNA Sequencing

Since there are six topics, and there may be less than six members in the group, some people may need to be experts in more than one subject. This means that there should be three experts per topic per class. You may work together as you prepare to be an expert witness. You may use any sources you choose: textbooks, library sources, journals, web sites, etc.

3. You need to come to class prepared to present information on the topic for which you are the expert. You may do this in any way that you wish. In effect, you will "teach" the class about your topic. Any handouts or overheads that you intend to use need to be given to your instructor in advance, so that copies can be made for everyone in the class. You need to be prepared to use your information and the test results that pertain to your topic to argue for either company.
4. On the day of the case study, you will be told whether your group is representing SeedGene, ExOil, or the arbitration panel. The situation is that ExOil has decided to sue SeedGene for patent infringement and an arbitration panel has been assigned to hear the case.
5. The case study will go as described below. First, student expert witnesses will report on the procedures or topics they researched. Then, there will be a debate as to the merits of the suit brought by ExOil against SeedGene. Here's what will happen:
  - a. Students will present topics for which they are expert witnesses. Going from group to group, present topics in the order given above. Ultimately each group will have two presenters. After each topic is presented, ask if the other two experts have anything to add. This is not the persuasive portion of the case study; you are NOT to present your stance here. Just the information so everyone is well informed.
  - b. After topics are presented, you will have ten minutes to consult and decide how to use your information and your test results to argue for your company. Arbitration panel can take a break at this point.
  - c. ExOil will go first since they are suing. As a group, you will present your case against SeedGene, using the data collected in class and the data given in the case study handout. This should take fifteen to twenty minutes.

- d. SeedGene will present their defense against ExOil's accusations, using the data collected in class and the data given in the case study handout. This should take fifteen to twenty minutes.
  - e. ExOil has five minutes to rebut and present final argument.
  - f. SeedGene has five minutes to rebut and present final argument. NOTE: During this presentation process, the arbitration panel may ask questions to clarify a point. They may not argue with the companies.
  - g. Companies can now take a break and the arbitration panel has ten to fifteen minutes to make a decision. The panel will decide for either ExOil or SeedGene.
  - h. Arbitration panel presents their decision and the reasons for that decision.
6. A summary of the case study proceedings is due the next class period, one per group. For the company groups, the summary should include key points used in defending their position and supporting evidence from pertinent lab procedures. The arbitration panel's summary should include all the information needed to make their decision and justification for their decision. All members of the groups will receive the same grade.

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