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Who Owns the Genome? Human Genetics and Intellectual Property

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1. The U.S. Constitution gives Congress the power “to promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective writings and *discoveries*” (emphasis supplied). The first Congress, in 1789, exercised this power to enact our country’s first patent law. Ever since, the exclusivity provided by patents has been the principle mechanism for inducing private sector investment in scientific research and development.
2. The great inventors of the 19th Century used patents to fund their research and to build new industries. Examples: Ericsson, McCormick and Edison.
3. In the case of *Diamond v. Diehr*, 450 U.S. 175 (1981) the Supreme Court held that “anything under the sun that is made by man” is subject matter for a patent.
4. In the late 20th Century the patent incentive gave rise to venture capital investment in the biotechnology industry. Today, the use of sequence technology to discover useful properties of human genes is at the very core of biotech research and development.
5. The law governing patenting of discoveries involving gene sequences is no different from the law which protected the discoveries of Louis Pasteur, Thomas Edison, or Thomas Watson. “Whoever invents or discovers any new and useful process or, machine, manufacture, *or composition of matter* may obtain a patent therefore” (35 U.S.C. 101) (emphasis supplied).
6. For over one hundred years the U.S. has been granting patents on compositions of matter which occur naturally in nature but which have been transformed into a purified state

isolated from nature. Early examples were Louis Pasteur's patent on "yeast, free from organic germs of disease, as an article of manufacture" and a patent on purified adrenaline.

7. Patents do not confer ownership of genes, genetic information, or sequences. ***Patents can be secured on discoveries involving genes and sequences which have specific, substantial and credible utility.*** These patents do not cover compositions of nature in their natural environment, but rather isolated and purified compositions.
8. If an isolated and purified DNA molecule can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene it is patentable.
9. Other inventors may discover separate uses of an isolated DNA molecule or a useful protein and these discoveries are separately patentable – but, they may not be utilized during the life of the underlying patent without a license from the underlying patent holder. This is nothing new. It is a principle which has always applied to research and development in chemistry and biology in the United States.
10. The patent principles underlying biotech research are no different from those underlying research in fields such as electronics, computers and mechanical devices. In those disciplines for many years it has been often necessary to obtain licenses to underlying technology to develop new and separately patentable products. History shows that business practices quickly evolve which provide easy access to such licenses at a reasonable cost. In the area of gene sequencing, such licensing activity appears to be the business model underlying companies such as Celera.
11. In recent years the courts have held these principles to apply to new areas of innovation. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) spoke to the patentability of life forms, and the *Diehr* case dealt with computer software. After each one of these cases critics argued that research and innovation would be harmed by the exclusivity granted to the patent holders of the breakthrough innovations. We now have over 20 years of experience to show that this has not been the case. An example – from a contemporary critic of intellectual property rights, Berkeley Law Professor Pamela Samuelson – demonstrates the point. In 1984 in her "Manifesto Concerning Legal Protection of Computer Programs" she stated that patenting software would stifle innovation. With 17 years of hindsight we can see that her concerns were unwarranted.
12. Patents on discoveries involving DNA sequences are supported by the Constitution and Acts of Congress as interpreted by the Supreme Court. Any restrictions on patent subject matter would have to involve legislation changing the basic – 212 year old – structure of the patent law. Without very serious evidence of a problem this would not seem prudent.