UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR PATHOLOGY;

3. In 1969, I joined the Medical Research Council Laboratory of Molecular Biology, Cambridge, where I researched the cellular and genetic structure of the nematode worm, *C. elegans*.

4. I became involved in genomics starting in 1983, and played a central role in both the *C. elegans* worm and human genome projects. In 1998 I and my colleagues

[redacted]

be sequenced.

5. From 1992-2000 I served as the first Director of the Wellcome Trust Sanger Institute in Cambridgeshire. During my tenure as Director, the Institute grew from 15

[redacted]

human genome, and discusses the importance of ensuring that information contained in our genome be freely available for the benefit of all.

9. A full copy of my current curriculum vitae is attached as an Exhibit.

Genes and Genetic Sequences

10. Genes and human genetic sequences are not inventions. They are naturally occurring. They are the most fundamental information about humanity, information that is – or should be – common heritage.

11. Genes are the basic units of heredity in all living organisms. A gene is a

[redacted]

14. The genetic code is similar to the English alphabet, except that it consists of

copyrighted), the informational content of a human gene sequence is fixed. While many inventive steps have been necessary to allow us to extract and read a genetic sequence, the ordering of the 4 letters is determined by nature.

18. The slight variations that occur among individual genomes are of great interest to some scientists, because they are thought to account for some of the differences that we see among us. These "typos" or mutations can be in the form of the

21. Progress in sequencing was slow the first two decades following the discovery of DNA. The first practical method that allowed sequences of many thousands of bases to be read out was invented by Fred Sanger and his colleagues at Cambridge England,

overlapping pieces were produced, and cloning them randomly (the so-called shotgun approach). Each piece was sequenced by an ingenious method involving replication enzymes, radioactive labels and size separation of the resulting complex mixtures in an electric field. The beautiful patterns that emerge look rather like a bar code, and can be

23. Our ability to sequence genes has been predicated on advances in numerous areas, including chemistry, biochemistry, instrumentation, and computing. Some of these

[redacted]

apply to *processes*. They do not apply to the data flowing through them.

24. Gene sequencing is used in diagnostic testing. A gene sequence can be examined to determine if it contains any alterations or mutations that have been associated with a particular genetic condition.

25. In order to sequence, or read a gene, we have to remove it from the cell of an organism and place it in a form so that it can be replicated outside of the body. Most commonly, we use a technique called PCR to replicate many times over small segments

gives a monopoly over this information, regardless of the person from whom the gene is taken or the sequencing process that is used.

Information Sharing in Genomic Research

28. From the point of view of scientific research, human genetic sequences are as basic as you can get in terms of biological information. They are as basic as the elements in the periodic table. Patenting a gene or genetic sequence impedes scientific progress much the same way that patenting a naturally occurring element such as oxygen or gold would impede science.

29. From the very beginning of the Human Genome Project, most scientists and even some private companies recognized the importance of keeping the genome freely available to all. In 1994, the pharmaceutical company Merck funded a massive drive to generate genetic sequences and place them into public databases. By doing this Merck not only gave the entire research community, public and private, free access to valuable genomic data; it also made those sequences much more difficult to patent.

30. In November 1995, a team of researchers at the United Kingdom-based

BRCA2 was sequenced by the Sanger Centre. Over the next two weeks, the ICR team confirmed their results and identified five additional mutations. But the day before their

by deposit into a public database, and would not take out patents on it. We stated: "All human genomic sequence information should be freely available and in the public domain in order to encourage research and development and to maximise its benefit to

34. Although the genome as a whole is in the public domain, patents are now issued or pending on some 25% of human genes. These patents stand in sharp contrast to the terms of the Bermuda meeting and threaten to undermine scientific and medical

37. Patents on human genes and genetic sequences are deleterious to the practice of science. Because gene patents tend to cover all uses of that sequence, they are a disincentive to further research on those genes. Patents on genes damage accessibility to

38. Patents on human genes will be deleterious to unraveling their role in medical