Letters

The Human Genome Project and Patents

The Human Genome Project, developed largely thanks to the initiative and energy of American scientists, aims primarily at obtaining sufficient understanding of the human genome so that any gene whose alteration is responsible for a disease will be in "terra cognita" and thus easily identified and analyzed. Apart from its interest for the comprehension of disease mechanisms, indispensable (but not necessarily sufficient) for therapeutic intervention, this project was to furnish vast amounts of information on the structure, regulation, and evolution of genetic material.

The protagonists of the Human Genome Project have insisted on the necessity of free and rapid circulation of information. This requires the creation of sophisticated databases that can be continually updated and consulted by any laboratory in the world. This indispensable fluidity of circulation of scientific information is endangered by the attempt of the U.S. National Institutes of Health to patent partial complementary DNA (cDNA) sequences and by the decision of the Medical Research Council in Britain to charge for access to their project's database (News, 11 Oct., p. 184). These attempts to commercialize basic data from the study of the human nucleotide sequence could be the death warrant of one of the most prodigious projects the scientific world has known: the unraveling of the human genome with the aim of bringing hope to the tens of million of people in the world who suffer from genetic diseases.

Once the gene associated with a specific disease is located, it may be possible to develop methods of prenatal diagnosis or therapeutic drugs. In these cases, the rights to the intellectual property of those involved must naturally be recognized. However, a description of a short sequence of DNA or of cDNA is not an invention. It is knowledge about a part of the natural world that exists independently of the scientist, like the discovery of a new star or a new physical law. If the main argument for patenting cDNA sequences is that they are obtained thanks to innovative procedures, then let the procedures themselves be patented, but not the sequences established as a result of those procedures.

It would be prejudicial for scientists to adopt a generalized system of patenting knowledge about the human genome. This would increase costs and penalize low-budget research teams and countries with fragile economies. In addition, such a development would be ethically unacceptable. A patent should not be granted for something that is part of our universal heritage.

I hope that reason will win the day and that scientists and those responsible for research policy in the countries involved will refuse to embark on an adventure in which science and the human conscience would suffer and which would destroy the high hopes raised by the Human Genome Project. The irony is that principle could be sacrificed in the name of a profit that may well prove illusory—even for the biotechnology industries.

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The American Society of Human Genetics (ASHG) has followed the Human Genome Project with great interest, and considers it to be of great potential benefit to the field of medicine. The ASHG is deeply concerned about the recent submission of patent applications for expressed sequence tags (ESTs) by scientists at the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH). We believe the issuing of such patents would likely do more harm than good and that the impact on the Human Genome Project and on the field of medicine should be carefully examined.

The ASHG has not opposed patenting of genetic information with utility—recombinant clones used for the production of human proteins (such as factor VIII, growth hormone, and erythropoeitin) and gene probes used for diagnostic testing, carrier identification, and prenatal diagnosis of diseases (such as cystic fibrosis, muscular dystrophy, and the fragile X syndrome). The attempt to patent ESTs, however, is another matter.

We do not consider that the three tenets of patentability (novelty, nonobviousness, and utility) have been met. There is nothing novel about the identification of ESTs. An EST is simply a DNA sequence of a short segment of a complementary DNA (cDNA) clone that is picked more or less at random from a set of cDNA clones obtained by standard, published procedures. The idea of using a sequence as a genetic marker or tag is an obvious approach that has been extensively discussed in the human genetics community and it is the basis of ongoing genome projects both within and outside the United States. Scientific experience suggests that an EST itself is unlikely to have commercial utility. The anticipated utility of an EST is simply that one could be used as a

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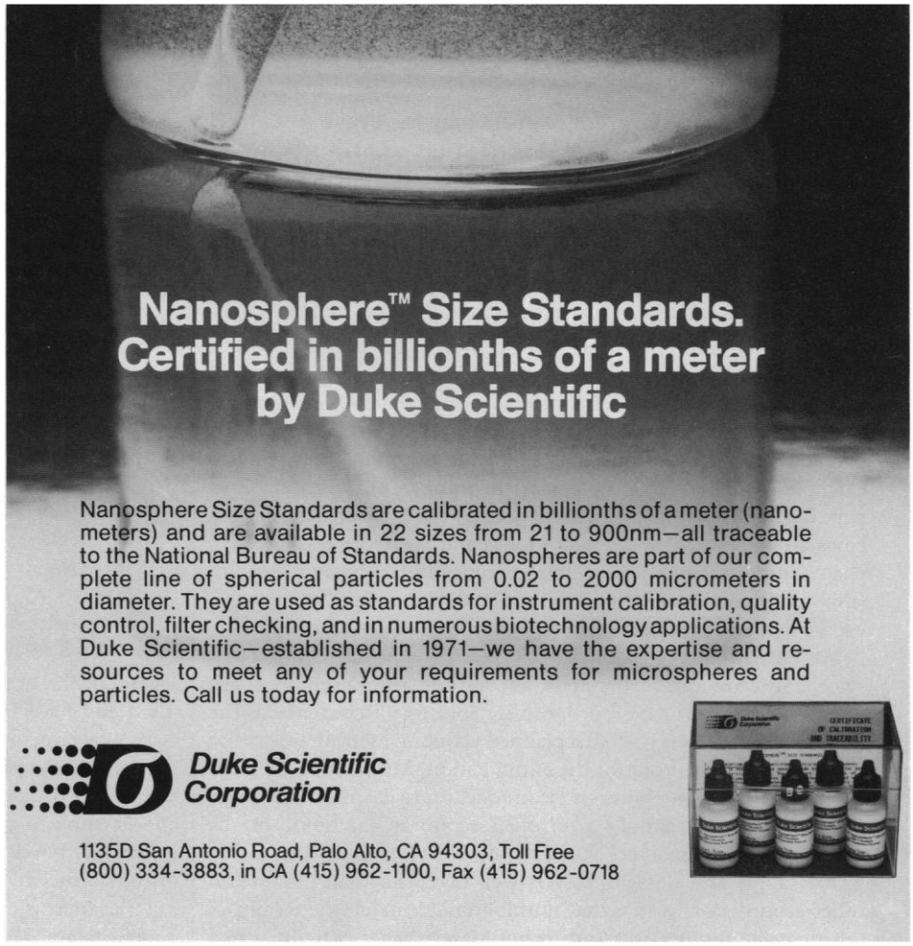

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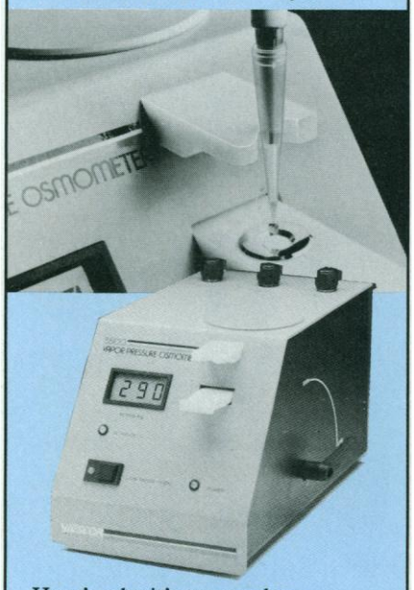

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research tool to identify the remainder of the coding region of the gene. The utility would not be known until additional research was completed, and it would probably rest with the full cDNA, the genomic clones containing the gene, or the protein product of the gene, not with the EST itself. The EST is, at best, a starting point for further research and should not be patentable.

The ASHG is concerned that patenting of ESTs may be detrimental to the interests of the Human Genome Project and to society. The project should be an international collaboration. The international Human Genome Organization (HUGO) has stated this principle since its inception in 1988. It should not be a competition between laboratories and between countries to see who can "own" the largest portion of the human genome to exploit. Under such conditions the information would not be shared between the competing groups until after patents were secured, and duplication of effort would be impossible to avoid.

Because an EST is part of a gene, different ESTs from the same gene may be isolated by different laboratories. Furthermore, a gene is often part of a gene family, so that one EST may recognize more than one gene. We anticipate major problems when several research groups end up with competing patent claims for the same gene or genes.

Normally, a patent ensures that a gene will be available for all researchers and for any company willing to license it. We fear that in the case of ESTs it may have quite the opposite effect. The academic community is unlikely to put major research effort into an EST-identified gene or its protein product if someone else already has the right to license its use. In the commerical sector there may be reluctance to invest in research on EST-identified genes when a small but unknown fraction of them will turn out to have commercial utility, and when the useful ones may be contested by patents on other ESTs from the same gene.

The ASHG urges the U.S. Patent and Trademark Office to give high priority to the resolution of the EST patent issue. One argument for patenting ESTs has been that if they were published without patenting this might compromise the patentability of a future diagnostic or therapeutic procedure based on a gene or gene product derived from an EST in the public domain. What is needed without delay is a statement from the Patent Office about this potential problem. If it is not a problem, then it takes away the main argument for patenting ESTs. If it is a problem, then perhaps the best course is to rethink current patent law and to amend it to ensure that genome research is not thwarted by laws developed in simpler times to deal with simpler issues.

An international collaborative venture as bold as the Human Genome Project should not be jeopardized by the possibility of irrevocable damage inflicted by EST patents, the majority of which may never have any commercial utility. Let us strive to ensure that patents are obtainable at a stage in the process that will still allow commercial exploitation of genetic information, but not so early in the process that it will stifle individual scientific endeavor and lead to international chaos.

Human Genome Committee and
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Respect for Vitamin C

In the second of two News articles about the Linus Pauling Institute of Science and Medicine (Briefings, 11 Oct., p. 192; Research News, 18 Oct., p. 374), my claims about ascorbate (vitamin C) are described as "hype." I contend that my statements about vitamin C are not hype except in the minds of critics who believe that vitamin C has no function except to prevent scurvy and that larger intakes have no value. I continue to accept the evidence that the optimum intake of this vitamin for an adult human being is between 2 and 18 grams per day (more in times of illness). Part of this evidence is that almost all animal species manufacture vitamin C in liver or kidney cells, and that the daily amounts manufactured, converted to the body weight of a human adult, lie in the range of 2 to 18 grams, and more in periods of stress.

The result of ingesting such a minute amount of this vitamin as 60 milligrams per day, the U.S. recommended dietary allowance, is that human beings are in poor health, age rapidly, and experience a high incidence of and mortality from many diseases. Vitamin C is not a drug. It is a nutrient which, taken in the optimum amounts, offers an opportunity for great improvement in human health.

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The 18 October Research News article about vitamin C was an excellent presentation of some of the recent issues in vitamin C research. Your readers may be interested to know that the complete proceedings of the 1990 National Cancer Institute Symposium, which was mentioned in the article, will be published in the December issue of the *American Journal of Clinical Nutrition.*

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