

'The human genome itself must be freely available to all humankind'

Bruce Alberts, president of the US National Academy of Sciences, and Sir Aaron Klug, president of the Royal Society of London.

GenBank for other commercial competitors to reuse it". But one leading genome scientist says, "People should be free to circulate complete copies of the database, with additions of their own, if they want to; that makes for healthy bioinformatics. If they are not allowed to do this, the data is not being released according to GenBank standards."

Gilman dismisses this. He claims that the public project rejected an offer by Celera to put the data in GenBank, provided that those accessing it accepted that any use of the data



Venter: ending speculation.

would be freely accessible and not used to compete with Celera. "They said the terms of their international agreements are such that they can put no such limitation on the data."

The public project has been studying a similar 'click-wrap' contract, but this time intended to ensure that all those taking data — including Celera — agree to keep it open to all other potential users.

One burning question is whether leading scientific journals will agree to publish Celera's human genome, or whether they will prefer to publish that of the public project. Flood Bloom, for example, editor in chief of *Science*, is expected to publish a statement on this in tomorrow's issue of his journal.

At present, *Science's* policy is that "archival data sets (such as sequence and structural data) must be deposited with the appropriate data bank and the identifier code should be sent to *Science* for inclusion in the published manuscript," adding that the coordinates of this deposition "must be released at the time of publication".

Nature's policy is to require sequence data to be deposited in GenBank or a database of equivalent unrestricted accessibility, with an accession reference included in the publication. "Clearly we need to keep abreast of the changing landscape of databases, and the increasing involvement of private interests," says Philip Campbell, the editor of *Nature*. "It would be absurd to be fundamentally opposed to private database ownership, but the confidence of researchers and the public's stake in the content of the human genome are both of paramount concern." (See page 317.)

But some researchers are concerned that *Science's* policy does not explicitly require open access to data. Bloom told *Nature* that the magazine "will continue to advocate free access to nucleotide sequence data. Public databases are facing a challenge from the clash between the needs of two cultures — academia and industry. We at *Science* urge open, constructive dialogue between all parties so that unrestricted access to information can be assured, while still allowing enough protections that the biotechnology industry can flourish."

Declan Butler

"Through a public-private initiative of international proportions, science is about to provide the world with one of the most significant intellectual achievements of all time — the complete sequence of the human genome — which will provide a detailed map all of the genes in each cell that provide the blueprint for human life.

The implications are enormous. Last week, US President Clinton and UK Prime Minister Blair issued a joint statement applauding the effort. They emphasized the decision by scientists working on the Human Genome Project to release rapidly all of the information emerging from the project into the public domain, and urged scientists around the world to adopt the same approach.

We commend this powerful statement. But we also know that action by the world's scientists is not enough. More attention must be given to striking the appropriate balance between public and commercial interests.

Determining the sequence of the genome is similar to completing the list of the chemical elements: it tells us about the basic components, but not about how they behave in combination. In other words, it gets us to the starting line for a massive increase in understanding, but does nothing by itself to provide us with that understanding.

With the completed genome sequence, we will have all the instructions for making the 50,000 or more proteins present in the human body. But we will not know what each protein is for; still less about how the thousands of genes work together to produce and maintain the human body. And we will not know how the expression of a gene or genes can go wrong in the course of a disease.

In short, a huge amount of work will remain to be done. This will require effort in both the public and private sectors for generations to come. It is likely to lead to numerous breakthroughs in health care, benefiting all sectors of society. It is also likely to lead to numerous legitimate opportunities for creating wealth, underpinned by patent protection for the inventions and innovations of the individuals and companies involved.

What type of patent protection makes sense? Patent laws are based on the principle that public disclosure of a valuable new invention through the patenting process

should be encouraged and rewarded, allowing others to use and build on the invention to create additional benefits to society. In return, the inventor is rewarded with monopoly rights over the use of the invention for a limited period of time.

It is critical that the benefits to the public be at least reasonably commensurate to this reward. Given the enormous potential of the human genome sequence, the granting of broad monopoly patent rights to any portion of it should be regarded as extraordinary — and occur only when new inventions are likely to confer benefits of comparable significance for humankind.

It is a trivial matter today — using a computer search of public databases — to use DNA sequences to identify new genes with particular types of biochemical functions. In our opinion, such a discovery should not be rewarded with a broad patent for future therapies or diagnostics using these genes when the actual applications are merely being guessed at.

The intention of some university and commercial interests to patent the DNA sequences themselves, thereby staking claim to large numbers of human genes without necessarily having a full understanding of their functioning, strikes us as contrary to the essence of patent law.

Those who would patent DNA sequences without real knowledge of their utility are staking claims not only to what little they know at present, but also to everything that might later be discovered about the genes and proteins associated with the sequence. They are, in effect, laying claim to a function that is not yet known or a use that does not yet exist. This may be in current shareholders' interests. But it does not serve society well.

Scientists are at the very early stages of this work: knowledge of the human genetic sequence is only the first step. The next will be to understand how the tens of thousands of genes that make up the genome work together to create the machinery that operates the human body.

This will be a huge scientific undertaking. For it to work effectively and bring widespread benefit as quickly as possible, it is vital that all researchers have access to the full genome without charge or other impediment. The human genome itself must be freely available to all humankind. ■