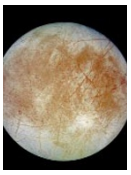

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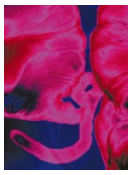

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NIH opposes plans for patenting 'similar' gene sequences

Washington

Sharp differences have emerged between the US National Institutes of Health (NIH) and the Patent and Trademark Office (USPTO) over gene patenting. The disagreement centres on whether a patent should be granted on a genomic sequence of unknown function merely because it is similar to a separate sequence whose function is already understood.

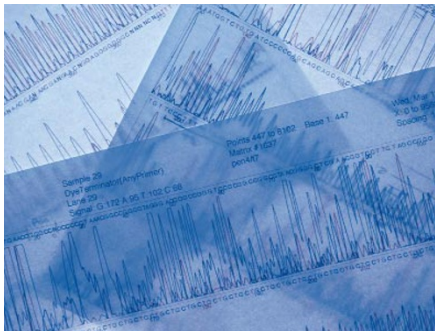
USPTO officials argue that patents should be granted on such a 'homologous' sequence if the two sequences are sufficiently similar to make it likely that the biological function of the product of the new sequence can be predicted with a high degree of confidence. But NIH officials, backed by groups such as the Association of American Medical Colleges (AAMC), are challenging this interpretation.

Although such logic may be applicable to products such as chemical compounds — where two compounds with a similar structure can reasonably be expected to have similar properties — NIH officials argue that a difference in a single base pair in a gene sequence can have important functional implications.

The USPTO is currently revising its rules for awarding gene patents to apply stricter criteria in judging whether an invention can be considered genuinely useful (see *Nature* **403,** 3; 2000). Most of the changes, released in draft form just before Christmas, have been widely welcomed. They would, for example, mean that it was no longer possible to describe the utility of an expressed sequence tag as being merely to 'fish' for genes of unknown function.

But the proposals on sequence homology have drawn criticism. In its comments on the draft, for example, the AAMC argues that researchers can often use automated programs to 'guess' the identity and function of a protein encoded by a gene based on the similarity of a fragment to other known genes. "Such suppositions of utility are technology driven, and require little scientific insight or creativity," writes AAMC president Jordan J. Cohen.

The biotech industry appears divided on the homology proposal. While some genomics companies would continue to benefit from the granting of patents based primarily on homology — as was the case recently, for example, when Human Genome Sciences was issued a patent on the CCR5 chemokine receptor later found to be the key receptor for HIV (see *Nature* **404,** 322; 2000) — others apparently feel that it could stifle innovation in the field.



CHRIS KNAPTON/SCIENCE PHOTO LIBRARY

Sequence suspicions: questions remain over when genomic data should be patentable.

But the NIH is unequivocal in its comments. Jack Spiegel, director of the NIH's division of technology transfer and development, argues that it is extremely difficult to make an accurate prediction of the biological function of a protein solely on the basis of the similarity of its sequence to another one.

"Minor changes in the nucleotide or amino acid sequences of […] molecules may produce profound changes in biological activity," writes Spiegel, adding that "homology in an unpredictable art cannot, by itself, provide a specific utility".

The National Advisory Council for Human Genome Research puts it even more bluntly: "Finding partial sequence similarity is an obvious and non-inventive step." Other critics point out that, if patents are granted based solely on homology, the patent holders will have little incentive to continue to a full characterization of the gene product — but could claim the rights to the results of other researchers who later did this.

It remains to be seen how far the USPTO takes on board such criticisms. Although the new guidelines are already being implemented in judging patent applications, a final version will be published within a few months. The USPTO says it is not anticipating "major changes" from the current draft. **David Dickson**

Shareholder sues Celera over loss

Washington

PE Corporation, the parent company of Celera Genomics, is facing legal action from one of Celera's shareholders. The investor claims that information published by Celera misled him into losing money during the recent collapse in the company's share price. Both companies are dismissing the charge as baseless.

The class action lawsuit alleges that when PE Corporation was seeking investors in a 'secondary offering' at the end of February, it failed to disclose the existence of negotiations between Celera and principals in the public Human Genome Project (HGP).

If the case advances, it will investigate a tumultuous time in Celera's stock prices. On 29 February, the company sold 4.37 million shares at $225 each. For a week, the share price rose, peaking at nearly $260 a share.

But negotiations over a possible collaboration between Celera and the HGP on sequencing the human genome broke off about a week later. The impasse — and rancour behind it — soon became public and Celera's stock began slipping. The share price then plummeted on 14 March, triggered by media reports of a joint statement by US President Bill Clinton and British Prime Minister Tony Blair backing the HGP's free information policy (see *Nature* 404, 324; 2000).

PE Corporation says it has done nothing wrong. "We feel that the suit is totally without merit," says Lyn Christianson, a spokesperson for the company. Paul Smaglik