



HUGO INTELLECTUAL PROPERTY COMMITTEE STATEMENT ON PATENTING ISSUES RELATED TO EARLY RELEASE OF RAW SEQUENCE DATA

May 1997

HUGO, having reviewed recent developments in the field and, in particular, having taken note of the Principles agreed at the International Strategy Meetings on Human Genome Sequencing*¹ in Bermuda in February 1996 and February 1997, and of the practice of the U.S. Patent and Trademark Office (PTO) on granting patents on Expressed Sequence Tags (ESTs) as recently reported in *Science* 275: 1056:

- **reaffirms** its Statements on Patenting of DNA Sequences of 1992 and 1995, clarifying the fact that HUGO does not oppose patenting of useful benefits derived from genetic information, but does explicitly oppose the patenting of short sequences from randomly isolated portions of genes encoding proteins of uncertain functions;
- **regrets** the decision of some patent offices, such as the U.S. PTO, to grant patents on ESTs based on their utility "as probes to identify specific DNA sequences", urging these offices to rescind these decisions and, pending this, to strictly limit their claims to specified uses, since it would be untenable to make all subsequent innovation in which EST sequence would be involved in one way or other dependent on such patents;
- **urges** all large-scale sequencing centres and their funding agencies to adopt the policy of immediate release, without privileged access for any party, of all human genome sequence information in order to secure an optimal functioning of the international network, as well as to avoid unfair distortions of the system;
- **stresses** that only the policy of rapid publication and free availability of human genomic sequence information will secure further international co-operation of large-scale sequencing centres;
- **emphasises** the differences between the U.S. patent law, which provides for a so-called one year "grace period", allowing the authors of published data to subsequently file patent applications for inventions based on such information, and the patent laws of practically all other countries, which do not contain such a provision and where therefore no protection for, or based on, published data can be acquired;
- **calls upon** the law makers to enter negotiations aimed at reaching an agreement on the introduction of a "grace period" along the lines of the U.S. law, which should precede the Paris Convention Union priority term, and which will eventually provide conditions putting all participants in the international network on an equal footing;
- **expresses** the hope that the free availability of raw sequence data, although forming part of the relevant state of the art, will not unduly prevent the protection of genes as new drug targets, which is essential for securing adequate high risk investments in biology, and will not result in a shift of activities of the pharmaceutical industry to searching for compounds that give marginal advantages against known targets rather than taking risks with new targets.

This Statement was prepared by the Intellectual Property Rights Committee of HUGO and approved for release by the Council of HUGO, May 1997

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