*DEFYING ITS PARENT*

# NIH PANEL AGAINST GENE PATENTS

*A draft letter intended for top federal officials criticizes the Venter patent applications and their potential impact.*

IRVINE, Calif.—Researchers from companies and universities stepped up their outcry against a recent move by the National Institutes of Health (NIH, Bethesda, MD) to patent complementary DNA (cDNA) sequences derived from fragments of human genes isolated by researcher Craig Venter of the National Institute for Neurological Disorders and Strokes (*Bio/Technology* **9**:1310, Dec. '91). The outcry was heard at a meeting here last month of an advisory panel serving both the NIH National Center for Human Genome Research (NCHGR) and its counterpart in the Department of Energy (DOE).

After a heated discussion about how best to make its views known, the advisory panel invited several California-based patent attorneys to help draft a strongly worded letter. Intended for top federal officials, the draft letter criticizes the Venter patent applications and their potential impact.

"We're asking taxpayers to pony up a lot of money to sequence the human genome," says one of the attorneys, Thomas Kiley, who is a former general counsel and vice president of Genentech (So. San Francisco, CA) and now an independent patent attorney in Hillsborough, CA. He says that the Venter patenting controversy raises practical as well as political problems not only for the human-genome program but also for anyone conducting research in biotechnology. Venter's patenting attempt "is only an extreme example of a widespread practice in biotechnology that seeks to control not discoveries, but the means of making discoveries," Kiley says.

Current ambiguities in patent law can lead to situations where the "patent system is used to enjoin research," Kiley warns, calling that prospect "repugnant." He recommends that the patent law be changed so that federal agencies, including NIH and DOE, "can decline to patent inventions made by their employees when the agency determines that is not in the public interest." He also dismisses the argument that the Venter patents are necessary for transferring that segment of technology into widespread commercial use. "If the public is paying for the generation of information, then give it to the public and let the market sort out what to do," he says. "Companies will find another way to make money."

The Venter patent applications already have put a subtle crimp in genome-program policy making. DOE genome-program administrators, with encouragement from their NIH counterparts, have been drafting guidelines for the sharing of mapping and sequence data as well as material resources. In principle, members of the advisory committee agree with provisional recommendations calling for unpublished findings to be made available for incorporation into appropriate data bases within six months of being entered into an individual laboratory's data base. However, the Venter hullabaloo raised red flags, leading higher officials within DOE to question whether such a policy is consistent with the technology-transfer and U.S.-competitiveness policies now favored by the Bush Administration. **—Jeffrey L. Fox**

# FASTER AND MORE ACCOUNTABLE GENOME PROJECT

Last month's advisory-panel meeting also saw the scientists and administrators in charge of the human-genome project look for ways to get a firmer grip on the burgeoning program: They want to develop a clearer picture of actual progress and to ensure that promised achievements match available resources. Thus, as interim goals solidify, the project leaders are considering whether to increase substantially their reliance on contracts rather than grants as a way of supporting and perhaps more closely managing this federally sponsored effort.

James Watson, director of NCHGR, has begun laying the groundwork for the program to shift more activities into contracts and out of research grants. "It's my belief that the program has got to change emphasis. To get the job done, we need contracts, not grants, with about half the budget to move into contracts," Watson says. Those contracts should involve "larger sums of money" than current grants, but they should still be subject to peer review, he says, adding that the "extent to which they are done within universities or industry is an open question." Watson also suggests that the genome program eventually become part of a new Institute for Human Genetics at NIH.

This changing perception about the need to reshape the genome program in part reflects a sense that current genome-mapping efforts need closer management and also that pressures will continue growing to take critical measures of the program's overall progress. The very prescriptions for measuring progress "could affect how people proceed with their efforts," says advisory-panel member Maynard Olson of Washington University School of Medicine (St. Louis, MO). At his urging, other panel members agreed to begin assessing general physical-mapping progress in terms of an "ordered marker" approach, which is akin to how genetic mappers chart their findings.

Several distinct efforts to construct maps of each of the human chromosomes are now under way. However, so far, no one is trying systematically to mesh information from the newer index-mapping efforts with that obtained from other approaches to mapping. Since last April, investigators have already attained minimally sufficient coverage with this new approach for at least 12 chromosomes, according to panel member Helen Donis-Keller, also of Washington University. She says that by June investigators should be able to assemble available data into a uniform format for the full set of human chromosomes and to publish the interim findings as soon as possible.

Compiling data from other mapping efforts to develop a more comprehensive chromosome-by-chromosome picture of the human genome poses a bigger challenge. For now, that effort is likely to be impeded by the diffuse nature of the undertaking as well as the independence of the investigators participating in it. Nonetheless, members of the advisory panel recommend that such a comprehensive effort begin. **J.L.F.**