to a substantial share of the human genes. "It is offensive," says Berg. To patent attorney Thomas Kiley, former general counsel at Genentech, Venter's strategy is the latest manifestation of an already unhealthy trend toward "insubstantial" patents based on "the means of making the discovery rather than on the discovery itself. [Venter's] tags," he says, "leave the hard work of deciphering the gene to someone else."

Not surprisingly, Venter and Adler are intent on dispelling those arguments. "These are not unknown fragments," asserted Venter at last week's press briefing. "There is so much information contained in the 300 to 500 base pairs that it is more specific than fingerprints at identifying you." Added Adler: "They are markers for chromosomes, and they are potentially useful as polymerase chain reaction primers [for amplifying and cloning the genes]." While conceding uncertainty over whether the fragments meet the utility requirement of patent law, Adler says, "there are a number of uses well short of biological function that [could] satisfy the law."

Such statements aren't likely to persuade the critics, who see Healy saying that she is not committed to patents while NIH seems to be doing all it can to see its applications succeed. It has, for example, narrowed the scope of its second application. "In the first application we did what most attorneys do: We claimed everything that reasonably follows from the actual research result," says Adler—in other words, the "tags," the full-length genes, and their proteins. Not only did the breadth of the first NIH claim draw the ire of the scientific community, but to Genentech's Stephen Raines, vice president for patents, it also reduced NIH's chance of success. This time, NIH has claimed the tag and the gene but not the protein. Raines suspects that Adler has recognized that "it is a little dangerous to ask for the world. As the claim gets narrower, that usually helps support the argument of patentability. I think Reid would very much like to see that patent issue."

In what seems to be a concession to the critics, NIH has agreed to make the application public within a few weeks. According to Adler, the patent commissioner has also agreed to an expedited review, a move welcomed by all because it could mean a decision in 1 or 2 years instead of 4 or 5.

As opposed as they are to the patent application, even the critics want to see it carried through to the end, to the Supreme Court if need be. "We need a definitive answer," asserts Berg. "Withdrawing the patent would resolve nothing." Indeed, he adds, even if NIH withdrew the application, Venter or others could file on their own.

Spurred on by this debate, the major countries participating in the Genome Project are attempting to clarify their policies—specifically, how to reap the economic benefits of the project while ensuring open exchange of scientific information. A new interagency committee, formed under the auspices of the Office of Science and Technology Policy, is looking at the broad implications of gene patenting and will report to Bromley by June. In England, where the Medical Research Council (MRC) has been accused of keeping its gene data secret, the government will announce its policy within a few weeks, says Dai Rees, the MRC secretary.

Both Rees and Healy agree that relations have improved since last fall, when the two sides were trading accusations across the Atlantic. "NIH was the first to be put on the spot," says Rees diplomatically. "It was easy for everyone else to be critical." Says Healy: "We are all in the same dilemma," adding that NIH is also talking informally with the French and Japanese. Once the national policies are sorted out, Healy, Rees, and others hope to engage in formal talks. Rees is pushing for an international agreement not to patent these gene fragments, but he doesn't see Healy clamoring for the same. "I don't think an agreement not to patent is out of the question for NIH," he says cautiously. "But I doubt whether it is the preferred course of action." Until a decision is made, academic and industry researchers will be left with uncertainty over what in fact is patentable—and the knowledge that within the next 6 months or so, NIH will file yet another patent application on several thousand more gene fragments. ■ **LESLIE ROBERTS**

The Advisory Committee Protests

"At the 3 January 1992 meeting of the National Institutes of Health Department of Energy Subcommittee for Interagency Coordination of Human Genome Research there was an extended discussion of the NIH decision to apply for patents covering the base sequences of short cDNA segments obtained by Dr. Craig Venter, and to file additional claims for thousands more such sequences as they are determined.

We are unanimous in deploring the decision to seek such patents. The subcommittee is particularly concerned that the claims widely reported in the press extend far beyond the partial cDNAs themselves to include the genes from which they derive and the proteins they specify. We believe such claims are inappropriate and deleterious to science because they establish false end points for identifying genes and their function. Already, the publicity attending these claims has generated a wave of consternation amongst scientists here and abroad because it is widely held that such practices will create undesirable distortions in the conduct of basic biomedical research. Our immediate concern is that the filing of such claims undermines the activities of the Human Genome Project. There is also a strong likelihood that the pursuit of such patents will set off an international "patent race" and thereby compromise or destroy the international collaboration that we regard as essential for the work ahead.

We doubt seriously the social utility of patents that aim to control the "raw material" from which the discovery efforts of others will proceed and of patents on substances whose biological activity and utility remain to be established. Indeed, the ensuing uncertainty and confusion over competing ownership claims is likely to delay substantially the potential benefits from the Human Genome Project for the biotechnology industry and the American public.

Our discussions lead us to conclude unequivocally that the NIH claims for the patentability of random partial cDNA sequences are potentially damaging to the very scientific efforts NIH is promoting. However, because such patent claims have already been submitted, we believe that it is in the public interest and in the interest of science to determine promptly whether such patent claims meet existing legal standards and whether such standards are appropriate to the present case. To benefit both the scientific community and the biotechnology industry that determination should be authoritative, so as to govern all such patent applications, by whoever filed.

Accordingly, we request the cooperation of all relevant institutions of the federal government in obtaining that determination in an expedited and open process in which the views of all interested parties may be heard and considered. For that purpose, we request that NIH open to public inspection and copying their patent application(s) and the claims that it has filed as well as continuing proceedings regarding them before the United States Patent and Trademark Office. This would afford interested parties opportunity to comment." ■