ROUND ONE

PTO NIXES NIH'S DNA PATENTS

WASHINGTON, D.C.—At least on a preliminary basis, the Patent and Trademark Office (PTO, Arlington, VA) rejected a controversial patent application for partial sequences of human genes. The patent was filed by Craig Venter, formerly of the National Institutes of Health (NIH, Bethesda, MD) and now head of The Institute for Genomic Research (TIGR, Gaithersburg, MD), a newly formed, not-for-profit entity in the private sector.

Initial rejections of patent applications by PTO are commonplace, however. So this particular patenting effort could remain a policy quagmire.

NIH and Venter's first patent application, which claims nearly 2,400 segments from human genes, provoked a firestorm of criticisms. Some of it has come from researchers overseeing efforts to map and sequence the human genome, including James Watson, the former head of the NIH Center for Human Genome Research (Bethesda, MD). They fear that patents could interfere with genome research progress. Still other criticisms come from social activists who assert that such patenting will convert ethical nightmares into reality, turning "all life" into matter "subject to patenting and ownership by private companies," as Andrew Kimbrell of the Foundation on Economic Trends (Washington, DC) suggests.

Congressional hearings

Earlier this year, Senator Mark Hatfield (R-OR) called for a moratorium on patenting of human genes and gene segments, saying such a moratorium would allow Congress and the Administration time to design an "appropriate policy apparatus." However, Hatfield withdrew his bill calling for a moratorium, which NIH officials and other critics of the idea consider crippling to biotechnology, when other members of the Senate agreed to convene hearings where opinions on these patenting issues could be aired.

At the first of those hearings in September, Venter offered his proposal for a legislative compromise. Formulated by TIGR attorneys as an amendment to U.S. patent law, the key element of his proposal states: "Prior art shall not preclude patentability of an amino acid or a nucleotide sequence solely because such prior art discloses a portion of such sequence." In other words, a patent or other published description of a DNA sequence would not by itself keep someone from patenting the full gene or gene product and thus would not automatically prevent them from enjoying the benefits of eventual commercial development.

This approach "will enable the continued free exchange of valuable scientific information without threatening the continued development of new, life-saving technologies," Venter says. It also helps to overcome what some patent attorneys consider a "perverse" situation if Venter's applications for partial gene sequences were to be approved at PTO. That is, Venter might be able to claim technology rights for which he did considerably less work than did some other researcher, whose narrowly defined but more thorough efforts came later.

Venter's former boss, NIH director Bernadine Healy, continues to defend his research approach to genome analysis, along with his efforts to obtain patent protection. She argues that the patent filings have sparked a needed debate and that "no outcome is forced by the NIH decision to file for patents." Nonetheless, Healy and other NIH officials are unwilling to accept the initial rejection from PTO as decisive on the unsettled policy questions that surround the Venter patent applications.

Initial rejections of patent applications by PTO are commonplace. So the patenting effort could remain a policy quagmire.

ABC and IBA

Both biotechnology trade organizations, the Association of Biotechnology Companies (ABC, Washington, DC) and the Industrial Biotechnology Association (IBA, Washington, DC), continue to endorse the open debate on these issues. They admit, though, that they have not reached a consensus view on how to resolve them.

During the September congressional hearing, for instance, David Beier, vice president of Genentech (S. San Francisco, CA), summarized a joint statement from the two groups. On the central issue, the statement is noncommittal: "It is not clear, however, that patents should be sought for partial gene sequences whose functions are unknown."

Even so, the two trade groups continue to back NIH for filing patent applications, arguing that a failure to file could result in the forfeiture of foreign rights to do so. "It would be ironic if, after U.S. taxpayers paid for the research, U.S. companies have to pay a licensing fee but foreign companies do not," Beier says.

Nonetheless, biotech companies are worried that, even if they do most of the costly development work on a product, they will still be required to pay licensing fees to NIH if patents are forthcoming. Or, worse, a company may lose marketing rights for a particular product if NIH reaches an exclusive agreement on that product with a competing firm. Added to these concerns are fears that the race to file patents could lead to "new record keeping burdens" for companies and "substantial litigation," says Beier. Such a race could also add enormously to the current biotechnology patent application backlog at PTO.

—Jeffrey L. Fox