Utility is a concept mostly important for chemical and genomics patents, for which inventors may not know the function of a chemical or gene at the time of filing. The revised utility standard rejects EST patents claiming broad rights to associated genes and proteins on two grounds: A DNA fragment is not useful as a probe for a gene without specifying what is being probed for; and a DNA fragment cannot be used for protein isolation without stating what the patent office calls the protein's "real world" use. The new written description standard—which, like the utility standard, will apply to all pending applications—also rejects EST patents: Sequences of cDNA fragments are insufficient to describe the genes they are associated with, and therefore are not sufficient to claim rights to them.

John Doll, the USPTO director of biotechnology patent examination, says the revisions are unlikely to affect patents for full-length cDNAs or SNPs (single nucleotide polymorphisms), which usually have narrowly based claims. But the chances that EST sequences alone can be used to claim genes and proteins, he says, are "slim and nil." EST applicants whose patents are officially rejected will be free to appeal in federal court, and because potentially billions of dollars are at stake, a court fight over EST patents looks certain. If so, it is possible the patent office's rejection of EST patents by two different standards is a preemptive strike, as it could be harder to overturn two patent standards than one.

The guideline revisions, which will probably take effect by September, will not make all gene patent controversies go away, however. There is still the issue of function. A case in point is the recent outcry over the award of the CCR5 patent to Maryland-based Human Genome Sciences (HGS), declared by some as an outrageous decision by the patent office. A few years ago, several groups discovered that a cell surface protein now called CCR5 is an HIV co-receptor essential for viral entry into cells. HGS played no part in the discovery of this function, but had already applied for a patent on the gene. Since receiving the patent, HGS has licensed other companies to use CCR5 for anti-HIV drug discovery programs.

William Haseltine, CEO of HGS, expresses sympathy for the researchers who lost out on the patent, but he says that HGS made its application based on its demonstration that CCR5 was a receptor for several inflammatory chemokines, and useful as a tool for discovery of anti-inflammation drugs. If someone else patents use of CCR5 for HIV-related applications, HGS will be ready to consider a licensing arrangement.

The CCR5 case is not unique, according to Rebecca Eisenberg, professor of patent law at the University of Michigan. She recalls a similar story a few years back involving the receptor of leptin, an obesity regulation hormone: One group discovered the receptor's function; another owned the gene. With so many cDNA patents still pending—including a staggering 7,500 from HGS alone—Eisenberg thinks the CCR5 and leptin receptor cases may be the tip of the gene patent iceberg.

Tom Hollon, Bethesda, Maryland

UNAIDS releases long-awaited HIV vaccine guidelines

Courtesy of SmithKline Beecham Pharmaceuticals

After almost two years of consultation, the Joint United Nations Programme on HIV/AIDS (UNAIDS) has released its version of guidance points for HIV vaccine trials. The guidelines will be an important point of reference for developing countries, where many such trials are likely to take place.

One issue that has dominated the discussions leading to the release of this document is the level of care and treatment given to participants who become infected with HIV during the course of a trial (*Nature Med.* **4**, 874; 1998). Guidance point 16 of the document advises that "a consensus on the standard of care and treatment, its duration, and who will bear the costs" should be reached before a decision is made to begin HIV vaccine testing, and says, "Sponsors should seek, at a minimum, to ensure access to a level of care and treatment that approaches the best proven care and treatment that are attainable in the potential host country."

Guidance point 16 goes on to recommend that such a care package should try to include anti-retroviral therapy, tuberculosis prevention and treatment, treatment for other sexually transmitted diseases, prevention/treatment of opportunistic infections, counselling and palliative care, including pain control and spiritual care.

Activists Peter Lurie and Sidney M. Wolfe of the Public Citizen's Health Research Group have been quick to respond to the document. Although in a letter to the executive director of UNAIDS, Peter Piot, they say that the effort is an improvement over previous language, they go on to write that it still leaves large loopholes that most researchers can exploit.

For example, by asking vaccine developers to provide treatment "at a level consistent with that available in the host country," they claim that UNAIDS has played into the sponsors hands, as this statement gives "just enough wiggle room for researchers to provide no or inadequate treatment to those acquiring HIV infection during the trial in countries where anti-retrovirals are not available."

The 18-point guidance document states that "HIV preventive vaccine trials should only be carried out in countries and communities that have appropriate capacity to conduct independent and competent scientific and ethical review," and that "The research protocol should outline the benefits that persons participating in HIV preventive vaccine trials should experience as a result of their participation."

In other vaccine news…

Last month saw a commercial boost for the Global Alliance for Vaccines and Immunizations (GAVI) (*Nature Med.* **6**, 238; 2000), with large vaccine donations by four pharmaceutical companies, valued at US$150 million. Merck pledged a donation of one million doses per year for five years of the hepatitis B vaccine Recombivax; American Home Products will donate 10 million doses of hemophilus influenza type-B conjugate vaccine; SmithKline Beecham is to expand its African pediatric malaria vaccine program, conducted in collaboration with the US Walter Reed Army Institute and the UK's Medical Research Council; and Avenits is to donate 50 million doses of polio vaccine. GAVI has received requests for these and other vaccines from countries with incomes of less than US$1,000 per capita GNP—26 from Africa, 11 from Eastern Europe, 6 from Asia, 3 from Latin America and 1 from the Middle East.

Karen Birmingham, London