clear that DOE will not withdraw the regulations entirely, as many of the critics have urged. Restrictions are needed, he said, because of the widespread incidence of terrorist-related violence.

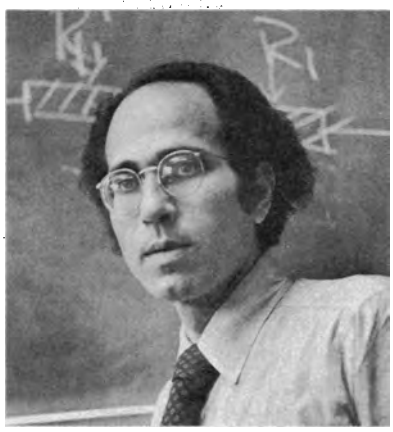
This rationale drew a sharp response from Allan Adler, speaking for the American Civil Liberties Union. Arguing that DOE's regulations should be seen in the context of other Reagan Administration attempts to restrict access to information, Adler argued that the Administration's "obsession with purported activities of foreign agents and lurking terrorist threats continues to push it toward increasingly dubious practices of information control."

DOE is planning to hold a public hearing in Chicago in late September, and will then begin the process of drafting the final rules.—COLIN NORMAN

Columbia Awarded Biotechnology Patent

Columbia University has been assigned the ownership of a patent covering genetic engineering techniques that might become widely used in the biotechnology industry. The patent covers both the procedures for moving genes into cultured mammalian cells and the products that result from such procedures. It is based on the research of Richard Axel of Columbia College of Physicians and Surgeons and his collaborators Saul Silverstein and Michael Wigler, who is now at Cold Spring Harbor Laboratory.

Although it is too soon to estimate the likely commercial success of the patent, the procedures developed by Axel and his colleagues are being used extensively in basic research. Mammalian cells may also have some advantages over microbes—now the favored host cells for gene-engineering—for synthesizing useful proteins on a commercial scale. Though microbes are generally easier and cheaper to grow, they frequently do not secrete protein products into the growth medium, thus necessitating sometimes expensive recovery procedures. Mammalian cells also may be better suited than microbes to produce certain complex proteins. "Large companies with huge facilities for animal cell culture" already exist, Axel says. For them, the inherent advantages in the mammalian-based genetic technology might outweigh any alternatives.



Ida Nathan

Richard Axel

Has several other patents pending.

The patent, which contains 73 claims, is the first granted of several that Axel and his various collaborators have pending. This patent* describes a process called cotransformation whereby two or more unrelated genes are moved simultaneously and integrated stably into mammalian cells growing in vitro. One of those genes serves to improve the chances for accompanying genes, whatever they happen to code for, to move successfully into the recipient cells, according to Axel, who notes that this research appeared in the scientific literature 3 years ago.

There are a number of strategies for synthesizing useful proteins in mammalian cells, each with its own advantages. The principal alternative to cotransformation is to use viral genes to bring other genes into cells. Its main disadvantage is the inevitable presence of those viral genes, which in some instances carry oncogenic (malignant) potential into cells. Axel's procedure avoids this risk. Moreover, he says, the use of cotransformation may broaden the choice of host cells and facilitate the playing of "genetic tricks" in which a desired gene can be amplified a thousandfold or more. Some of those tricks as well as procedures for controlling cotransformed genes are described in applications still pending before the Patent Office, he says.

Because this research was performed at Columbia, Axel and his colleagues have assigned full ownership rights to the university. The office of science and technology at Columbia is planning to offer this know-how to industrial partners on a nonexclusive basis, according to William Ragan, who heads the office.

The granting of such a broad patent to Axel and his collaborators could be a sign that the Patent Office will not become overly strict in judging applications in the genetic engineering field. Observers have speculated that the delay of Stanford University's patent application—which covers products resulting from recombinant DNA-based procedures undertaken in microorganisms—is, in part, due to the broad nature of its claims. That patent application is based on methods developed by Stanley Cohen of Stanford and Herbert Boyer of the University of California, San Francisco. Though a patent was granted for the processes they described, an application covering products resulting from the technique has been pending for several years.

The Columbia University patenting experience thus is different from Stanford's. "We captured both in one," exults Columbia's Ragan, referring to the process and product claims embodied in the Axel patent. Another difference is that Columbia has sought patent protection for these cotransformation procedures outside the United States. Stanford sacrificed such protection because Cohen and Boyer disclosed their techniques before applying for patents in Europe and Japan. (The U.S. Patent Office permits a 1-year grace period after public disclosure before disqualifying an application.)

At Columbia, inventors are assigned a portion of net royalty income that might result from licensing agreements, according to Ragan. The normal policy calls for net revenues to be apportioned to the inventors, to the inventors' labs (or some other inventor-designated fund within the university), and to the university's general revenues. The formula for this distribution varies, depending on the amount of the net income from royalties, but it is intended to provide both a direct incentive to the researchers and a means "to plow money back into the research area," Ragan says.—JEFFREY L. FOX

*U.S. patent 4,399,216