

# A One-Stop Shop for Gene-Splicing Patents

*Stanford and University of California officials propose a novel way to license patents to biotechnology companies*

*San Diego*—Two administrators at Stanford and the University of California have proposed a novel plan that would dramatically change the way patents important to genetic engineering are licensed by universities to the burgeoning biotechnology industry. The proposal is designed to cut administrative fuss and legal fees for companies and universities during licensing negotiations and to speed laboratory findings into commercial use.

The outline of the plan is basically this: Universities would pool their patents that cover biotechnology techniques or "tools" and license them to a newly created foundation. The foundation would act as a clearinghouse and sublicense the patents, providing one-stop shopping for biotechnology companies needing a variety of patents. Royalties would be paid to the foundation although most of the revenues would be funneled back to the schools.

The architects of the plan are Neils Reimers, director of Stanford's Office of Technology Licensing, and Robert Ditzel, the University of California's patent administrator. Stanford and the University of California are among the leaders in gene-splicing research. They described the "pool proposal" for the first time publicly at a conference held here 1 and 2 March by the Industrial Biotechnology Association, the industry's trade group. Though the exact details of the pool proposal have yet to be worked out, the administrators took the occasion to float a rough form of the plan before executives and patent attorneys from companies including Cetus Corporation, Biogen, Agrigenetics Corporation, Hoffman-La Roche, Inc., and Schering-Plough Corporation.

The concept raised more questions than it answered. Most participants were dubious that the plan would fly. They were particularly concerned that the proposal would violate U.S. antitrust regulations. They also asked how the foundation could guarantee that important patents would be put into the pool.

Nevertheless, companies and universities initially have taken a fairly high interest in the pool proposal though none has committed itself to participate in such an agreement. Seed money to enable Reimers, Ditzel, and Stanford grad-

uate student Mark Edwards to pursue the idea over the past several months came from contributions of \$3000 apiece from the Monsanto Company, Research Corporation, Abbott Laboratories, Eli Lilly & Company, Schering-Plough, SmithKline Beckman Corporation, and Hoffman-La Roche. Stanford, the University of California, and, reportedly, Harvard and other universities have refrained from signing licensing agreements involving gene-splicing patents to see if the pool proposal would attract industry support.

Ditzel and Reimers suggest that a clearinghouse for university patents could address several problems that they think industry and schools now face in

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**A proposal to pool university patents "has its problems, but it's better than the alternatives."**

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licensing agreements. Companies currently need a variety of patented gene-splicing techniques to produce a potential product. Under the present system, companies have to go from campus to campus to negotiate numerous licensing agreements. Universities spend valuable time and money to reach a contract with each company for the same patent. Given this cumbersome system, companies are not inclined to license and may go ahead and use the technique because the patent is difficult to enforce. The universities lose potential royalties. Companies that have taken out a plethora of patents may end up paying high transaction costs.

To simplify this process, a clearinghouse called the University Licensing Association for Biotechnology (ULAB) would be created. The foundation, either nonprofit or for-profit, would handle the licensing agreements after the schools are issued the patents. (Filing costs would be paid by the universities.) ULAB would offer a blanket license to all patent rights and a company could pick and choose which patents it wanted.

In return, ULAB would charge a royalty of perhaps \$25,000 or 1 percent of

net sales, whichever is greater. It would keep one-quarter of the revenues to cover its administrative expenses and also to fund fellowships. A formula for dividing the royalties among the schools is being worked out, but there are some potential problems. For example, a major university might contribute many patents of minor importance, but a smaller school may offer one of major significance. Should the two schools receive the same royalties or not?

In any case, Reimers and Ditzel propose that the schools' net revenues be used to support more research and education, especially in biotechnology.

Industry officials at the meeting saw the concept as fraught with problems. The association's executive director, Harvey Price, told Reimers and Ditzel after their presentation that reaction from members has fallen into two categories "skeptical . . . and *really* skeptical."

In response to questions about potential antitrust violations, the university administrators said that the plan contains a special provision created to avoid a monopoly. The provision gives companies the option to license a single patent, rather than the entire pool. Reimers said that a few antitrust lawyers, who had been informally consulted on the issue—including William F. Baxter, head of the Justice Department's antitrust division—said that the proposal could be drawn up to conform with antitrust laws. Reimers acknowledged, however, that the issue needed more rigorous review, adding that an in-depth study would cost an additional \$70,000 to \$100,000.

Whether universities would contribute their "good" patents cannot be foreseen right now, Reimers and Ditzel said. Ditzel conceded that schools would have to offer all of the patents on biotechnology techniques for the idea to work. He said it was not clear if the proposal would make such an action mandatory.

Cetus chairman Ronald E. Cape noted that unless ULAB offered important patents, "It is far wiser for industry to find out what it wants, go to the university, go for a project it wants, and then negotiate for exclusive rights." He also pointed out that leading researchers may not be able to participate in ULAB because "anybody who's anybody is now affiliat-

ed with a company." David Padwa, chairman of Agrigenetics wondered whether the proposal would have a "chilling effect" on university-industry agreements.

Ditzel and Reimers lacked good answers. "There's a whole host of questions," Ditzel said. He and Reimers reiterated the need to know whether the idea

was worth pursuing. They have set an arbitrary date of June to drop work on the proposal if no further interest is expressed by universities or industry.

Despite Cape's apparent skepticism, he urged the two men to continue. "It's an extremely profound proposal." Hugh d'Andrade, senior vice president at Schering-Plough added some encourage-

ment. Industry, he said, is currently faced with two choices in the licensing of patents—negotiate individually with universities or we use the technique anyway, which constitutes infringement. Neither is attractive or acceptable. The pool proposal "has its problems, but it's better than the two alternatives."

—MARJORIE SUN

## Hit List at EPA?

A "hit list" of targeted scientists advising the Environmental Protection Agency (EPA), an artifact from the first days of the Reagan incumbency, became the focus of an investigation in Congress on 4 March. That day, the House Science and Technology Committee approved sending subpoenas to two former EPA officials—Kitty Adams, former special assistant to Anne (Gorsuch) Burford, EPA's administrator, and to Warren Wood, former aide to James Sanderson and Rita Lavelle, both former EPA officials. The subpoenas seek documents, magnetic tapes, and computer diskettes which are thought to contain detailed checklists used in screening scientists and consultants for their political views.

The investigation, one of several the House has begun on the politicization of EPA, centers on a cryptic document that appeared on 1 March in five congressional offices. It is a list of 90 scientists on boards at EPA, giving cynical comments on their competence and ideological outlook. It appears to be a survey of industry opinions.

The hit list was released first by Senator Gary Hart (D-Colo.) but was quickly snapped up by Representative James Scheuer (D-N.Y.). He chairs the House science subcommittee on natural resources, agricultural research and environment and is leading one of the inquiries into EPA's toxic waste program. He persuaded the full committee to issue the subpoenas and also to endorse a letter to Burford requesting interviews with five current EPA staffers, including John Hernandez, the deputy administrator, and John Daniel, the chief of staff.

In releasing the hit list on 1 March, Senator Hart explained that it had come from an anonymous tipster, who called to say that this was just one of several such documents made available to Reagan appointees at EPA in 1981. The caller said this political package was collated by Louis Cordia, who worked at the conservative Heritage Foundation, served as a specialist on EPA matters during the transition between the Carter and Reagan Administrations, and now is deputy director of EPA's Office of Federal Activities. Although Hart's staff seemed to know little about the source of this information, Scheuer's press aide, Marcus Kunian, says it came from a "responsible professional at EPA" who is known to Scheuer and has proved accurate in the past.

The document, which is undated and unsigned, lists 90 scientists by name, and opposite their names gives comments such as the following: "clean air extremist," "smooth but extreme environmentalist," "reported to be liberal and environmentalist," "get him out, horrible," "very good, keep," "get him out fast, extreme anti-nuclear type," and so on. None of the EPA officials contacted by

*Science* seemed to doubt its authenticity. However, an EPA spokesman did say that it must have been produced by someone outside the agency.

Cordia was quoted in the *Washington Post* as saying the list may have come from one of 15 boxes of documents he was planning to remove from his office on 11 February. Today, he says that he never saw the list before 1 week ago. A *Post* reporter contradicts him, saying Cordia conceded that many personnel checklists like this were prepared during the transition period early in 1981. The 15 boxes, Cordia says, contain excess research materials for which he has no space at EPA. The agency's inspector general has taken them into custody for safekeeping.

Cordia maintains that the hit list, whatever its origins, never played a part in EPA appointments to advisory boards. Although some members of EPA panels believe the agency has been remiss in seeking scientific opinion, nearly all who spoke with *Science* backed Cordia on this point: there has been no ideological purge of the advisory boards. The total number of advisors on standing committees has decreased from around 70 to 37 since 1980, and the number of committees has gone down from five to three. But most said that EPA had retained a fair balance of opinion.

"I haven't seen anything to make me believe they have manipulated the scientists," says Karim Ahmed of the Natural Resources Defense Council, an outsider who frequently testifies against EPA actions. Edward Ferrand, New York City's chief air quality official and a member of EPA's science board for 8 years, said the same. "I'm a Democrat and I could be described as an environmental liberal," Ferrand says. "I know they got rid of a lot of people, but I haven't noticed any drastic change" in the kind of appointments made.

Terry Yosie, EPA's executive director of the science advisory board, describes the hit list as "unfair and reprehensible." He says he "totally disavows" the document: "Whoever prepared it was not dealing from a full deck." Yosie says he did not consult with Cordia in making nominations to the board, and "to the best of my knowledge," hit lists like this one were not used to screen candidates.

EPA has been criticized for shrinking the size of the advisory board and for failing to appoint any women or minority members. Yosie reports that he is now planning to expand the board's size from the present 37 members to "between 50 and 60." Why? Looking over the agenda for 1983, Yosie saw that "we have an expanded work load." EPA apparently is considering advertising the new vacancies in order to create a large pool of candidates.

—ELIOT MARSHALL