Monsanto Gives Washington U. $23.5 Million

The company considers its new university agreement a "strategic investment" for expansion into the health field

A $23.5 million, 5-year research agreement between Washington University and the Monsanto Company ranks among the largest so far in the current university-industry sweepstakes, rivaling the $70 million contract between the Massachusetts General Hospital and Hoechst AG that provides funding for 10 years for a new department of molecular biology at the hospital (*Science*, 11 June, p. 1200). Each of the many university-industry agreements that have been reached recently represents an effort to preserve academic values while also acknowledging corporate needs. The newest agreement, announced by Monsanto on 3 June, has two distinctive features in this regard.

The Academic-Industrial Complex

This is the third in a series of occasional articles about the emerging relationships between industry and universities.

First, the Washington University–Monsanto contract is an "institution-to-institution" agreement, quite deliberately drafted to deviate from the majority of arrangements in which corporate funds are earmarked for research by one or two senior investigators of the company's choosing (*Science*, 28 May, p. 960). Under terms of the contract, medical school faculty whose research meshes with the scientific aims of the collaboration may apply for the Monsanto funds, which will be awarded by an advisory committee composed of four scientists from each institution. Washington University chancellor William H. Danforth told *Science* that "This will be like an internal granting agency to which people can come for all or part of their funding." David Kipnis, head of the department of internal medicine at the university, will be chairman of the advisory committee. He maintains that the "institution-to-institution" character of the new agreement will alleviate "elements of divisiveness" that may crop up when one or two superstars control significant corporate funds. "We're very much breaking the pattern in this regard," he says.

The second feature of the Washington University–Monsanto arrangement that sets it somewhat apart is the extent of constant, intimate collaboration it anticipates between researchers at the two institutions. Whereas most of the new contracts contain provisions for some training of corporate scientists and for occasional interaction, this deal provides for what Howard A. Schneiderman, senior vice president of Monsanto, terms a "true partnership." Dozens of company scientists may be working on campus at any one time, once the agreement is in full swing, he notes, adding that Monsanto researchers will not be "token" members of the collaborative team. Indeed, the desire for close collaboration was one of the reasons Monsanto decided to deal with Washington University. Says Schneiderman, not only is it a "major research university," it also has the distinct practical advantage of being "only 15 minutes away" from company headquarters in St. Louis.

The Washington University–Monsanto arrangement, which Schneiderman describes cheerfully as "the culmination of a long love affair between two institutions," is a clear sign that Monsanto, one of the country's largest chemical producers, is serious about moving into the pharmaceutical business. "This is a real strategic investment on Monsanto's part," Schneiderman said in an interview with *Science*. After all, $23.5 million spent at Washington University is $23.5 million that will not go to the company's in-house labs. Calling the contract a "very hard-nosed, pragmatic move," Schneiderman acknowledges what other corporate officers have said about turning to academe as the source of talent and data in biotechnology. "We believe we'll get more at Washington University than we'd get by spending the money in-house," he says, "but we'll be expanding our own capacity too."

Although Monsanto has research agreements with scientists at a number of major academic institutions, its $23 million, 12-year contract with Harvard (*Science*, 25 February 1977, p. 759) is in part the inspiration for the Washington University deal. The Harvard-Monsanto contract, which provides support for research by Judah Folkman (see story on p. 1304), was a major factor in the company's move into pharmaceuticals. That contract "sensitized Monsanto to the health care area as one to move into. Don't underestimate the importance of that," Schneiderman states.

The scientific focus of the Washington University–Monsanto venture will be on proteins and peptides that modify cellular behavior. The point, of course, is to go from basic studies to research that is "directly applicable to human diseases." Neither party to the agreement will discuss research expectations with any precision; Kipnis says only that the modulation of polypeptides is a field "on the verge of explosion." Understanding peptide regulation has implications for a multitude of diseases, including malignancy, arthritis, immune disorders, hypertension, and blood clotting, Kipnis observes. Schneiderman says that "if everything works right, we'll see a few products approaching the marketplace by the end of the decade, given luck and a few people lighting some candles."

Industry's legitimate, undisguised self-interest in sponsoring academic research is an obvious source of worry to university scientists, who feel distinctly uncomfortable in the corporate milieu. Thus, efforts to negotiate can be prolonged. The mating ritual between Washington University and Monsanto lasted 3 years and included a retreat to which a dozen scientists from each side were invited. Altogether, some 15 to 18 university researchers participated in discussions leading up to the agreement, which has helped generate enthusiasm for it, Kipnis says. The fact that they also more or less "kept their mouths shut" until it was worked out is also considered an important element in the successful negotiation.

The initial step, Kipnis reports, was to agree on certain "baseline rules" for a contract. First and foremost, he says, was the decision to make it an "institution-to-institution" deal and to identify a field of research to pursue rather than specific products; thus, proteins and peptides. A commitment to put a "significant" amount of money into purely basic research was also crucial. (The

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agreed-upon figure is 30 percent.) "From the very beginning, we insisted on this," Kipnis recalls. Yet another requirement was a provision for a separate, outside advisory committee, with no ties to either institution, to provide external review of the scientific quality of the collaborative research and also to assess the effect of the contract on the company and university. Once these terms, designed to protect academic values, were agreed to, the rest, apparently, was easy.

During the first year of the Washington University–Monsanto agreement, $3 million will be available to researchers from six departments (biochemistry, immunology-microbiology, genetics, medicine, pathology, and pharmacology) eligible to compete. Eventually, the "internal granting agency," as Danforth calls it, will accept applications from any member of the medical school faculty.

As is the case with all university-industry contracts, this one contains provisions regarding patents and licenses. Patents will be held by the university, which will license Monsanto to develop them. Exclusive licenses will be granted for inventions emerging from work solely supported by Monsanto. According to Edward MacCordy, assistant vice chancellor for research, faculty who submit applications to the eight-man Washington-Monsanto advisory committee will have to disclose information about all other research plans and sources of funding. The committee can reject applications that would present a challenge to Monsanto's rights, particularly if another profit-making company is involved. One question that looms large where licenses are concerned is this: What happens if a company-sponsored researcher ends up in a productive collaboration with a colleague whose funds come from the federal government. According to MacCordy, federal patent law, as revised by Congress in 1980, allows the university to own the patent and to license it on an exclusive basis "for a limited term, not for the life of the patent," with priority going to U.S. companies. Thus, a company would not have the same protection it could get from exclusively funded research but still would have a chance to get a head start on its competitors.

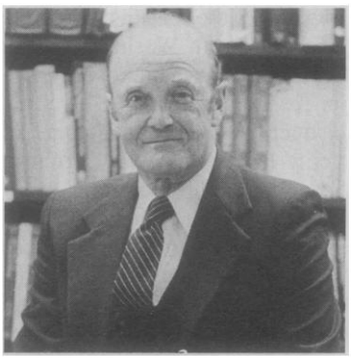
Other provisions of the Washington University–Monsanto agreement include these:

• **Royalties**. Should commercially useful drugs or diagnostic tools result from the research, royalties will go to the medical school and relevant departments and laboratories. In no case, Kipnis emphasizes, will individual faculty members get any personal financial reward.

Because no one has any real idea of what might come out of the collaboration or what it might be worth, royalty rates have not been set. Instead, says MacCordy, "they will be negotiated on a case-by-case basis if something develops." The money from royalties "could be an important by-product" of the agreement, chancellor Danforth observes, "but that isn't our main reason for going into this."

David Kipnis

"We're breaking the pattern. . . ."



Howard A. Schneiderman

"I've been a great marriage broker."

• **The "deep pocket" provision**. In addition to contractual protection of its academic virtue, Washington University sought protection of its endowment. There is an attitude among the public that universities have "deep pockets," MacCordy notes, citing concern about the possibility of a product liability suit a decade or two down the road. "The issue is fairly new, but it is an especially serious threat in the medical area," he says. Monsanto will indemnify the university for all licenses it receives.

• **Publishing**. Washington University scientists will be free to publish their data, but the company will review manuscripts first. In the event Monsanto wants to file a patent application, submission to a journal can be delayed for at least 30 days. Provisions such as this are quite common now in university-industry agreements, although they were resisted initially by faculty who did not like the thought of any enforced delay at all.

As several persons have noted, once you point out the obvious—that routine publishing delays far exceed 30 days—a brief delay in manuscript submission is accepted as one of the costs of doing business with business. Furthermore, once patent considerations have been taken into account, it is often in a company's interest to have its academic brethren publish. "It is," notes MacCordy, "the best possible publicity," because it does a lot to establish the credibility of the science.

One of the more contentious issues in this area has to do with foreign patents. In the United States, one can file for a patent up to a year after disclosure of an idea or invention. Abroad, any disclosure (including discussion at a lecture or seminar) may preclude a patent filing. There are few satisfactory solutions to this problem (short of silence). However, MacCordy suggests that the close collaboration between corporate and academic scientists anticipated here may be useful as an early warning system. If Monsanto researchers see something coming along, the company can be notified and foreign patents filed before informal disclosure destroys rights overseas.

With general concerns about what corporate ties will do to open communication and easy collaboration among researchers, another issue is gaining currency as more and more university-industry deals are struck. That is, fear that corporate funds will drive out government money. There is no way that industrial support of research can ever fully substitute for government funding, virtually everyone agrees. Nevertheless, the subtle perception that campuses with substantial corporate ties are less in need of federal funds appears to be taking hold. At Washington University and elsewhere, there are reports that grant applicants are getting a cool reception from federal peer review committees. According to Kipnis, the Monsanto agreement "allows us to explore new areas freely and to expand." New faculty recruitment is anticipated and money will be available for instruments. "It does not relieve society of its obligation to support science," he says. If the price of corporate support is the loss of federal funds, universities may find the price too high. All around, as MacCordy observes, "the acid test will be in how many of these agreements are renewed."—BARBARA J. CULLITON