FDA to Clear Platinum

With Food and Drug Administration approval imminent, a platinum-containing anticancer compound licensed under Research Corporation's Invention Administration Program will shortly be marketed in the U.S.

Discovered by Barnett Rosenberg and his coworkers at the Michigan State University (R & I, Winter 1972; Winter 1977-1978), the preparation is known as cisplatin. It has been found effective for treating patients with advanced cancer, especially testicular and ovarian cancer. Bristol Laboratories, a division of Bristol-Myers Company, will market the drug under the trademark Platinol.

Clinical studies indicate that Platinol, used with combinations of other anticancer drugs, provides an optimal therapy for testicular cancer.

Wonder Drugs

peptide appears to prevent ovulation. A practical contraceptive based on the work might be economical, nonimmunogenic and flexible as to method of administration. Further, it would lack the side effects attributed to steroid hormones.

Although assessments vary as to the present and future usefulness to medicine of peptide chemistry, investigators express varying degrees of optimism. A major stumbling block is lack of information. Despite spectacular progress in recent years, there are vast areas—the exact structures of natural peptides, proteins, enzymes and hormones and their interrelationships—that must be carefully explored before one can design molecular remedies for metabolic abnormalities.

Nevertheless, the tantalizing bits of information thus far collected and successful efforts to utilize that information bode well for the future. "It's clear that many metabolic processes involve cleavage of peptide bonds and that control of such processes offers promising possibilities," says John Yankeelov.

Bruce Erickson of Rockefeller believes that synthetic peptides in increasing number will be applied to biological problems in the 1980s. "I have the feeling that it's going to be a slow, steady process," says Erickson, "but I'm definitely encouraged by what I've seen in the last five years. Given sound, intelligently focused structure-function studies, there's a great future in peptide synthesis—especially as applied to drug development."

patent pitfalls 18

Patent Policy Battle Rages in Congress

Born anew in the bitter winds of last December, the stormy controversy over who should hold patent rights to inventions resulting from government funded research seemed to be attracting less attention by midsummer.

Appearances are deceptive, however, for the dog days of August saw the debate joined by Sen. Bob Dole (R.-Kans.) who charged that the Department of Health, Education and Welfare "is suppressing lifesaving medical technology." Accordingly, Sen. Dole promised to introduce a bill, cosponsored by Sen. Birch Bayh (D.-Ind.), that would expedite the release of patent rights to universities and small businesses.

The story begins last year with the introduction in the House of the Thornton-Teague bill (R & I, Spring 1977). Designed to spur technology transfer, the measure provided for wider use of Institutional Patent Agreements (IPAs) such as those made by the Department of Health, Education and Welfare and the National Science Foundation. The agreements automatically release to institutions certain rights to inventions made in sponsored research.

The Thornton-Teague bill rallied a number of opponents, among them Sen. Gaylord Nelson, Chairman of the Small Business Subcommittee on Monopoly and Anticompetitive Activities. In hearings held by Sen. Nelson last December, witnesses denounced IPAs as part of the "federal patent giveaway." Among the points made: inventions should belong to the taxpayers if they foot the bill for the research. Releasing exclusive rights to inventor and institution, it was claimed, permits the establishment of monopolies that can charge exorbitant prices for the fruits of tax-aided work.

The February publication by the General Services Administration of revised federal procurement regulations sparked still more debate. Drafted by the Office of Management and Budget in response to recommendations from a subcommittee of the Federal Council for Science and Technology, the new rules—while not as sweeping—have much the same intent as the Thornton-Teague bill. They allow wider use of IPAs by the executive granting agencies and set uniform standards for administering them.

The GSA regulations were bound to be controversial, and strong reactions came not only from Sen. Nelson, but from Sen. Russell B. Long (D.-La.) and Ralph Nader. In a letter to GSA Administrator Jay Solomon, Nader stressed the constitutional issue first raised in a public interest lawsuit filed in 1973: that release of patent rights in inventions made with government monies constitutes illegal disposal of government property (R & I, Spring 1974). Responding to an urgent request from Sen. Nelson, GSA delayed implementation of the new regulations for 120 days.

Charging that the revised rules would "give away government patent rights to drugs, living organisms and other inventions resulting from billions of dollars of federally funded research and development," Sen. Nelson scheduled hearings in May and June for representatives of the academic community, patent management organizations and other spokesmen in and out of government.

Opposing views aired

Appearing on behalf of a number of major universities, Thomas F. Jones of M.I.T. strongly defended IPAs. Downplaying the potential financial return ("minimal"), Jones argued that universities are far better equipped than government to pursue licensing and development of their inventions.

Testifying at the June hearings, Donald R. Dunner of the American Patent Law Association commented that proper patent policies should put real world economics first; that government has not done its job unless research results reach the consumer. "IPAs," said Dunner, "place initial responsibility for commercializing research results on the inventing institution—which has the most interest in, and knowledge of, the invention of its own creation."

Decrying the notion that such inventions allow institutions to reap untold wealth at the expense of the taxpayer, Willard Marcy, Research Corporation Vice President—Invention Administration Program, noted that only a few college and university inventions ever generate significant royalty income. "Government should encourage research and provide all possible means for bringing it into broad use," Marcy stated. "Extension of the IPA approach to other granting agencies can only be

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Patent Policy Battle

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constructive." Carrying this suggestion a step further, Patent Counsel Howard W. Bremer of the Wisconsin Alumni Research Foundation testified that government-wide IPA arrangements would not only provide an effective means for transferring technology, but they might well be made mandatory.

New GSA regulations now in effect

Whether or not further congressional action is forthcoming, the 120-day suspension of the new GSA regulations was lifted on schedule July 18. While this may be an interim measure pending further developments, the action is not without effect.

An unusual effort to liberalize patent policy through administrative action, the regulations are designed to cover research under contracts as well as grants. In addition to permitting wider use of IPAs and setting consistent standards for them, the rules remove the ceiling on the amount of royalties that can be returned to the inventor, and allow universities to work with for-profit management companies. While the rules strongly encourage nonexclusive licensing when possible, they provide for five-year exclusive licenses—rather than the present three—when necessary to spur commercial development.

Useful as the GSA rules might be in spurring technology transfer, however, congressional action may be needed to satisfy the critics: public interest groups, the Justice Department's Anti-Trust Division and congressional opponents. Among other arguments, these critics maintain that Congress—and not the Administration—must rule on the disposition of the "property" represented by patent rights. Proposing that Congress legislate in this area are Senators Dole and Bayh.

Motivation for Sen. Dole's charge that HEW is suppressing medical technology can be found in an HEW decision made over a year ago to withhold positive action on releasing patent rights pending a full review of policy and procedures. Although tentative approval was given the case-by-case waiver of patent rights "when necessary to attract risk capital," the Department's IPAs came in for serious criticism. These delegate to others the power to decide whether or not, and how, inventions will be developed, suggested an HEW attorney. By exercising this power itself, the agency can "regulate the availability and cost of inventions made with HEW support..."

Senators Dole and Bayh regard the HEW attitude as expressed above as one of "over-management" and of "lashing out" against medical science. And, while HEW's internal review continues, a number of promising medical discoveries languish on government shelves. The Dole-Bayh bill would reduce what is seen as bureaucratic interference with technology transfer.

Introduced Sept. 13 under the title of "Small Business Nonprofit Organization Patent Procedures Act," the proposed legislation would establish a uniform policy for releasing rights to inventions made at universities, nonprofit organizations and small business firms. All would be permitted to take title, subject to conditions similar to those contained in the present IPAs. Included here would be government rights to paid-up licenses and the right to take title to unreported or unpatented inventions. March-in rights would be exercised if effective steps were not taken to achieve application of an invention.

A novel feature of the Dole-Bayh bill is a payback provision that would reserve for the government 50 percent of all net income above $250,000 received by a university from licensing an invention—not to exceed, however, the amount of government funding directly related to making it in the first place.

If congressional action is taken, it will climax decades of study and debate over the complex issues that surround government patent policy. A resolution to the conflict may be in sight, however, if only because of a perceived lack of industrial innovation in the U.S. and the trade deficit with such high technology countries as Germany and Japan.

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P. O. Box 7365
Madison, Wisconsin 53707

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Research Corporation
405 Lexington Avenue
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