

say conclusively, however, that the company never engaged in black boxing or sanding off numbers.

Interviews with representatives of larger firms indicated that companies are more likely to patent electronics inventions when they hold the promise of leading to mass consumer sales. A number of people cited not only the several thousand dollars it costs to obtain a U.S. patent, but also the \$50,000 or more needed to enforce the patent through the courts once it is granted. "By a straight, 10 percent rule, you have to be able to make at least \$500,000 in sales from something to justify the cost of a patent."

The ultimate mass-market electronics item has been the hand-held calculator, which is protected by hundreds, perhaps thousands, of patents, according to a spokesman for Hewlett-Packard Co. and a lawyer for the Bomar-Ali Corp. Jack Goldhammer, a lawyer with the Philadelphia firm of Seidel, Gonda, Goldhammer, which represents Bomar, explains that in the early days of the device, Bomar and the other companies in the forefront of the development obtained patents on every conceivable aspect. Today, Bomar (which has stopped making calculators), Hewlett-Packard, and Texas Instruments hold most of the key patents.

A spokesman from one of these companies estimates that the hand-held calculator sold in department stores or sta-

tionery shops may be covered by "a couple of hundred" patents and cross-licensing agreements. Everything is covered, including the plastic case, molding, design of the front, battery, battery charger, printed circuit, keyboard, input encoder, central processing unit, and whichever display technique it uses—crystal or light-emitting diode. The same thing is true, the spokesman noted, for many other mass-consumption items such as cars or hi-fi sets.

Science's interviews turned up no easy method for determining whether black boxing and other techniques are as widespread as some in the electronics field claim or whether their use has increased while patenting activity has declined. The interviews did, however, turn up a wide variety of complaints about the patent process. Sources of the complaints ranged from small inventors who maintained that it is useless in such a fast-moving field to a high GE official who wished patents were better suited to protecting industrial know-how and processes, which need safeguarding, too.

Government officials interviewed, who usually said they were unaware of potting, number sanding-off, and other techniques, nonetheless were uneasy with wholesale use of patent data as an index of innovative activity in any specific field. "I hadn't heard of black boxing," says an aide to Jordan Baruch, Assistant Secretary of Commerce for Sci-

ence and Technology, who is heading the President's innovation study due in April. "But it's pretty commonly known that there's an increasing reliance on trade secrets instead of patents . . . that belies the use of patent figures as an index of innovation." Beyond that, the aide said, officials involved in the study know very little. Part of the study, headed by Robert Benson, director of the patent division of Allis-Chalmers Corporation, will examine patents.

Several government officials noted that the black boxing issue is only one of many criticisms of the patent system. Echoing the remarks of the GE official, they noted that the patent system is not well suited to protecting industrial know-how. There also has been a continuing controversy related to electronics, namely whether and how much computer software can be patented. Finally, innovative activity in the communications privacy field—that is, in encryption and voice scrambling—has been hampered in the last year by a little-known section of the patent regulations that allows the government (in this case the National Security Agency) to classify the work of private inventors.

So while policy-makers in Washington are having second thoughts about the patent system, some people in the electronics industry have made up their minds that for them, at least, patents are only marginally useful.—DEBORAH SHAPLEY

1976 Swine Flu Campaign Faulted Yet Principals Would Do It Again

The swine flu campaign launched by President Ford in March 1976 still defies any simple evaluation. Some 48 million citizens were inoculated, more than twice the number even reached before in a single flu season, yet the threatened new flu strain failed to show up. So was the campaign a necessary insurance policy nevertheless, or an empty triumph, or an avoidable fiasco, or none of the above?

The new Administration's health secretary, Joseph Califano, had among his first tasks on taking office a decision on whether to resume the swine flu campaign after it had been halted by discovery of the rare side effect known as Guil-

lain-Barré syndrome. "This swine flu situation surprised and bedeviled me," Califano has written. He commissioned a review of the campaign from Harvard political scientist Richard E. Neustadt, a leading student of the presidency. Neustadt and a colleague, Harvey V. Fineberg, have written a beguilingly readable postmortem which was published last month.*

In the foreword of their report, Neustadt and Fineberg diagnose seven "leading features" of the decision-making for the swine flu program. They are:

**The Swine Flu Affair. Decision-Making on a Slippery Disease.* Richard E. Neustadt and Harvey V. Fineberg (U.S. Government Printing Office, Washington, D.C., 1978).

Overconfidence by specialists in theories spun from meager evidence.

Conviction fueled by a conjunction of some preexisting personal agendas.

Zeal by health professionals to make their lay superiors do right.

Premature commitment to deciding more than had to be decided.

Failure to address uncertainties in such a way as to prepare for reconsideration.

Insufficient questioning of scientific logic and of implementation prospects.

Insensitivity to media relations and the long term credibility of institutions.

Flu, they say is a "slippery disease," meaning that the changing antigenic character of the virus makes it hard to produce an effective or long-lasting vaccine. It is also hard to estimate how much illness is caused by flu and how much by the many similar viruses with which it is often confused. Such uncertainties mock the objectives of a swine flu campaign, say Neustadt and Fineberg:

What a basis on which to build public consciousness and to seek support for preventive medicine! What a basis on which to risk the

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whereas if it were too high the risk involved—given China's lack of experience and industrial capacity—would be too great. Thus the medium-range proton machine was settled on.

American physicists observe that the goal of completing the new accelerator in 5 years is quite optimistic. With shortages of young, trained scientists and deficiencies in important technological industries, the project will be challenging. Many components needed for a large accelerator—such as fast electronics, precision power supplies, modern computers, and ferrite materials—are not manufactured in China.

A site for the accelerator has already been chosen. It will be located about 30 kilometers from Peking, near the burial tombs of the 13 emperors of the Ming Dynasty. Work is due to begin in late fall.

Director of Los Alamos Laboratory Resigns

Harold Agnew has announced that he intends to resign the directorship of the country's original nuclear weapons research facility, Los Alamos Scientific Laboratory, effective 1 March 1979. In his letter of resignation, he said that he was protesting certain restrictions that have been imposed on the laboratory in recent years.

One factor Agnew cited in his decision was "my frustration with what I consider to be a continuing inequitable distribution of defense program funding by the Department of Energy" between Los Alamos and its major competitor, Lawrence Livermore Laboratory. Both laboratories have diversified to encompass a range of scientific fields, but this comment apparently refers to Livermore's traditionally higher budget for weapons. Other factors Agnew cited were "dissatisfaction" with the salary policies of the University of California, which administers both laboratories, and a "lack of advocacy of the total [Los Alamos] program."

Agnew, who worked in Enrico Fermi's group at Chicago and was present when the first nuclear pile went critical in 1942, is only the third director of the Los Alamos Laboratory. His predecessors were General Norris Bradbury and Dr. J. Robert Oppenheimer.

William D. Metz

high reputation of an establishment like CDC! What a basis, for that matter, on which to expose 40 million people to an unknown risk of side effects! And all this on the word of experts, overconfident in theories validated through but two or three pandemics, without any proper review of their logic by disinterested scientists. It is not that conclusions were inconsistent with evidence, but that the paucity of evidence belied the force with which the conclusions were advanced.

This is strong language, but the reader would be quite mistaken to infer from that and the seven decision-making flaws that Neustadt has identified any clear errors in the logic of the swine flu program. He believes the program was correct at least up to the stage of manufacturing the vaccine. "I think, given the evidence, that to do anything less would have been irresponsible," he said in an interview.

The flu campaign designers decided against the obvious option of stockpiling the vaccine, and waiting for an epidemic before immunizing, because they believed from experience with previous flu campaigns, that there would not be time to get the vaccine into people once the flu had struck. Two or three of the advisers to the swine flu campaign favored stockpiling, but the clear majority were against it. Except in the light of hindsight, it may be hard to see what should have been done differently. Neustadt, however, considers the fault to lie in too narrow and inbred a circle of advisers. The participation of more "disinterested scientists," those with no "personal agenda" in favor of public medicine, might have ensured a different decision. That could be so, but at least one adviser believes Neustadt underestimates the diversity of input. "We were no pure culture. We were as broadly constituted as a workable sized group could be. The relative unanimity among us arose because of a hard body of science pointing to what should be done," says June Osborn of the University of Wisconsin.

Neustadt also criticizes the memorandum of 18 March 1976 which initiated the swine flu campaign. Written by David Sencer, then director of the Center for Disease Control, the memo laid out cogently the case for responding to the threatened new strain, stressing in particular the option for a full fledged inoculation campaign. Neustadt considers that Sencer should have spelled out the uncertainties more explicitly, and should not have rolled all the decisions together in one yes-or-no package in a way that was tantamount to holding a gun at Ford's head.

The Neustadt-Fineberg review criticizes Sencer more than any other official, often with accusations that seem

hard to substantiate. The memorandum of 18 March, they allege, "reads as though it were deliberately designed to force a favorable response from a beset Administration that could not afford to turn it down and then to have it leak." Sencer, now an executive with a New Jersey medical supply firm, vigorously denies that he intended to leak the memo. "I have never leaked anything. If they said that they have a real misconception of what was going on," Sencer says.

Another instance when Neustadt has apparently been able to read Sencer's mind is in the suggestion that Sencer held his political superiors in low esteem: "Sencer pushed his bosses without stint. They were his constitutional superiors but that gave him no pause. Cooper aside, they were laymen. Sencer evidently held the not uncommon premise that the boobs could not be trusted to decide right on their own." "I certainly don't think that," says Sencer. So how does Neustadt know? "That is the conclusion we draw from the narrative before you," says Neustadt. Besides, that is an attitude "held by a great many chiefs of government organizations." But why not give the reader the benefit of knowing that Sencer happens to deny holding it? "On the matter of do we quote Sencer on what he would believe in retrospect after having been burned, we have to make a serious judgment on whether what he says is meaningful," is Neustadt's answer.

Neustadt's explanation of his methodology would seem to offer no compelling reason for preferring his suppositions over Sencer's denial. Sencer was shown a draft of the Neustadt-Fineberg review but confined his corrections only to questions of fact. He declined the offer to write an appendix lest it look like an apology.

Like others involved in the campaign, Sencer still believes that, in the light of the knowledge then available, the right decisions were made. "Placed in a similar position again I would certainly have made the same recommendations as I did then," he says. Flu virologist Edwin Kilbourne, asked if he would still have made the same decisions, says "Absolutely, unequivocally." Kilbourne regards the swine flu campaign as a "milestone in public health" because it brought to light new problems, as a result of which "we are now better prepared for a pandemic." Osborn says she would have done the same again: "I have never been able to come up with a better rationale." Califano seems to be of the same opinion. In an interview pub-

lished in the 3 April 1978 *Medical World News*, Califano says "The toughest decisions I think I've had so far are the public health decisions. I reviewed that swine flu situation, and I am not sure that anybody would have made any different decisions [from those] the prior Administration made on swine flu."

A possible confusion in the Neustadt-Fineberg is that its tone in many passages implies blame for things done

wrongly, although its intention, says Neustadt, is quite otherwise. "Caught in the same situation, I might well have done the same thing," says he. His narrative draws praise as well as criticism from those involved in the swine flu program. "It is a reasonably accurate description. I think he has done his damndest to be fair and objective," says John Seal, scientific director of the National Institute for Allergy and Infec-

tious Diseases. "The descriptive part is well done—their book is a qualified success," comments June Osborn.

The swine flu program is probably still too recent to be judged in perspective. Even if it were not the best course of action, it was at the least a rational response to an unknown risk. After the next pandemic, its good and not so good results may stand out more clearly.

—NICHOLAS WADE

NAS Saccharin Report Sweetens FDA Position, But Not by Much

A panel of the National Academy of Sciences (NAS), in a report on 4 November that offers few surprises, has concluded that the artificial sweetener saccharin poses a potential carcinogenic risk to humans, albeit a comparatively low risk. The report, which was the NAS's fifth on the sweetener since 1955, is the first by them to reach this conclusion; it also concludes for the first time that saccharin promotes the development of cancer initiated by other substances. The report calls particular attention to an alarming increase in the consumption of saccharin by children under 10 years of age, but carefully avoids any recommendations for action by the Food and Drug Administration (FDA), which commissioned the study as ordered by Congress 1 year ago.

The study does not at first blush resolve the largely political issue of whether or not the FDA should be permitted to proceed with its intended ban of saccharin. It was the FDA's announcement of the ban, which was strongly opposed by the general public, that prompted Congress to bar the action pending completion of this study and a broader Institute of Medicine (IOM) report on food safety policy, due in February 1979. Reaction to the saccharin report on Capitol Hill has largely been muted, owing in part to its release 4 days before the congressional elections. Congressional staff members have already dubbed it "OTA 2," however, after a 1977 report by the congressional Office of Technology Assessment (OTA) that reached the same conclusions. "The NAS has given us not one whit of additional help on the policy problems," said a staff member on the

Senate Subcommittee on Health and Scientific Research. "It certainly doesn't clinch the debate for proponents of the ban."

Neither does the report offer any solace to the saccharin and soft drink industry, however. To the extent that the report, with the imprimatur of the NAS, is as definitive as intended, it lays to rest much of the industry's propaganda surrounding the 1977 study of saccharin by the Canadian government. That study was the third of three two-generation feeding studies to produce evidence that saccharin is carcinogenic in rats and really the only new evidence available to the NAS since its last, inconclusive report in 1974. Contrary to the industry's claim about the Canadian study, its results are not confounded by the dose levels used, by the alleged impurities of the saccharin tested, or by the use of test animals to predict a hazard for humans, the NAS panel determined. "Further studies to establish the carcinogenicity of saccharin are not needed." Short-term and single-generation saccharin studies, many of which produced negative results, are in accord with this determination because uniformly positive test findings are neither expected nor likely, said the panel, chaired by Emmanuel Farber, a pathologist at the University of Toronto, under the broader supervision of an IOM coordinating committee headed by Frederick Robbins, dean of the school of medicine at Case Western Reserve.

Additional studies were recommended in three areas: techniques for the quantitative extrapolation of animal test results to humans, the significance of in-

utero exposure to toxic substances, and the mechanisms of cancer promotion—each an issue of science with implications broader than the debate over saccharin itself. Current knowledge of the first of these is insufficient to predict numerically the number of human bladder cancer cases that will result from continued exposure to cancer, the NAS concluded. This is something of a slap at the FDA and the National Cancer Institute (NCI), both of which had made such predictions (the NCI had said 600 to 700 cancer cases a year would result). The NAS said the range of estimates was so broad—between 0.0007 and 3640—as to defy precision.

Children Are Particularly Vulnerable

Despite its refusal to make a precise risk assessment, the NAS did target several groups whose risk of cancer from saccharin consumption is greater than that of others. One such group is children below the age of 10 years, one-third of whom consume saccharin-containing food products. Since 1972, saccharin consumption among children in this group has jumped 160 percent, according to market data used by the NAS. Although exposure has increased for all age groups, largely because everyone has been drinking more and more soft drinks, children are particularly vulnerable in this trend. The amount they consume relative to body weight makes them the group with greatest exposure, the NAS noted. "The data which showed that 10-year-old kids are lining up and pushing 'Tab' buttons in machines all over America made a big impression on the panel," according to one of the members. "What will happen when the latency period is up?"

Also disturbing was the finding that the highest proportion of saccharin users for members of each sex falls in the 0 to 9 age group for males and the 20 to 39 age group for females. The carcinogenicity of saccharin has been found only in male rats first exposed while their mothers