logical implications are not understood. And, according to the report, "despite renewed interest in microbial contamination of foods, current efforts are inadequate to cope with problems associated with rapid changes and new developments in the food supply."

The subcommittee report culminates in a discussion of the development and use of microbiological criteria for food. It is a very circumspect treatment. The report notes that it is premature to set legal microbiological standards for food, other than milk, and water. The latter are homogeneous liquids which may be readily subjected to heat and filtration or chemical treatment in closed systems. "On the other hand," the report says, "solid foods cannot be filtered, vary widely in formulation and in the kind of processing to which they are subjected, and are handled in closed systems with difficulty. In addition, their production facilities are widely dispersed, so that control is difficult."

Other practical difficulties intrude. There is really no consensus on what specific criteria should be applied (which organisms should be included, and in what number, which methods should be used for sampling and analysis). If microbiological standards were written into law, the report says, an enforcing agency might be hard put "to prove that a bacterial level in excess of the standard was dangerous to health or was indicative of decomposition or filth."

Case For Uniformity

Industry, which has been concerned about the hazards implied in the new processes and, in fact, is largely responsible for initiation of the subcommittee study, is concerned that new microbiological standards be reasonably uniform across the country, so that "trade barriers" are not erected. Efforts by the leading national organization of food and drug officers to promote a model law in states considering such legislation appears to be having some success.

It is widely recognized, incidentally, that most state and local health authorities are ill prepared to enforce a microbiological code, and that money for trained personnel and new facilities would have to be found.

From all of this it is clear that the trail being blazed in food technology needs some tidying up, by public health officials, microbiologists, and other food scientists.—JOHN WALSH

Patents: Industry, Universities Renew Debate on Who Gets Rights to U.S.-Sponsored Medical Research

After more than a year of relative quiet, the question of government patent policies is again receiving concentrated attention, as government agencies and other interested parties move toward a clarification of the policy memorandum issued by President Kennedy in October 1963.

The Kennedy memorandum was the first attempt to cope on a government-wide basis with a major problem growing out of the skyrocketing federal investment in scientific research: Who should have the patent rights to inventions discovered on government grants and contracts? Although this was a topic on which ideologues on all sides were vociferous (some calling anything less than full government retention a "giveaway," others regarding government holdings as an attack on free enterprise), Kennedy took a middle ground. The memorandum rejected a "single presumption of ownership" on behalf of the government and provided that in certain cases patent rights could be acquired by the contractor. In one area, however, that of "exploration into fields which directly concern the public health," the memorandum was definitely weighted in favor of government retention. In this it followed a long-standing policy of the Department of Health, Education and Welfare (parent agency of the Public Health Service and the National Institutes of Health) under which the government generally took title to medical discoveries made by researchers on agency funds.

Now the pharmaceutical industry, supported to a certain extent by some university representatives, has begun to protest this policy and is seeking a change. The industry contends that this policy has produced (i) "an accelerating decline of medical research co-sponsored by industry and government" and (ii) "an increased strain on the traditional university-industry bonds which have been such an important segment of this country's efforts in medical research." The first of these, according to a document recently made available by the Pharmaceutical Manufacturer's Association (PMA), the industry's trade association and Washington lobby, is largely the result of HEW's "confiscatory policies" and its reluctance to recognize that "the contribution of industry in providing private financing and know-how to develop and market a drug deserves a compensatory degree of market exclusivity." The second, the statement claims, is caused by "unrealistic government patent policies toward academic grantees, its refusal to recognize the right to appropriate financial return for them, and the inability of the industry to compete with the government financially for university research facilities." These policies, the PMA statement asserts, are "rapidly erecting a 'Berlin Wall' between the pharmaceutical industry and a heavily financed governmental research program."

What the industry seems to be saying, in short, is that if the government always takes the patent regardless of industry's contributions to the same research (either in the form of outright grants to researchers or in the actual development of a product first discovered on a government grant), industry's incentive to continue such cooperation will—and by implication, the productivity of medical research—decline.

The only trouble with the industry's position is that there does not seem to be much solid evidence for it. It is true that in the past 2 years the number of new drugs placed on the market has declined, but this is thought by most observers to be related chiefly to the effects of more stringent marketing requirements of the Kefauver-Harris drug laws of 1962. The link between the decline and any asserted breakdown in university-industry relations seems remote. Evidence of a "breakdown" is itself lacking, since the pharmaceutical industry appears to have spent over $2 million more in R&D expenditures at academic institutions, medical schools, hospitals, and nonprofit institutions in 1964 than it did in 1963. (The industry-wide total for such expenditures in 1964 is estimated to be $15.2 million.) In addition, the industry is able to supply no statistical evidence of a deteriorating relationship, and when asked for specific examples, PMA could contribute only a handful of anonymous illustrations which it recently solicited from its member firms. These offer several statements of the case but tell nothing at all about the potential seriousness of the events described. (There is, as yet, no reason to think that industry anxiety over patent rights has ever deprived the public of a valuable drug.) One company, for instance, said, "There have been dozens of cases in which we have had to give up any idea of cooperation with university people and others because they have had govern-

ment grants." Another reported that it receives "numerous requests to screen compounds," but that it now refuses to do "any of this work where the compounds were prepared under government grant, since such government grantees are unable to give the company assurance of any significant exclusive rights." Comments received by PMA from universities on the same point were equally vague. The following appears to be typical: "Many of the compounds which I produce are potential pharmaceutical agents. Yet, they cannot or will not be tested simply because the government has first claims and a pharmaceutical company will not test under these circumstances." Industry officials are trying to assemble more concrete evidence to support their case before the government, but so far their demonstrations have been wholly anonymous. It appears to be a mild case of "verdict first."

Although its effect on industry-university relations is unclear, the problem of who should have the rights to research cosponsored by industry and government is nonetheless a real one. The Kennedy memorandum did not take the problem into account, and one of the industry's fears is that it will lose patent rights to the government even in instances where the government's contribution to the research is smaller than its own. So far, however, this complaint is chiefly an abstract one, for no one has collected facts and figures demonstrating how disputed rights have been assigned in particular cases. Both the Kennedy policy and HEW regulations appear to leave enough loopholes for equitable solutions to such disputes, and there is no evidence that government ownership either has been or will be an immovable rule.

The position of the universities is nowhere stated as explicitly as that of the drug industry. It appears, however, that the universities' main interest is in obtaining patent rights themselves, not in ameliorating the effects of the "deteriorating relationship" with the drug houses, and that the main reason for cooperation is a mutual interest in seeing the regulations altered. If universities were allowed to take title to discoveries made on public funds, it would be under the theory that an educational institution could administer a patent in the public interest as satisfactorily as the government can. Under this theory, HEW already has agreements with 17 universities permitting them to hold titles, and it makes awards on a case-by-case basis to several others. If this were extended, presumably the universities would then dicker with drug companies about arrangements for industrial-scale testing, development, and marketing of new products, much as in some instances the companies now dicker with the government.

A question left unanswered when the competing claims to patent rights arising from government research contracts are sorted out is whether any of them make any sense in the era of big science. None of the claimants has much resemblance to the independent inventor the patent system was originally designed to encourage. The closest, perhaps, is the university investigator who makes a discovery, but even he is distinguished from his predecessors by the absence of personal risk. The university is chiefly the clerk, the government is the paymaster, and industry frequently is the manufacturer of a finished product designed by someone else.

The inapplicability of traditional rules appears to be partly responsible for the fog in which most discussions of the patent problem become enveloped. But despite the blur, government agencies and the interagency Patent Advisory Panel, a body established by the Kennedy memorandum, under the Federal Council for Science and Technology, are forging ahead, attempting to adjudicate conflicting claims without masterminding anything like a revolution in the patent system or the concepts underlying it. Revisions and extensions of the Kennedy memorandum are expected to be issued sometime in January by the Patent Advisory Panel, the first fruit of efforts directed toward another goal of the 1963 policy, that of bringing some unity into diverse agency practices. The new statements are expected to offer the agencies guidelines for applying the basic policy in particular instances, perhaps amplifying permissible exceptions to the general policy of government retention. How far the guidelines will go in lessening the complaints of industry and the universities is uncertain, though both parties have been conferring with government officials behind the scenes, and both wear an air of mysterious hopefulness. One brake on possible moves toward a dramatic change in emphasis on government retention is the alertness of a small band of Senate liberals to any threat of "giveaway" of the fruits of government-sponsored research. Interested congressional investigators—most notably Democratic senators Long of Louisiana, Morse of Oregon, and Anderson of New Mexico—have been relatively quiet for the last year, while the Kennedy policy was being tried out and developed, but it is likely that they would take up the cry once again if the principle of government retention appeared seriously threatened.

—ELINOR LANGER

Announcements

Announcement has been made of the formation of the **Indian Brain Research Association** (IBRA), a nonprofit, scientific, and educational organization. IBRA has announced plans to publish *Brain News*, a bimonthly newsletter, designed to apprise members of current news in neurology, with particular emphasis on brain research, teaching, and related professions. Further information on IBRA is available from B. Mukerji, Director, Chittaranjan National Cancer Research Centre, Calcutta.

The department of botany of the **U.S. National Museum**, in Washington, D.C., which includes the U.S. National Herbarium, has announced a moratorium on the receipt and shipment of specimens. The moratorium is the result of plans to move from the Smithsonian Institution building to the Museum of Natural History building. It has therefore been requested that between 1 April and 31 October, no specimens be shipped to the department, and no specimens be requested for loan.

The **University Corporation for Atmospheric Research** (UCAR), which operates the National Center for Atmospheric Research in Boulder, Colorado, has announced the creation of a Council of Members, and the election of five U.S. universities to UCAR membership. The council, to be comprised of a scientific representative from each member university, will perform the function of "scientific review," to help insure that research and facility programs of the Corporation "are responsive to the changing needs of the atmospheric sciences and of the university community." The five newly elected members are the universities of Colorado State, Alaska, Colorado, Texas, and Utah. Other members are the universities of Arizona, California, Chicago, Cornell, Florida State, Johns Hopkins, Michigan, New York, Pennsylvania State, St. Louis, Texas A&M, Washington, Wisconsin, and M.I.T.