## The Future of Flavoring Ingredients

Mr. Goossens: The Honorable Robert W. Kastenmeier is a Democratic Representative for the State of Wisconsin in the United States House of Representatives. In his first years in the Congress he was a strong defender of individual rights, and as a member of the Judiciary Committee, he was an outspoken advocate for the strongest possible civil rights bills. In 1969 Congressman Kastenmeier became Chairman of the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the House Judiciary

Committee. Over the last few years, the Subcommittee has devoted itself to a revision of the copyright law, and more recently a revision of the patent law. Major hearings are scheduled in April to review the need for changes in the patent laws to increase innovation and to spur incentives for research and development. Congressman Kastenmeier also serves on the Interior Committee and in this capacity has played an important role in setting policy on a broad range of national concerns.

## The Future of Legislation

By The Honorable Robert W. Kastenmeier (D) Wisconsin Chairman of the Subcommittee on Courts, Civil Liberties and the Administration of Justice of the U.S. House of Representatives Judiciary Committee

Last Saturday's (April 12, 1980) Washington Post carried the latest in its series of articles on the relationship between Congress and the National Institute of Health. The theme of that particular story was in part the question whether the NIH grant system is flexible enough to support and reward scientific innovation of the kind that will lead to substantive biomedical breakthroughs. The *Post* feature focused on the difficulties faced by nonscientist legislators attempting to assess the efficacy of sophisticated technical proposals. Ward Sinelair, the author of the story, posed the question: "How, for example, is a man like Bob Michel who has spent most of his adult life in Congress, supposed to know the merit of studying the stereochemistry in valine and leucine metabolism?" (the actual title of a proposed grant). To many of you who have devoted your lives to science and scientific

research these terms have real meaning and their use is a part of everyday language. But in the halls of Congress, you will find very few members who used the scientific laboratory as a springboard to public office.

Yet, increasingly, scientific policy is synonymous with public policy. Congress is being called upon to make more and more decisions that involve complex scientific issues. Obvious examples are in the medical area. There is now growing pressure on Congress to change statutory policies such as the Delaney Clause's absolute prohibition on cancer-causing food additives. This particular debate has received national attention because of the saccharin issue. There, Congress took ad hoc action to enable saccharin to remain on the market.

While this issue is within the jurisdiction of Congressman Waxman's Subcommittee on Health, and not my subcommittee, I mention it because of its relevancy to research and innovation and because of your intense interest in the subject. The broad question, highlighted by the saccharin debate, is whether some kind of risk-benefit analysis should be applied to food additives. A major report by the National Academy of Sciences has recommended that carcinogenic food additives be ranked either high, moderate, or low risks. I am told that Congressman Waxman's subcommittee will consider the issue next year. If it does, you can be assured there will be substantial controversy over any changes. Congress will find itself embroiled in difficult scientific questions. Among them will be questions regarding the reliability of animal data in assessing human risk and questions about whether there is any safe level of exposure to a carcinogen. Such issues are extremely complex, and it may well take Congress more than a few years to make

any final decision about such changes in the law.

Of more particular interest to you, I know, is reform of the FDA process. Again, this is a subject which will probably be taken up next Congress by Mr. Waxman's subcommittee. As to the raging debate of whether alcoholic beverage labeling should be regulated by FDA or the Bureau of Alcohol, Tobacco and Firearms, I have not heard enough of the argument to have reached a considered judgment. I can tell you, however, that you will have full support in assuring that the matter is resolved so that you will not have to grapple with duplicated or inconsistent regulatory requirements.

Innovation is yet another area where science issues and public policy issues are becoming increasingly intertwined. No longer can we expect a lonely inventor in his basement laboratory to come up with the kind of scientific breakthroughs that will enable us to heat our homes, feed our families, or fuel our economy into the twenty-first century. Meaningful research of the kind that leads to new products and processes to benefit the American consumer requires the financial, personnel, and physical resources of great corporations, universities, or the federal government. For example, in certain high technology fields such as drugs, the National Science Board now estimates that about 90% of all patents are assigned to corporations rather than individuals. This means that—like it or not-congressmen like Bob Michel and myself are going to be more and more involved in science and innovation policy. This is so not only because the Congress decides the priorities and budgets of the great government research organizations like NIH, but because we also must legislate with respect to the regulatory structure, tax policies, and of course the patent system, which affect the way private business approaches scientific innovation.

I know that many of your organizations are deeply dependent upon the patent system to provide the capital incentive necessary to the development of technology which will improve the diets of millions of people around the world. It is in this area—patents and patent policy—that my congressional committee assignments bring me into direct contact with the world of technology and innovation. The subcommittee on Courts, Civil Liberties and the Administration of Justice, which I chair, has—in spite of its name jurisdiction over all patent, trademark, and copyright legislation in the House of Representatives. Indeed, one of our problems in dealing with an area like patent policy is that it must compete with many other pressing issues for attention. My own subcommittee currently has 210 bills pending before it on subjects ranging from courts and legal services to search warrants and wiretapping to corrections and prisons and, of course, patent, copyright and trademark law.

For specific issues to emerge in the form of reported legislation they usually must be either simple and uncontroversial or have a powerful political constituency supporting them. It has been my experience that patent issues seldom fall into either of these two categories

My own background in the patent area dates to the 1960s when we held extensive hearings on the recommendations of the Presidential Commission on Patent Law Reform. These hearings paralleled a similar effort to revise the Copyright Act. Although both subjects were highly technical and complex we met with much greater success in the copyright field. We found that the opposing parties in interest with respect to copyright revision legislation were able to negotiate their differences and reach a united position. This ability for the private sector to resolve its differences independent of congressional arbitration resulted in drafting a bill which ultimately was successfully enacted in 1976. Opposing segments of the patent community were never able to develop a similar united front. As a result highly technical legislation in the patent area never developed the momentum necessary to successful legislation.

If legislation has an organized political constituency it can develop the momentum necessary to passage even if it is complex or controversial. I believe that we may be witnessing such a phenomenon now in the patent field—in spite of past problems. As many of you may know, in May of 1978 President Carter called for a major domestic policy review of industrial innovation. This effort was designed to afford the issue of industrial innovation the highest level of policy attention by the executive branch and was supervised by a cabinet level coordinating committee chaired by the

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Secretary of Commerce.

An advisory committee of more than 150 senior representatives from the industrial, public interest, labor, scientific, and academic communities participated in the review. A major focus of the Advisory Committee was patent law and patent policy as a stimulus to industrial innovation. When the committee's 300-page report was issued last year a major segment contained recommendations on patent policy.

On October 13, after reviewing the Advisory Committee's recommendations, the President sent a major message to Congress, outlining a program to stimulate industrial innovation in the United States. This program is embodied in legislation that would accomplish the following:

- establish a uniform government policy on ownership of patent rights in government funded research
- create a system of reexamining doubtful patents at the request of any party
- revise the fee structure of the patent office to provide a better financial basis and better services in the office
- create a unified court for patent appeals to eliminate the uncertainty created by conflicting decisions by different courts

In addition, we have introduced legislation reflecting the recommendations of the Commission of New Technological Uses of Copyrighted Works, which is designed to end confusion as to when computer programs are protected from infringement under our copyright laws.

We have set aside five days for hearings on these and related proposals. To emphasize the importance of the subject matter, the Secretary of Commerce testified as our first witness. We have now heard three days of testimony, with the final two sessions scheduled next week.

In addition to these proposals, the Domestic Policy Review raised other issues that have not yet found their way into legislation, but will undoubtedly find their way into the legislative and policy debate sooner or later. Among these other issues are

- extending the term of patents where regulatory delay has prevented prompt commercialization
- specific patent protection for new life forms created by recombinant DNA technology—an issue now before the Supreme Court
- the creation of new categories of patents, which would receive more thorough examination and higher protection.

At present I cannot predict which if any of these proposals will become law—but the common thread which connects all of them suggests momentum toward action of some kind. This common thread is the desire to make the patent system more effective in stimulating the creation of new products and processes—a goal that must be met if we are to improve the productivity of our industry and create new jobs to displace those lost because of outmoded technology.

Science Indicators, published by the National Sci-

ence Board, has recorded a steady decline in expenditures for research and development in the United States in recent years. This corresponds with rising research investments in other advanced industrial nations. Given the fact that the health of our economy depends increasingly on our competitiveness in the international marketplace, this is a serious development. The proposals that are now being considered by our House subcommittee are designed to make private investment in R&D more attractive and to encourage the optimum use of government funded research by U.S. industry.

An illustration of the importance our foreign competitors place on the certainty of patents as an incentive to scientific innovation is seen in the resources they devote to the patent system. The European Patent Office is projecting a 1980 workload of 40,000 patent applications. It has a staff of 3,000 and a budget of \$115 million. By contrast our own patent office will be expected to handle 103,000 new applications with a staff of 3,000 and a budget of only \$93 million. Since the quality of each patent examination is important in determining the certainty that the patent is valid, and therefore worthy of investment of risk capital, this is a disturbing comparison. The quality of U.S. Patents and our patent system may not be keeping up.

Of course, finding remedies to these problems is the purpose of our current congressional effort looking at the patent system. It is beginning to look as if the long stalled effort to revise patent policy is beginning to revive—in large measure because a constituency for change is beginning to develop. The personal emphasis by the President is a part of that development and has already brought disparate departments of government such as the Commerce Department and the Justice Department together for the first time in many years. There also appears to be a renewed interest among private industry groups such as yours. This is understandable, since the economic health of so many of your companies depends largely on investing sizeable amounts of capital on new technology—and that investment is safeguarded in large part by the patent system.

Clearly the machinery of government is beginning to respond to the need to create a better climate for industrial innovation—whether it be in the patent area I have discussed or in areas of regulatory reform or taxation.

However, one word of caution: Neither the Congress nor any other institution of government is doing its job if it favors one particular group within industry at the expense of another—especially when we try to operate within the context of the general public interest. Therefore, I would advise companies in this industry not to become too insistent on any specific rigid policy. If all groups interested in stimulating industrial innovation work together to develop a consensus on legislative reform I believe we will achieve success. And the end result will be the enhancement of return from America's greatest resource—the human intellect—which since the First Congress in 1789 has been nurtured and protected by the patent system.