ASTE Case Jun. 77
Petitions Stopped Aug. 77

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Patent Hearings Dec. 77 (Attack on Ancker-Johnson/Chang Report)

Mar. 78 (Attack on GSA - IPA)

Sept. 78 Bayh-Dole

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Nelson

NELSON ASKS HALT TO PATENT GIVEAWAYS

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WASHINGTON, D. C., MARCH 21 - Sen. Gaylord Nelson (D-Wis.) has asked the Office of Management and Budget (OMB) to postpone a regulation giving away government patent rights to drugs, living organisms and other inventions resulting from billions of dollars of federally funded research and development.

Nelson asked OMB's Office of Federal Procurement Policy (OFPP) to delay a regulation scheduled to go into effect this week - which grants colleges and universities the right to patent and develop inventions made in the course of federally financed research expected to total $3.6 billion next year.

Nelson is chairman of the Senate Small Business Committee and its Monopoly Subcommittee, which held three days of hearings in December to open a long-term study of government patent policy.

In a letter to Lester Fettig, OFPP administrator, Nelson requested the delay "to permit Congress to hold hearings on the history, legal basis and implications of Institutional Patent Agreements (IPAs) as an implement of Government patent policy."

Nelson pointed out the 1974 law creating OFPP directs Fettig to "prescribe policies, regulations, procedures, and forms" for government agencies in their procurement of research and development services giving him authority over a change in regulations announced by the General Services Administration (GSA).

Nelson wrote that the questions to be asked about the GSA change permitting and inviting wide use of a standard IPA include:

"Its history. Expanded use of the IPA was proposed by an interagency committee in 1975. What happened between then and Feb. 2 of

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this year when GSA announced the change? Is the GSA action an expression of government patent policy by the Carter Administration, or is it the will of a prior administration being discovered only now in the fine print of procurement regulations?

"Further," he wrote, "the IPA is founded not on statutory law, but on the memorandums and policy statements of President Kennedy in 1963 and President Nixon in 1971. Indeed, the GSA action marks a major new phase in the evolution of policy by exception, since the IPA is founded on 'exceptional circumstances' and 'special situations' clauses in these presidential patent policy statements."

Some policy questions stem from the IPA the Department of Health, Education and Welfare has been using for about a decade, and differences between it and the new standard agreement announced by GSA, Nelson said.

"Whether recombinant DNA research inventions developed with HEW support should be handled in the same way that drugs and other university discoveries are ought to be a major policy question in its own right, yet the National Institutes of Health have decided, at least for the present, that they can be under current HEW patent agreements.

"The GSA action could expand the IPA into all the areas like this one not covered by statutory requirements, in the same way that air expands to fill a vacuum," he wrote. (In DNA research, genes from virtually any living organism can be transferred to single cells from certain completely unrelated organisms.)

"Further, questions should be asked about differences in the two IPAs.

"For example, the HEW agreement permits a university to assign its invention rights to a 'nonprofit patent management organization'," Nelson noted. "The GSA version would do the same but omits the word 'nonprofit'. Granted that both nonprofit and for-profit patent management organizations will attempt to maximize their returns in promoting the licensing of university discoveries, what is the reason

for the change?

"Also, the GSA version appears to go beyond HEW's -- it may be nothing more than greater candor -- in allowing an agency, at the request of the university, to 'use its best efforts to withhold publication' of invention disclosures until a patent application is filed.

"Does that mean," he asked, "an agency could collaborate in withholding publication of a scientist-inventor's research results until his university secured its commercial rights in them?

"Would the GSA action create a new class of information that could be withheld from disclosure under the Freedom of Information Act? Would this standard IPA create new grounds for closing a meeting under the Federal Advisory Committee Act?"

HEW now has patent agreements with 72 institutions. (Its agreement with the University of Wisconsin became effective Dec. 1, 1968.)

To qualify for an IPA, a university must show it can oversee development and marketing of an invention. The HEW Patent Branch reports that 167 patent applications were filed from 1969 through the fall of 1974 under IPAs.

Where a university does not have a patent agreement, it can ask HEW for ownership rights by petition after an invention has been made. HEW says yes to about 90% of these petitions, having reviewed 178 of them and granted 162 over a period of years.

Nelson noted in his letter to Fettig that the GSA action "is bold enough and broad enough to warrant your attention, for it would apply to a majority of the agencies through which President Carter's 1979 budget proposes to obligate $3.561 billion for research and development support to colleges and universities."

Problems being examined in his Monopoly Subcommittee study of patent policy include:

*Economic concentration brought about by granting patent monopolies for discoveries which result from government-financed research and development grants and contracts.

*Whether the government is giving away too much and getting all that it pays for with its R&D dollar.

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