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MC CLELLAN RECESSES PATENT HEARINGS, WILL RESUME LATER: Chairman of Senate Subcommittee Says He Will 'Expedite' Bill, But Wants All Views Presented.

Chairman John McClellan of the Senate Judiciary subcommittee on patents, trademarks and copyrights recessed his hearings on Federal government patent policy July 7, but said he would return to the subject later. McClellan said that while he wanted to "expedite" the legislation, he also wanted to let all witnesses be heard on the complicated subject. Before the subcommittee are S. 1899 by Senator Russell Long (D., La.) that would give the government title to patents developed in a project in which any government money had been invested; S. 789 by Senator Leverett Saltonstall (D., Mass.) and S. 1809 by McClellan, both of which would set an overall patent policy for the government, with patent rights generally going to the party that had spent the most money on a project; and S. 1047 by Senator John J. Williams (R., N.J.), which would urge, but not quite require, that government departments stop purchasing from overseas firms that had pirated U.S. drug and other patent rights.

During the two days of hearings, McClellan's questions indicate he believes an exception from the overall policy should be made for drugs and other developments in the health field. He thinks that in this area the government possibly should take title to all patents, but he listened carefully to witnesses who tried to explain to him that such a policy would impede production of life-saving drugs. The subcommittee has heard a total of 26 witnesses. McClellan, in announcing the hearings would be resumed later, said he wanted to hear from any person or organization that has an interest in the problem.

In opening this set of hearings July 6, McClellan said "many people" favor a uniform Federal policy of allocation of patent rights. In his questioning, he made it clear that he was firmly opposed to the Long bill that would put into law the "government take all" policy, with a few exceptions.

First witness was Rep. Emilio Q. Daddario (D., Conn.), who has been active on similar legislation in the House. He said the question was not one of "black and white," and that in some cases the government should share patent rights with the company, medical school or other institution that had received the grant or contract. In general, he favors the McClellan bill. Daddario emphasized that often the contractor makes "heavy contributions" to the project, and that denying patent rights, particularly to small contractors would be "down right disastrous" to them. Among some of his other points: agency heads should have authority to negotiate patent rights "because they can't take title in all instances"; patent rights should be allocated on an equitable basis; in general he favors the McClellan bill; if an inflexible policy is adopted, there

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there will be duplication of research because many firms won't take government grants or contracts.

McClellan emphasized that in some cases the contractor's know-how is important. Daddario said that some organizations might refuse government contracts if they can't have patent rights. McClellan also brought up the possibility that in the drug and other health fields the government might be justified in keeping the patent rights so the invention or discovery would be available to "all the people." Daddario plans to introduce a House bill modeled on the McClellan bill.

J. Edward Welch, deputy general counsel, spoke for the General Accounting Office. He traced the growth of U.S. patent law and policy, said some drug prices have been raised to an "unwarranted extent" under patent protection, but was inclined to feel that there is enough flexibility in the present law and that no drastic changes are needed.

For Department of Defense, J.M. Malloy, deputy assistant secretary for procurement, restated DOD's policy: Let the patent rights rest with the contractor to give him incentive. He said that under any other policy, defense department might have to deal with a second rate company, and "we might lose the companies with the highest degree of competency." He also said that there might be instances where a firm would not "assign its best people" to a project, or hesitate to report all its discoveries if it were not to get patent title.

Speaking for Department of Health, Education, and Welfare, James M. Quigley, assistant secretary, did not take a firm position in any direction. He said the Long bill would be acceptable "if amended," and that the McClellan bill was regarded the same way. He did emphasize that HEW would prefer to operate under the policy laid down by President Kennedy in October of 1963 for a while longer, and comment on any prospective legislation in the light of this added experience. At this point Chairman McClellan commented that he "wouldn't mind" putting off a decision, but that others on the committee might have different ideas.

Representing the American Chemical Society was Charles C. Price, head of the chemistry department at the University of Pennsylvania. In his prepared statement he said in part:

"The American Chemical Society believes that there are two major public benefits stemming from patents: (1) The stimulation of disclosures of new scientific and technical information. (2) Providing incentive for the frequently massive investment necessary to convert an invention into a product available to the public. The second of these purposes would be seriously undermined and controverted by the basic philosophy inherent in S. 1899 (Long bill).

"Furthermore, we believe that Section 4(a)2 of S. 1809 (McClellan), in fact, would serve the same undesirable purpose for the area of 'public health, welfare and safety' and therefore urge deletion of this principle. If incentive for investment necessary to make inventions available to the public is necessary in other areas, it should certainly be available to stimulate development in such vital areas as 'health, welfare and safety.'"

Price also said that the three years allowed for a patent holder to reach the market under the Saltonstall bill "is considerably short of the interval commonly required for the development of chemical processes and products." Under questioning by McClellan he said the Long bill would not allow enough incentive to develop an invention, which

often is seven or eight years; that "invention is very cheap," but that developing a useful product often is expensive; argued with McClellan's apparent views on drugs and other health products, because "drugs that cure diseases" take a long time to develop from the discovery to the drug store. He said often there is a "vast investment" before a pharmaceutical discovery is found of value to human patients.

Dr. George E. Wakerlin, medical director of the American Heart Association, described the problems of such public-supported organizations in the field of patents. He told how often projects are supported by two or more sponsors, including the Federal government, and said that under these conditions it would not be equitable to give the government total patent rights. His main appeal was to give HEW wide discretionary power to allocate patent rights. He emphasized the distinction between the invention or discovery and the complicated and expensive process involved before the product is made available to the public.

Dr. Howard I. Forman, president of the Philadelphia Patent Law Association, said he thought the best idea was to combine the McClellan and Saltonstall bills, with amendments that would make the final law "more flexible." He argued that the public should receive the "whole story" on the government patent policy dispute, rather than just be exposed to scare "government give-away" headlines, a reference to the Long bill. He emphasized that "utilization," not discovery, was the important point as far as the public is concerned. Under the government-take-all policy, he said, too many inventions and discoveries would "go down the drain" for lack of development. Under questioning by Senator Quintin Burdick (D., N.D.), Forman said he didn't see how the government-take-all policy would work. If the government didn't develop the invention and put it on the market, that would be wrong. If the government got into the commercial market, that would be wrong too under our system of society.

Prodded by Chairman McClellan for examples of how government patent ownership would retard development of drugs, Forman told the story of an invention that would preserve blood for longer periods of time. It isn't yet on the market. A private institution and NIH jointly sponsored the research, on about a 50-50 basis. Then it was discovered that only five manufacturers had the capability of developing the invention into a marketable product. Of these only one, Baxter Laboratories of Morton Grove, Ill., was willing to discuss processing. It was estimated that this step would cost $1.5 million. Under the Kennedy 1963 directive, NIH said it could grant Baxter only a five-year exclusive rights to the patent. In four years, Baxter estimated, it could recoup only a fraction of its investment. Furthermore, NIH insisted that any inventions that Baxter developed along the way would have to go to the government. After two years of negotiations along these lines, Baxter dropped out of the picture, saying it couldn't afford this sort of a deal. Now, under a better arrangement with NIH, another laboratory is undertaking to develop the blood-preservative, but it isn't yet on the market.

McClellan wondered if it is ordinary practice for companies to turn down government contracts of this nature. Forman said "fewer and fewer" companies are willing to develop a drug when they have no patent protection. He told of one instance when the government asked five companies to undertake a similar contract. All refused. They were sent second letters, asking if they wouldn't do it as a public responsibility. All replied they couldn't and wouldn't. Forman said this form of attempted "intimidation" discourages other firms from taking on government research projects when there is no patent protection.