

December 15, 1977

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SIGNED

Nelson Hearings

PATENT BRANCH, OGC
DHEW

DEC 19 1977

David Guberman

In the event the Commerce Department should decide to testify at the upcoming hearings, I have prepared for whatever use they may be to you draft testimony. Since Commerce will be testifying before a hostile committee, I believe it would be futile to attempt to go into detailed discussion. This testimony is designed to possibly impress upon Senator Nelson that the issue is not as simple as he seems to believe. It is also an appeal to the other members of the Committee who are not committed to a position and who might be persuaded to prepare minority (or hopefully majority) positions in the event the Committee decides to issue recommendations as a result of its hearings. If small business (and university) indignation over these hearings and the manner of their arrangement is strong enough perhaps other members of the Committee will see fit to attempt to extricate themselves from the (I hope) untenable political position in which their Chairman and staff may have put them.

Attachment

✓cc: Norm Latker

Gentlemen:

The release which announced these hearings and a number of other facts surrounding the arrangement of these hearings indicate that those who arranged them already believe that they know what Government patent policy should or should not be. I am appearing before you, therefore, with no illusions that everyone here is really interested in an impartial examination of the question of Government patent policy. Nonetheless, I welcome this opportunity to at least put before you some thoughts that might lead you to look more seriously beyond the mistaken, albeit sincere, arguments or more properly slogans which Mr. Gordon and possibly others of his zeal have apparently successfully impressed some of you with to date.

I respect the fact that some members and staff of this Committee sincerely believe that patent policies that favor leaving rights to inventions in contractor or grantees are anti-competitive or monopolistic. I believe that Mr. Gordon and others who advocate this are sincere. I ask only that you also trust my sincerity when I tell you that I firmly believe that, in fact, the patent policies that are advocated by Mr. Gordon are anti-competitive and that those of us who support a patent policy that normally allows contractors or grantees to retain rights do so on the basis that, among other benefits, such a policy will promote competition. However, the sincerity with which a view is held is not evidence of its correctness. I do not ask that you believe me just because I say that, I am sincere. But neither do I feel that you should accept uncritically whatever my opponents tell you just because they sincerely claim it is in the name of "competition." I ask you to go beyond slogans and catchwords such as "giveaway" and to look at the realities and likely results of various policies.

Before beginning an examination of patent policy, I would like to emphasize something it is imperative to understand if this issue is ever to be properly resolved. In particular, some understanding of the dynamics of competition and economic growth are sorely needed. Typically discussions of "competition" are centered around a given product and concern the factors that will result in or deter competition in a given industry. Unfortunately, these classical modes of analysis, while useful in some contexts, have some important limitations. In particular, they do not really explain the form of competition that truly allows our economy to grow and which prevents it from becoming even more oligarchical than it already is. Gentlemen, I submit to you the maxim which is by no means original with me that the key to economic growth and competition in this country is the introduction of new products and new technologies--in other words innovation. I believe it was Joseph Schumpeter who termed this "the gale of creative destruction." I would ask whether there is anyone in this room who would seriously contend that our economy, indeed our political freedoms, would not be in serious trouble if, for example, in 1977 we were still producing the same products as we were in 1930 or 1950 or even 1960. If that were the case our economy would have truly stagnated, all the Government policies in the world would not have prevented the concentration of numerous industries in the hands of a few large companies, and this Nation would be in serious trouble.

Now, I am not so naive as to believe that Government patent policy alone is the only factor that will effect innovation. But I will warn you that with over half of the research done in this country being supported by the Government, we had darn well be sure we understand the effect of Government patent policy on the transformation of the results of that research into new

commercial products and processes. Now, I cannot tell you that a Government patent policy that provides for or favors title-in-the-Government is absolutely going to bring about the stagnation that I have described. Many other factors are at work. But I am totally convinced that such a policy will tend in that direction. If you assemble a baseball team with the best pitching and fielding in the league you might win the pennant even with a line-up of .200 hitters. But if you were the manager, I'm sure you would be more confident if you had some hitting.

But ^{before} I present the general conclusions that I have come to with respect to alternative patent policies, I believe it useful to give a concrete example of the real impact Government patent policy can have. Opponents, of course, will argue, as would I, that anyone can make up hypotheticals to prove that one policy is superior over another. Of course, I believe that the hypotheticals that I would cite ^{are} ~~as~~ much closer to real life and more typical of it than those that opponents can conjure up. But leaving that aside, this example is not intended to be taken as a model of all Government R&D or all industry. It is meant, though, to illuminate in a very real way how adoption of a "title-in-the-Government" approach would inevitably result in a most unfortunate result.

A significant part of the research budget of the United States goes towards medical research and related fields such as biology or chemistry. Out of that research, new compounds are often synthesized in university or other laboratories. However, it is one thing to develop a new compound in a laboratory and another to determine whether it has pharmaceutical potential and, if so, how much potential, in what formulation and dosage, and with what side effects. The compound must be screened, tested further, and tested clinically.

An economical means of mass production may need to be developed. Its utility has to be brought to the attention of physicians, and a means of distribution is needed. These necessary tasks, all of which takes place after the laboratory synthesis of the compound, are now almost exclusively performed not by the Government, but by the drug industry; and the tasks are extremely costly. Leaving aside arguments over whether drug companies make too much money or improperly advertise or push some drugs, it ought to be quite clear that whether or not some internal reforms are needed that without drug companies, we will not have drugs. Experience, as well as common sense, should tell us that any given drug company is not going to engage its limited resources in the costly process of commercializing a new compound invented under someone else's Government grant or contract which its competitors can then market and replicate without going through much of the research performed by the first company. This is not to say that being first or other factors might not overcome the disadvantage of extra costs. But in making the initial decision to invest one cannot know with certainty what the ultimate facts will be. And often one could decide to rely on nonpatent factors only after some initial investment. We could, for example, hypothesize that a drug company might screen a nonpatented compound and do some initial testing, and based on that decide that the market potential is so high that they will go ahead regardless of patent rights. On the other hand, the market may be such that it would be unprofitable to proceed without exclusive rights. If you happen to be the unlucky soul who suffers from a relatively rare disease, it will probably be of little interest to you that the reason a known cure did not get produced was because it was made unprofitable by Government patent policy supposedly

designed to foster competition. In fact, you will probably never even know that relief or a cure was possible. Perhaps some day a relative will learn of it and complain to his Congressman who will then begin an investigation of the drug industry. But heaven forbid that anyone should ever suggest the real cause of the problem.

But, of course, the example given above hypothesized that the company was willing to undertake some initial screening and testing before making a decision. Again, while that makes an ideal hypothesis, in real life it seems apparent that drug companies do not behave that way. The managers of these companies, as practical persons, seem to find it more to their advantage to concentrate the development efforts of these companies on compounds which they can protect and control.

So what I am saying is that if you will look beyond slogans and passions and attempt to address the real ways that the drug industry operates you will find quite literally that a title-in-the-Government policy is going to have the tendency of condemning some person to suffering and an early death because the commercialization of some potentially life-saving compounds was made too risky or unattractive for private industry to undertake. I think you will also find if you really analyze the situation critically that it confounds reason, experience, and reality to believe that a title-in-the-Government policy will have the redeeming benefits of lowering the prices of other drugs or of leading to the development of some drugs which would not have been developed if the inventor^{ing} contractor held patent rights.

Hopefully having impressed upon you that we are dealing with an issue whose resolution can have profound impacts, I urge you to open your minds

and to be willing to engage in a detailed and realistic analysis of the issue. Let us not decide this issue through slogans or rhetoric. Let us all be willing to examine realistically and in some depth the realities of the situation and the likely results of alternative policies.

With this as background, let me summarize some of the conclusions that I have reached concerning the probable results of various Government patent policies.

1. A strict title-in-the-Government policy will lead to the commercialization of fewer new products than will a title-in-the-contractor policy and will thereby encourage rather than deter concentration in industry. Such a policy will have little or no effect on the prices of such products that are commercialized despite the policy. Such a policy will discourage small business R&D firms from competing for Government prime contracts and sub-contracts and will tend to encourage the concentration of Government-supported research in the hands of larger companies that are either already dominant in related commercial industries or which engage almost solely in Government work. It will also encourage firms to avoid the reporting of inventions made under their contracts which have significant commercial potential.

2. A deferred determination or case-by-case approach which includes the presumption that title should normally go to the Government has only minor advantages over a strict title-in-the-Government policy and is still inferior to a title-in-the-contractor policy. The deferred determination case-by-case approach entails significant administrative costs, favors larger firms that are more equipped to bargain over contract terms, and will result in fewer inventions being commercialized and might even have the

effect of raising slightly the prices of these inventions which are commercialized after waiver. As a practical matter the waiver process can provide no more assurance that a given invention will not be suppressed, overpriced, or used to create a monopoly than would the automatic granting of rights. These potential abuses are more hypothetical than real. In any case, the deferred determination process affords the Government no means of predicting that such behavior will occur. And the means of preventing or remedying such behavior, even if it were a significant "real world" possibility, is the mandatory licensing ("march-in") provisions that should be part of any policy.

3. A title-in-the-contractor approach (coupled with "march-in" and the ability of agencies in specific cases to use other clauses) will best promote commercialization of inventions, will give small business the greatest opportunity to participate in Government R&D, will best promote competition, will be least costly to administer, and will ensure against abuses as well as any other policy can.

Now, as I have attempted to emphasize throughout my testimony the manner in which I have arrived at these conclusions involves a rather detailed examination of the realities of the process and the various types of R&D supported by the Government. If the Committee is truly interested in a balanced review of this important issue, I would be pleased to prepare and provide you with a more detailed analysis and to discuss it with the committee as a whole or with any individual members. I have not, however, attempted to assemble such a detailed analysis for presentation today. I see no point in expending my energy and that of others in attempting to put together a rational analysis of this issue if it is simply to be ignored or distorted

by this Committee's staff to further their own predetermined, mistaken, and hardened views on Government patent policy.

For those of you who want to explore this with an open mind, I am more than happy to meet and discuss the issue. I believe that establishing the proper patent policies can have critical impacts, many of which I have not even mentioned today such as its effect on American inventions being developed by state-subsidized foreign firms to the detriment of American workers and industry. I do not wish to advocate a policy that will have adverse results that I have overlooked or failed to understand. If as the result of sane and sensible discussion my analysis can be shown to be incorrect, I stand prepared to alter my views. But by the same token, I sincerely hope that the members of this committee or any one else concerned with this subject will be willing to approach the matter in the same way.