

pany. I think we should examine this. I think very likely the period, because of the nature again of the industry we are talking about, should be shorter. Compulsory licensing at a reasonable——

Senator NELSON. You say the patent period should be shorter?

Mr. SQUIBB. The patent period, yes, the patent period. Let us talk about the 17 years first.

Senator NELSON. Yes.

Mr. SQUIBB. That is running first, and there is no point in talking about the NDA disclosure as long as the patent is in effect, so you have got 17 years given by the people for that drug. Traditionally in the Squibb family we think that patents are not desirable in drug lifesaving situations like this, but I think that perhaps that is too extreme a position in the current situation. Patents might be shortened. So when you are shortening the patents and giving perhaps a patent for 5 years exclusively plus required compulsory licensing after 5 years or after some determined period of time, I think then you reexamine your NDA in terms of what you do under the patent law, because you have to break the NDA if you are going to break the patent in practical effect. There is no point in saying the patent only has 5 years, if you have essentially a patent produced by your New Drug Application, which only applies to your product, and is too expensive for anyone else in a competitive situation to try to duplicate. It is often millions of dollars of work and time.

Senator NELSON. If you had compulsory licensing, are you saying that it would require the company holding the patent to disclose everything it knows about the product?

Mr. SQUIBB. Yes; and give a permission of the licensee to use the documentary protocols and terms that have been put in that NDA.

Senator NELSON. How much information is in there? For example, the argument is consistently made, which no doubt is correct, that even if you have the same chemical compound and the same proportions in a tablet, the mechanical formulation of it or the coating of the tablet or what have you may still affect the degree of physiological availability. Does the New Drug Application information disclose all the specific techniques for compounding and making the particular product?

Mr. SQUIBB. Yes; but I think that is the minor part of it. That is the least difficult part of it. NDA includes the background of the clinical testing, the toxicology, and the studies that have been made preliminary to the release of the product and the claims that are presented for the product are based upon the material that has been accumulated over a number of years and organized in the NDA. It may be \$1 million or \$2 million of expenditures involved there. There is a great deal in there which the new licensee coming into the situation would find it impossible to duplicate as he is faced with the opportunity to go into the market. If he had to do that, he just would not do it. I think that the consideration is whether you should or should not treat drug products, professional drug products on which a patent has been given, any differently from any other commercial item for which a 17-year patent is granted. If you are going to say it should be shortened, then you have got to effectively change your rules on NDA. This is needed so that you make it available in not just a token