because a very important process patent does not expire until July 1967. I was just wondering if you have any information on that.

Dr. LUECK. I do know this, that it was, in terms of patent rights, legally possible for other companies to market and distribute chloramphenicol in the United States from about October 4, 1966.

Mr. GORDON. But not if they needed the important process that you were using and had patented, and which expired, as I understand it, only a few months ago.

Dr. LUECK. I think that chloramphenicol could have been produced by a procedure, chemical synthesis that would produce a certifiable product as soon as the patent on chloramphenicol itself ran out in October 1966.

Senator NELSON. What was that?

Dr. LUECK. I think that other companies legally could produce chloramphenicol and distribute it in the United States as far as any patent rights were concerned——

Senator NELSON. So far as any what?

Dr. LUECK. Patent rights were concerned. They would, of course, have to have, to be legal, the approval of the Food and Drug Administration and the FDA would have to certify them batch by batch.

Senator NELSON. What did your Chloromycetin patent protect, then?

Dr. LUECK. It protected the product, the fundamental scientific discovery of chloramphenicol as a chemical entity and therapeutic agent.

Senator NELSON. But you are saying chloramphenicol could have been produced by anybody despite the patent?

Dr. LUECK. No; only after October 4, 1966, after the patent ran out, Mr. Chairman.

Senator NELSON. We will take this up when Dr. Slesser appears. I will just read one sentence on this question of USP standards and then submit it for the record in its entirety.

Dr. Miller, in a statement dated November 29, 1967, states:

> We are aware of six proven cases of clinical difficulties with drug products which did or could have met U.S.P. standards. * * * Of these proven cases, one involves a product believed to have been distributed only in Canada.

(The material referred to follows:)

STATEMENT BY DR. LLOYD C. MILLER, DIRECTOR OF REVISION, OF THE U.S. PHARMACOPEIA, NEW YORK CITY, NOVEMBER 29, 1967

The current U.S. Pharmacopeia lists about 900 drug substances or products prepared from them all for which suitable tests and standards are provided. The standards are sometimes questioned as being insufficient to insure that the products will give the full therapeutic effects expected of them.

We dealt with this topic with a statement made to your subcommittee on June 27, but perhaps too briefly out of a desire to save time. Some specific supplementary comments may therefore be in order at this time.

We are aware of six proven cases of clinical difficulties with drug products which did or could have met the U.S.P. standards. These are:

Item:	*Approximate date of discovery of problem*
Thyroid tablets	Prior to 1940
Bishydroxycoumarin tablets	1957
Spiromolactone tablets	1960
Aspirin coated tablets	1960
Prednisone tablets	1962
Diphenylhydantoin tablets	1967