

some examples at 8 and 10 and 12,000 percent higher than the world market price, is that correct?

Mr. DWINELL. The whole thrust of these new regulations is to eliminate those glaring differentials which were brought out at the previous hearing.

Mr. GORDON. May I ask a question here with respect to patents. This paragraph does not seem to distinguish between product patents and process patents. If a U.S. firm has a process patent, perhaps of little importance, will this entitle it to the special treatment you just mentioned concerning prices of pharmaceuticals sold in violation of U.S. patents?

Mr. DWINELL. Yes; we are directed by statutes specifically in that respect.

Mr. GORDON. Well, suppose a drug is developed overseas and is licensed on an exclusive basis to a firm in this country. Examples are Orinase or Lasix. How does that apply in such a case?

Mr. DWINELL. Since that is a legal matter, Mr. Gordon, I wonder if I could ask Mr. Grant to address himself to that question.

Mr. GRANT. Well, Mr. Gordon, what we are doing here is giving effect to the spirit of Section 606(c) of the Foreign Assistance Act. Section 606(c) prohibits AID from expending funds with respect to pharmaceutical products abroad which are produced in violation of a U.S. patent. The section provides that we may not expend funds for any pharmaceutical product manufactured outside the United States if the manufacture of such a product in the United States would involve the use or be covered by an unexpired patent, unless the manufacture is expressly authorized by the owner of the patent.

As you know, there apparently has been some great difficulty with respect to patented U.S. drugs being produced abroad in violation of the patent. Now, Section 606(c) is a provision which the Agency did not ask for. The Congress passed it and it is part of the mandate to us. The AID policy rule which Governor Dwinell just read to you with respect to excluding sales of a pharmaceutical sold abroad in violation of the U.S. patent from the group of sales which AID takes into account in measuring the maximum price AID will finance is simply a way of helping to carry out the purpose of that statute.

Mr. GORDON. Let me give you a specific example. Suppose you have a drug like chlorpromazine sold under the trade name of Thorazine, of which incidentally, the patent has already expired. Before the patent expired, the price to the Canadian Government by the developer was a little over \$2. The developer who is in France licensed an American company on an exclusive basis and the American company charged about \$32 to the American Government.

Now, in considering the prices, would you consider only the American price of \$32 or would you consider the price overseas of somewhere around \$2 even though the patent holder was a foreigner?

Mr. GRANT. Well, are you postulating a situation, Mr. Gordon, where the sale abroad is in violation of a U.S. patent?

Mr. GORDON. No.