infringement of product or process patents by a contractor in the production of an item for the Government. The clause is used to take advantage of 28 U.S.C. 1498 which provides that when a contractor infringes a patent with the authorization and consent of the Government, the patent owner's only remedy is by suit against the Government. The effect of that statute on drug purchases has been considered by the Comptroller General of the United States. He has held that it would be improper to reject a low bidder's offer merely because the bidder was not licensed to manufacture a patented article. The basis for his view was that Congress enacted 28 U.S.C. 1498 specifically to enable the Government to obtain or use patented articles from any source subject to the payment of reasonable compensation to the patent owner.

In addition to the authorization and consent clause, the indemnity provisions prescribed by paragraph 9–103 of ASPR are usually included in DSA contracts for drugs. These provisions require the contractor to indemnify the Government for patent infringement liability assessed against the Government as a result of the contractor's performance. Including such provisions is generally considered to be in the Government's best interest since it enables bids to be evaluated on an equal basis. It tends to encourage suppliers to become licensees of the patent owner, and thus in a position to sell not only to the Government but to the public as well. However, DSA assumes the full financial responsibility for patent infringement by deleting the indemnity provisions from the solicitation where this would result in a lower overall cost to the Government.

Lest there be some implication from the above that DOD does not actively solicit competition in procurement of drugs, exhibit 6 is a copy of a letter which was distributed by DPSC to their entire drug bidders list. Exhibit 7 is a copy of that list.

As can be seen from exhibit 6, DOD placed no legal impediments in the way of possible bidders, whether considering patented or unpatented items. The lack of response to exhibit 6 can probably be best explained in terms of industry self-protection.

In DMMB development of EC's, and DPSC preparation of specifications, we have found that a patent is only one form of protection for a proprietary item. It is very common to develop trade secrets subsequent to the grant of a patent. These secrets need not be made available to other than a licensee of the patent holder, and may be of such significance that they affect the therapeutic capabilities of the drug.

Secondly, we find that in many instances, only one company manufactures a non-patented item. Exhibit 6 contains multiple examples of this situation. We attribute the lack of additional bidders to several factors:

1. The established bidders, by virtue of existing plant equipment, capacity, special competence, know-how, or production scheduling, is able to underprice prospective competition. (For example, a DPSC solicitation closing on 26 May 1970, contained a 50% set-aside for small business. The buy was for 376,104 bottles of glyceryl guaiacolate syrup, FSN 6505–064–8765. Small business did not bid, and we are convinced that this omission relates to inability to compete on the price.)

2. Industrial secrets are closely protected by their developers. Many of our single source items have generic EC's but we do not know the necessary manufacturing techniques. Such factors as the sequence of combining substances, humidity, working temperatures, etc., have specific effects on the finished product. Lack of knowledge in this area may preclude or delay competition (as it did with our example drug, calcium carbonate and aminoacetic acid tablets).

3. It may not be profitable to obtain a new drug application (NDA) for Government sales only, and many small manufacturers lack the resources for national distribution in the commercial market.

In summary, by using the "authorization and consent" clause, and by considering bids or offers from firms, whether or not they are owners or licensees of a patent, DOD and DSA do take advantage of and use the authority provided in 28 U.S.C. 1498 in the purchase of drugs. This practice is well known throughout the drug industry.

Gentlemen, this completes my formal statement. At your pleasure, we may now review the exhibits which are appended to the statement, or I shall endeavor to answer questions for the subcommittee.