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TESTIMONY OF DR. MARC J. OSTRO

TO THE SUBCOMMITTEE ON PATENTS, COPYRIGHTS AND TRADEMARKS

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My name is Dr. Marc Ostro and I am here today to testify in favor of Senate Bill 1543 to protect patent owners from the importation of goods made overseas by use of a U.S. patented process.

I am Vice Chairman and Chief Science Officer of The Liposome Company (TLC) which is located in Princeton, New Jersey. We are a 4 1/2 year old biotechnology company whose focus is to develop novel drug delivery systems made from liposomes. The idea to form TLC goes back to the early part of 1980 when a group of venture capitalists headed by Jack Whitehead of Whitehead Associates and the International Nickel Company's Venture Capital Division agreed to put up seed money to finance the commercialization of liposome technology. Literally this company started in my living room, and in the 4 1/2 years that we have officially been in existence we have grown from a single employee to 63 and have hiring commitments to raise our employee number to 75 before the end of 1986.

I can say with a high level of conviction that had it not been for protective patent legislation the opportunity for such rapid growth would not exist. However, before I more fully explain the importance of patents in general and method patents in particular to TLC, I feel I should explain what a liposome is. Briefly, liposomes are microscopic

balloons whose membrane is composed of naturally occurring fats. Within these balloons we can place a wide variety of drugs, and by properly engineering the membranes we can among other things reduce toxicity of anticancer drugs, improve the efficacy of a wide variety of antibiotics and create a broad array of long-acting medications.

Since this technology has been extensively studied in university environments over the last 20 years (they were first produced by Alec Bangham, a British scientist, in 1965), there is a considerable amount of prior art in the public domain which in many cases makes product patents difficult to obtain. In spite of this difficulty we have filed 35 patent applications at a cost in excess of $1 million covering procedures to produce liposomes, the liposomes themselves, and the use of this technology to combat a variety of diseases.

Since we are a venture capital backed firm and do not yet have revenue from product sales, the $1 million spent on the filing of patent applications represents a considerable financial commitment for a small company. But in essence, these patent applications represent our current products. That is to say, we and other biotechnology companies similar to us have been able to raise substantial sums of money from private investors as well as large pharmaceutical companies by selling rights to use selected parts of our patent inventory. It is this money that will have allowed us to create by the end of 1986 75 new jobs in New Jersey. I think it is fair to say that if we cannot protect the subject

matter covered by these patents, we will be unable to bridge the financial gap between where we are now and our projected date for the introduction of our first pharmaceutical products.

Let me illustrate this point by giving an example. The basic raw material needed to produce liposomes is a chemical called lecithin derived from egg yolks and soy beans. When TLC was started, one kilogram of 99% pure egg lecithin would cost approximately $20,000. At that cost no liposome-based pharmaceutical product would ever be commercializable since the wrapper of the drug would cost, in some cases, as much as 100 times more than the drug itself. We have devoted 4 1/2 years and several million dollars to devise a process whereby we can now produce the same egg lecithin for as little as $200 a kilogram.

It is our conviction as well as the belief of a growing list of large companies that liposome-based products will make a substantial impact on the pharmaceutical industry. All the pharmaceutical companies producing liposome-based products will need this vital raw material. We therefore feel that its sale represents a significant commercial opportunity for us. If foreign competitors using the same process were able to import 99% pure lecithin into the U.S. at comparable prices, our investment of time and money would have gone for naught. As a small company, such a set of circumstances would dramatically reduce our rate

of progress towards reaching our goal of profitability. If such an infringement were to occur under Title 19, our remedies would be limited.

If we are to foster growth in our country and encourage venture capitalists and pharmaceutical companies to invest in new technologies, it is imperative that we prevent foreign companies from squeezing out and destroying the chances for small U.S. industries to develop to their full potential. Foreign competitors should not have an unfair advantage in competing with U.S. companies because of their freedom from our patent laws.

As a result of the existing loophole addressed by this Bill, foreign competitors who have made no investment in research and have taken none of the risks in developing a new technology can reap the rewards of our efforts. We feel that this Bill is an important step in closing this loophole. In fact, we feel that the Bill should go further than currently proposed by adequately addressing the difficulties in discovery when foreign defendents are involved. We would therefore encourage the Committee to consider reinstating provisions for the reversal of the presumption of noninfringement.