Statement

Pharmaceutical Manufacturers Association

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FOR THE

SENATE JUDICIARY SUBCOMMITTEE
ON PATENTS, COPYRIGHTS AND TRADEMARKS
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I am Gerald J. Mossinghoff, the President of the Pharmaceutical Manufacturers Association. I am accompanied today by Dr. Alan Lourie, Vice President, Corporate Patents and Trademarks and Associate General Counsel, SmithKline Beckman Corporation, and the Chairman of the PMA Patent Committee.

The PMA is a national trade association representing 109 pharmaceutical companies who are responsible for the vast majority of new drugs introduced in the United States and virtually all pharmaceutical research and development undertaken in this country. PMA companies rely on the incentives of our patent system in conducting their research and development activities and regularly obtain patent protection on the results of their efforts. S.1543, the Process Patent Amendment of 1985, would strengthen our patent laws by eliminating the opportunity for copiers to avoid infringement of process patents and effectively obtain free use of U.S. research and development expenditures. PMA therefore strongly supports enactment of this legislation. We note that this legislation is also supported by a broad range of companies and industry associations and that the President's Commission on Industrial Competitiveness recommended strengthening of process patents. President

Reagan's recently announced set of trade initiatives also cites to the need for better process patent protection.

S. 1543 would amend the patent code to give the owner of a process patent the right to bring an infringement action against someone who uses, sells or imports into the United States a product produced by the patented process. Thus a company would not be able to circumvent legitimate rights flowing from a process patent simply by practicing the process in a foreign country. This amendment is needed to eliminate a deficiency in our patent law and bring U.S. law into conformity with the patent laws of other major industrialized trading partners, including West Germany, France, and the United Kingdom. A provision for protection of the product made by the patented process is also included in the European Patent Convention.

The legislation will generally benefit companies which seek to patent innovative manufacturing processes, including pharmaceutical and chemical companies, and can be expected to have an immediate impact in the emerging field of biotechnology where product patent protection may not be available. Also the legislation should also help preserve domestic jobs since a manufacturer will tend to invest in U.S. manufacturing facilities if patent owners are more fully protected.

The principal oppostion to S.1543 has come from a trade association representing manufacturers of generic pharmaceuticals. The legislation

includes limitations which in our view adequately address any legitimate concerns the generic drug industry may have with this legislation. There is an appropriate provision in the bill which protects the innocent infringer. Also the legislation only applies to products produced or imported after enactment, and there is a grandfather clause to protect those already in substantial and continuous commercial production prior to enactment. The legislation would properly deter generic companies from importing drugs made by the U.S. patented process and force their suppliers to switch to an unpatented process. This should be no great burden since chemical compounds are generally able to be made by any of a variety of processes.

S.1543 is also consistent with the Drug Price Competition and Patent Term Restoration Act of 1984. That legislation facilitates the approval of abbreviated new drug applications at the time of patent expiration. If a patent holder has elected to extend a process patent, the generic copier should not be able to circumvent that patent prior to expiration by having the process performed outside of this country. I should note that a process patent, whether extended or not, will not preclude a generic company from selling a drug whose product patent may have already expired.

The bill should include a provision for reversal of the burden of proof in appropriate situations. We therefore ask that S. 1543 be revised to incorporate Section 295 in H.R. 1069, introduced by Representative Moorhead. A rebuttable presumption should be established in certain instances so that

a product that could have been made by a patented process is presumed made by that process. A shift in the burden of proof would not create a substantial hardship since the alleged infringer is in a much better position to establish that the product was made by an unpatented process. Such a shift is essential if the process patentee is to have an effective remedy against an importer since the laws of most countries do not have adequate discovery mechanisms of the types sanctioned by United States courts.

We also recommend some limited revisions to the grandfather provision in Section 3 to clarify that investments must be made in the United States by the person who wishes to import, use or sell the product produced by the patented process outside the United States. We would appreciate the opportunity to assist your staff in developing appropriate language.

This concludes my prepared statement. Dr. Lourie and I appreciate the opportunity to appear before this Subcommittee in support of S. 1543.