Statement of the National Association of Chain Drug Stores, Inc.

Before the Subcommittee on Patents, Copyrights & Trademarks

Senate Committee on Judiciary

Process Patent Amendments of 1985

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SUMMARY OF TESTIMONY REGARDING S. 1543

PROCESS PATENT AMENDMENTS OF 1985

NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.

1. NACDS is opposed to the Process Patent Amendments of 1985 because the legislation would make suspect all products offered for sale in a retail store.

2. Retailers have no way in which to ascertain the validity of a product and the processes used to make the product.

3. The legislation would be very disruptive to commerce and would make retailers vulnerable to expensive and complicated litigation.

4. S. 1543 would have a chilling effect on retail drug stores that dispense quality, less costly generic prescription drugs to patients and needy recepients.

Mr. Chairman and Members of the Subcommittee, my name is Nancy L. Buc and I am a partner in the law firm of Weil, Gotshal & Manges. My statement today is presented on behalf of the National Association of Chain Drug Stores (NACDS).

Founded in 1933, NACDS represents the management of 172 corporations that operate more than 18,000 retail drug stores and pharmacies throughout the United States. The chain drug industry currently employs more than one million people who work in corporate headquarters, regional offices, warehousing facilities, and retail drug stores. Annual sales for chain drug stores total about $25 billion, and that figure represents approximately two-thirds of all retail drug store sales in America. Corporate drug stores also account for one-third of all out-patient prescription drug sales in the United States.

On behalf of the NACDS membership, I very much appreciate the opportunity to testify at these hearings on S. 1543, the Process Patents Amendments of 1985, to explain why NACDS so vigorously opposes this bill. This bill would, if enacted, cast a black cloud over every product on retailers' shelves. The average chain drug store is some 10,000 square feet in size and it offers more than 12,000 different products for sale to consumers. S. 1543 makes virtually every one of those

12,000 products, foreign or domestic, into a potential lawsuit. If there is a problem with process patent enforcement, it's hard to imagine a worse solution.

Under S. 1543, any holder of a U.S. process patent who thinks a retailer is selling a product made by an infringing process can sue the retailer for patent infringement. The mere filing of the lawsuit makes the retailer liable for damages starting then and there, even though the retailer has no way of knowing whether it is infringing or not, and can't necessarily even find out. So the retailer must play process patent roulette - it must either risk a substantial damage award or discontinue the sale of the product. What is more, the retailer has to choose fast - before the court renders a decision, before the plaintiff has even put on a case. Forcing the retailer to choose so early gives all the advantage to the plaintiff, and makes even a somewhat casual lawsuit advantageous to plaintiffs.

It will be said, of course, that there are safeguards against casual lawsuits, but the supposed safeguards don't offer much real solace. For one thing, under current rules of pleading, the owner of a process patent can make a charge of infringement "on information and belief." Information and belief isn't proof, it's just enough of an informed guess to make it ethical to file a lawsuit; lots of plaintiffs who can ethically file a law suit can't win them, and lots of them can't even

survive a motion for summary judgment. Yet the retailer's liability does not await the testing of information and belief; it crystallizes immediately on filing. And retailers don't take much comfort in the availability of sanctions under Rule 11 for infringement actions brought in bad faith. S. 1543 plaintiffs can cause serious trouble even if they're in good faith, and most retailers won't go to the expense and trouble of proving bad faith.

It will also be said that this bill only makes retailers liable for failure to do what they should do anyhow - exercise their "leverage" over their suppliers. The retailer's vaunted leverage is largely mythical, for it is the very essence of retailing that no one product looms very large in the product mix. Moreover, most chain druggists, like most retailers, lack expertise in manufacturing in general. Remember, the average chain drug store stocks some 12,000 products. With 12,000 products in stock, the chain druggist would have to police 32 manufacturing processes a day, 365 days year, just to stay even.

Policing process patents is especially difficult. In most cases, there are a multitude of processes which could have been used to manufacture a particular product, and most of those processes would not involve infringement of the asserted patent. Nevertheless, under the proposed law, by merely making the

allegation of infringement and putting the retailer of the product on notice of the claim of alleged infringement, the retailer becomes immediately liable for damages.

In any event, even if retailers could police a few process patents here and there, it is horribly inefficient and therefore very costly to police a marketplace at the downstream stage. Requiring the process patent holder to go head to head with the real party in interest, the allegedly infringing manufacturer, would be cheaper, faster, and more practical.

A retailer's choice to drop a product instead of gambling on the outcome of process patent infringement litigation harms the retailer, of course, for the retailer loses the continuity of supply so essential to ordinary commerce. Competition and consumers will suffer, too, for S. 1543 is a wonderfully potent way to knock out competition - no need to compete on quality or price, just file an infringement case. Indeed, the very reason for the charge of process patent infringement will be a desire by the patent owner to get the customers to buy the patent owner's product rather than the allegedly infringing product. Thus, the legislation is designed and intended to promote the use of the coercive patent infringement litigation to alter the purchasing decisions of innocent customers in the chain of distribution.

When it comes to prescription pharmaceuticals, the ill effects of S. 1543 would be felt not only by consumers but by the State and Federal governments which finance Medicaid and Medicare. This is so because S. 1543 is, in fact, a blunt club which will be used to hit one of the most pro-competitive and cost effective elements in our health care system, generic drugs.

As the Subcommittee already knows from its deliberations in the 98th Congress in fashioning the Patent Restoration/ANDA Law, generic drugs are a safe, effective, and low-cost alternative to the usually more expensive brand-name prescription drugs. Pharmacists, senior citizens, labor organization and consumer groups have all supported enthusiastically the expanded use of generics and the relaxation of state laws and federal policies that would restrict the full use of these important medications. Today, the pharmacy department of a typical chain drug store stocks in inventory between 2,000 and 3,000 different prescription drug products, of which a significant number are generics. More and more generic drugs will be coming into the marketplace in the near future as a result of the landmark Patent Restoration/ANDA bill.

Generic drugs offer the potential for significant savings in health care costs, whether those costs are borne by individuals, insurers, employers, or the state or Federal governments. Indeed, major employers like Chrysler, numerous

insurers, and States like Connecticut are offering incentives to patients who use pharmacists who dispense generic pharmaceuticals. Also, the Department of Health and Human Services is seriously considering generic incentives. If S. 1543 is enacted, all these initiatives will be at risk, for a pharmacy doing its best to provide patients with low-cost, high-quality pharmaceuticals will surely be faced with process patent infringement cases, and will either have to raise prices so as to be able to afford to defend the cases or stop handling lawsuit-prone generic drugs. Either way, the public loses.

In conclusion, Mr. Chairman, NACDS members want to know why this bill has such a short fuse and is so one-sided. Why not wait to see who wins before imposing damages? Why not reimburse retailers for their costs of defending these cases, including attorneys fees, if plaintiffs lose? Most especially, why not require the process patent holder to fight its fight with the real party in interest, the allegedly infringing manufacturer? Whether in a Section 337 proceeding before the ITC or in a U.S. district court, let the U.S. patentee deal directly with its real opponent. Let the parties directly involved, who know the facts, resolve the issue. But do not force chain druggists to face coercive litigation in a fight that is not properly their fight.

Thank you.