



FDA's Proposal on Generics Pleases No One

by Stephen Barlas



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The Food and Drug Administration (FDA) must feel a little bit like Rodney Dangerfield: it “can’t get no respect.” Even as the agency tries mightily to lower the barriers to the marketing of less expensive generic drugs, the FDA is taking a beating by the generic pharmaceutical industry for not going far enough, by the brand-name pharmaceutical industry for going too far, and by interested drug-chain participants—such as the Academy of Managed Care Pharmacy (AMCP)—for everything in between.

The FDA’s proposed rule, announced in October 2002, reduces the number of categories of patents eligible for listing in the “Orange Book,” the FDA’s bible that dictates whether a brand-name company can keep a generic substitute off the market for 30 months while a patent-infringement action goes forward. Taking its cue from a study done earlier by the Federal Trade Commission, the FDA wants to exclude patents related to aspects such as packaging, metabolites, and intermediates from its Orange Book and to limit pharmaceutical manufacturers to one 30-month stay per drug. The FDA study found that drug companies sometimes get multiple 30-month stays for the same drug (see this column in the December 2002 issue of *P&T*).

Judith Cahill, executive director of the AMCP, thinks that the 30-month-stay pro-

vision, which was enacted as part of the landmark Hatch–Waxman Act of 1984, should be thrown out entirely. “Because the brand-name manufacturer can secure an additional 30 months of market exclusivity just by filing suit, the automatic 30-month stay invites litigation, regardless of the merits of the suit,” she says. She understands, though, that the FDA does not have the authority to eliminate the 30-month stay completely. As a result, she is urging the FDA to ask Congress to legislate it out of existence; however, Congress is unlikely to do this.

The FDA must be reeling, because even the Generic Pharmaceutical Association (GPhA), whose members are supposedly helped by the proposed rule, has assailed the proposal to limit brand-name companies to one 30-month stay. Kathleen Jaeger, GPhA president and chief executive officer, believes that the one 30-month-stay would make it *easier* for the big companies to delay the entry of generic drugs because of the legal peculiarities of brand-name/generic patent confrontations, which are very complex. Moreover, Ms. Jaeger is unhappy with the FDA proposal because it “leaves untouched certain existing forms of brand company abuse, such as late, frivolous patent listings where previous brand patents were not challenged.”

If you think that the GPhA’s unhappiness with the proposed rule means that the Pharmaceutical Research and Manufacturers of America (PhRMA) is ecstatic, guess again. PhRMA thinks that the proposed regulation “could be manipulated by generic applicants to deprive patent holders of the opportunity to obtain even a single 30-month stay.”

This is not the only objection that the

brand-name industry has to the proposal. PhRMA does not object to excluding packaging patents from the FDA’s Orange Book, but it thinks that patents for packaging that is “integral” to the product (as in a drug-delivery system) deserve entry into the Orange Book.

Donald Parman, vice president of legal operations for GlaxoSmithKline (Research Triangle Park, NC), believes that asthma inhalation devices, nasal inhalers, transdermal patches, and prefilled syringes all should be eligible for listing in the Orange Book. GlaxoSmithKline has become something of a poster child for “big drug” blocking of generic brands. The company has been in a legal battle for years with Apotex, a manufacturer of generic brands that wants to introduce a version of GlaxoSmithKline’s Paxil® (paroxetine), an antidepressant.

“Unlike drug containers and packaging, drug delivery aspects of integrated device/drug combination products are not distinct from the approved product,” Mr. Parman says. GlaxoSmithKline is taking this position partly because of its asthma drug, Serevent® Diskus® (a powder formulation of salmeterol xinafoate), which is administered through a specially designed plastic inhalation-delivery system (the Diskus).

Pfizer, Inc. (New York, NY), however, wants the FDA to take a considerably broader view of the word “integral.” Although Jeffrey Chasnow, senior corporate counsel, thinks that packaging—which is distinct from the drug product—should not be eligible for the Orange Book, he broadens the definition of “integral” to include “novel blister packaging which may be necessary to ensure safety or efficacy.” ■