Brand-Name Generic Deals Face End of the Line
Congress Likely to Ban Exclusion Payments

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Like a number of other Democratic congressional initiatives in the pharmaceutical area that stalled during the Bush administration, legislation limiting the ability of brand-name drug companies to slow the introduction of generic competitors is likely to move forward this session. Representative Henry Waxman (D-Calif.), chairman of the House Energy & Commerce Committee, and Representative Bobby Rush (D-Ill.) have reintroduced their Protecting Consumer Access to Generic Drugs (D-Ill.) have reintroduced their Protecting Consumer Access to Generic Drugs Act of 2009 (H.R. 1706). The bill bans “exclusion payments,” money paid by brand-name drug companies to generic-brand companies that have challenged a brand-name and generic drug manufacturers intended to keep generic drugs off the market.

Assistant Attorney General nominee Christine Varney reiterated that position to a Senate committee.

The Waxman–Rush bill is being sold as a natural component of any health care reform bill because it would make health insurance more affordable, both for consumers and the federal government.

Thomas Rosch, a commissioner of the Federal Trade Commission, said, “The threat that these agreements pose to our nation’s health care system is a matter of pressing national concern.”

Here is a recent example of the perceived problem. In September of 2007, Lupin Ltd., a company that manufactures generic drugs, invalidated a patent covering King Pharmaceutical’s Altace (ramipril), a medication for hypertension with nearly $1 billion in annual sales. King, however, had previously settled with the first generic-brand drug company to file its application with the FDA—Cobalt Pharmaceuticals—which had dropped its lawsuit as the price of settlement.

Because Cobalt was the first generic-brand pharmaceutical firm to file an application with the FDA, it was entitled to the 180-day exclusivity period granted under the Hatch–Waxman law. It remained for Lupin to pursue the expensive lawsuit and win. But its victory was somewhat hollow; even though Lupin won, it had to wait for Cobalt to start selling generic Altace and had to hold off selling its own version until Cobalt’s 180 days of exclusivity ran out.

Lupin was left with nothing—even though it was the party responsible for opening the market early for consumers and for funding the expensive lawsuit. Yet Cobalt, which had agreed to delay consumer access to the generic brand by abandoning its effort to knock out what proved to be a patent that never should have been issued in the first place, was able to “double-dip.” Cobalt was able to keep the money it was paid by the brand-name drug company to abandon the patent fight, and then it benefited from having the only generic brand on the market during the exclusivity period.

Bernard Sherman, Chief Executive Officer and Chairman of Apotex Inc., a major manufacturer of generics that supports the Waxman bill, says:

At first blush, the acceleration of Cobalt’s entry into the market resulting from Lupin’s victory may sound like a good outcome for consumers. However, no subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system.

It comes as no surprise, of course, that most pharmaceutical companies that make branded drugs oppose a ban on exclusion payments. Diane E. Bieri, Executive Vice President and General Counsel of Pharmaceutical Research and Manufacturers of America (PhRMA), argues that the ban might stop pro-consumer settlements, reduce the value of patents, and reduce encouragement for innovation.

“The sweeping prohibition could also have the unintended consequence of reducing generic companies’ incentives to challenge patents in the first place, as they will have to consider that their options of settling patent litigation will be dramatically reduced,” she states.

It is difficult to know whether PhRMA’s objections are legitimate. Only time will tell; the Waxman bill will undoubtedly clear Congress in some form or another, now that the Bush roadblock has been removed and the brand-name industry’s political clout has eroded.