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We are drawing close to the thirtieth anniversary of the Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman, enacted in 1984. Among other things, the Act grants generic manufacturers the ability to challenge the validity of a patent covering a brand name drug without incurring the cost of actually entering that drug market or having to risk the enormous damages that would flow from a finding of infringement. In other words, Hatch-Waxman made it a lot easier for generic drug companies to take on big pharma patents. Not surprisingly, the generic drug sector blossomed in the wake of the Act.[2] In 1984, generics comprised only 19 percent prescription drug volume and 36 percent of brand drugs had a generic competitor; by 2002, 47 percent of prescription volume was generic and nearly 100 percent of brand drugs faced generic competition.[3]

With the blossoming of generic drugs, however, came another trend: the rise of the "reverse payment" settlement. Typically when a patent infringement case is settled it is the putative infringer who pays the patent holder to close out the litigation. When a brand firm sues a generic drug maker for patent infringement, however, settlement payments run in the other direction: brand firms typically pay generic firms to drop their challenge and keep their generic versions of the drug out of the market for some period of time.[4] It is this aspect of brand-generic settlements that has earned them the moniker "pay-for-delay."

When we step back to consider the economics of brand drug sales versus generic drug entry, the emergence of pay-for-delay settlements after Hatch-Waxman should have come as no surprise. Brand firms spend hundreds of millions of dollars on R&D, clinical trials, and the various tasks required to obtain FDA approval.[5] Nor is FDA approval guaranteed: the average new drug takes somewhere between 10 to 15 years to go from lab to pharmacy, but only around 1

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[2] As the FTC observes, "More than two decades ago, Congress passed the Hatch-Waxman Act [in 1984] to encourage generic manufacturers to challenge patents that either are invalid or narrow enough to be designed around. The legislation has worked. Studies have shown that generic manufacturers have prevailed in the majority of patent challenges. The resulting generic entry, which often occurs well before patent expiration, leads to significantly lower prices and huge savings for patients and the health care system." (FTC press release on the filing of its suit against Solvay in 2009, http://www.ftc.gov/opa/2009/02/androgel.shtm).

[3] Hasneen Karbalai, *The Hatch-Waxman (Im)Balancing Act*, Harvard Law School Working Paper (2003), leda.law.harvard.edu/leda/data/551/Paper1.html.

[4] This period of time is a crucial element of these cases, as will be evident in the discussion below.

[5] *See* CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY, (CBO 2006) *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf; Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different ?*, 28 MANAGERIAL DECISION ECON. 469 (2007); and Josheph A. DiMasi, Ronald W. Hansen, & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003).

out of every 5,000 new drugs that start down the development path will ultimately be approved.[6] Hence brand drug prices tend to be relatively "high"—they must earn a reasonable return on their own investment costs plus cover the many dry wells that were sunk along the way.

Generics, on the other hand, have far fewer upfront costs. Under Hatch-Waxman, a generic firm can file an Abbreviated New Drug Application ("ANDA") as soon as the brand drug's New Molecular Entity filing reaches its fifth anniversary, and the generic need only supply the FDA with bioavailability studies to support that ANDA. Clearly the brand firm has a lot more money on the line in a patent infringement suit than the generic. This asymmetry in stakes then translates into an asymmetry in settlement talks: the brand firm may be willing to pay a sizeable amount to the challenging generic in order to maintain a few more years of brand drug exclusivity.

This rationale has not resonated with the Federal Trade Commission ("FTC"), however. It sees brand-generic settlements as unequivocally bad for consumers. As explained in its 2010 report, "'Pay-for-delay' agreements are 'win-win' for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand's monopoly profits. Consumers lose, however: they miss out on generic prices that can be as much as 90 percent less than brand prices."[7] Following this logic, the FTC concludes that such settlements cost American consumers $3.5 billion a year.

Thus, for 15 years—the entire second half of the lifespan of the Hatch-Waxman Act—the FTC has been battling pay-for-delay settlements. In addition to the staff report quoted above, the FTC has launched several high profile legal challenges, summarized in the chart below. The FTC's first effort, begun in 1999 against a settlement entered into by Hoechst Marion Roussel (now Aventis) and Andrx, was a success. The Commission argued that the pay-for-delay settlement between the two firms over Aventis' heart drug Cardizem was an unreasonable restraint of trade under Section 5 of the FTC Act. The case concluded with a consent decree that ended the settlement. But after this initial success, the FTC has suffered a string of setbacks: its 2001 suit against Schering-Plough (over potassium supplement K-Dur) was dismissed; its 2008 case against Cephalon's Provigil sleep drug is still pending; and its 2009 case against Solvay over testosterone replacement drug AndroGel just recently ended in another defeat, this time with the court squarely rejecting the FTC's arguments.

[6] Tufts Center for the Study of Drug Development, *Backgrounder: How New Drugs Move Throughout the Development and Approval Process* (Nov. 1, 2001), *available at* http://csdd.tufts.edu/newsevents/recentnews.asp?newsid=4 (last visited September 10, 2009).

[7] "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions", An FTC Staff Report (January 2010).

Table 1: FTC Challenges Pay-for-Delay Settlements, by filing year

Year Filed	Brand Company	Generic(s)	Drug(s)	Antitrust Violation Alleged by FTC	Court Outcome
1999	Hoechst Marion Roussel (now Aventis)	Andrx	Cardizem, cardiovascular and hypertension treatment	Settlement is unreasonable restraint of trade in violation of Section 5	April 2001 a Consent Agreement that terminated the settlement agreement resolved the complaint
2001	Schering-Plough	Upsher Smith Laboratories and American Home Products (AHP)	K-Dur 20 potassium chloride supplement	Settlements are illegal horizontal market allocation in violation of Section 5 (FTC) and Section 1 (Sherman); Schering monopolized and conspired to monopolize the potassium supplement market	July 2002 ALJ dismissed the FTC's complaint FTC appealed and full Commission sided w/FTC Parties appealed to 11th Circuit which reversed the Commission decision and dismissed the charges Supreme Court refused to take the case
2008	Cephalon	Teva, Watson, Ranbaxy, Mylan, and Barr	Provigil, sleep apnea treatment	Settlements are an abuse of monopoly power and are unlawful under Section 5(a) of the FTC Act	Still pending in U.S. District Court for the District of Columbia
2009	Solvay	Watson, Par, and Paddock Laboratories	AndroGel, testosterone replacement	Agreements unfair methods of competition that violate Section 5(a) of the FTC Act.	FTC filed in U.S. District Court for the Central District of California; case transferred to Northern District of Georgia District Court granted defendants' motion to dismiss FTC appealed U.S. Court of Appeals for 11th Circuit rejected the FTC appeal and ruled that "pay-for-delay" settlements do not violate federal antitrust laws

While the details have shifted, at the root of the FTC's arguments in these various cases is the allegation that pay-for-delay settlements amount to anticompetitive market sharing. Thus, the FTC maintains that patent validity and infringement are pivotal elements for the antitrust review of a settlement: if the brand firm is not likely to prevail on patent validity and infringement, then a settlement that involves a brand firm paying a generic firm plus a period of delay for generic entry can be interpreted as an anticompetitive pay-off for an otherwise eligible rival to not enter the market. The drug companies entering these settlements argue that there's nothing nefarious about them. Rather, they are simply a means for brand companies to protect and maintain their lawful patent terms and avoid lengthy and costly litigation.

In the Solvay case, the Eleventh Circuit sided with the drug companies. Making reference to a complicated culinary dish involving successively stuffed poultry, the court called "deciding a

patent case within an antitrust case about the settlement of the patent case, a turducken task."[8] In short, the court found the FTC's approach unworkable. Thus, the court stuck with a far simpler approach, holding that as long as the settlement does not expand the exclusionary scope of the original patent—that is, does not involve delaying generic entry beyond the statutory term of the patent—it is not subject to antitrust challenge.

Perhaps sensing this ultimate outcome in the courts, the FTC began a parallel legislative campaign against pay-for-delay settlements as well. In January 2010, when its Pay-for-Delay report was still hot off the press, FTC Chairman Jon Leibowitz was joined by several members of Congress in a press conference at which the FTC called for legislation that would prohibit such settlements.[9]

On May 24, 2012, however, the legislative approach hit a snag of its own. The U.S. Senate passed its version of the FDA User Fees bill, but voted against the amendment that would have banned pay-for-delay agreements between generic and brand-name drug companies.[10]

But don't assume that either the litigation or legislative setbacks spell the end of the FTC's efforts. In true Don Quixote fashion, it appears that the FTC may focus its efforts on Capitol Hill, rather than the courts, this time working for a stand-alone bill to prohibit pay-for-delay settlements rather than attempting to tack on amendment to another bill.[11] Only time will tell if the FTC will ultimately prevail, establishing that its target was indeed a dragon and not merely a windmill.

[8] Federal Trade Commission v. Watson Pharmaceuticals Inc., U.S. Court of Appeals, 10-12729, 11th Circuit (Atlanta).

[9] *See* FTC press release, http://www.ftc.gov/opa/2010/01/payfordelay.shtm.

[10] Rachel Slajda, "FDA User Fee Bill Easily Slides Through Senate", IPLaw 360 http://www.law360.com/ip/articles/343844?nl_pk=16c5fe89-57bf-4c62-9148-e0b241e2aaf7&utm_source=newsletter&utm_medium=email&utm_campaign=ip

[11] Kurt R. Karst, *FTC Commissioner Objects to Certain Provisions in Senate FDA User Fee Reauthorization Legislation*, (June 5, 2012), FDA Law Blog, http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2012/06/ftc-commissioner-objects-to-certain-provisions-in-senate-fda-user-fee-reauthorization-legislation.html.