The ban on "pay to delay" pharma patent settlements: shaving health care costs, fighting anti-competition, and patents — all rolled up into one

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2 July 2010 – The U.S. House of Representatives has passed a measure banning patent settlements struck between brand-name and generic pharmaceutical companies to delay the release of generic drugs. The goal? To shave nearly $2 billion off government spending over the next decade. The measure was tacked onto the Iraq and Afghanistan war funding bill.

The measure aims to the Federal Trade Commisssion (FTC) authority to initiate proceedings against any party that enters into a so-called "pay-for-delay" deal, in which the filer of an

abbreviated new drug application challenging the validity of a patent for a brand-name drug agrees to "anything of value" in exchange for forgoing research, development, manufacturing, marketing or selling the new generic alternative.

How do they work? It involves the concept of "parasitic value creation" in the pharmaceutical industry and how this occurs when a pharmaceutical company pays a generics company to stay out of the market. Pharma Company as a drug earning $400M profit per year, where the introduction of a generic competitor will lower profit to $180M for Pharma Company and generate $100M of profit for Generics Company i.e. a combined profitability of $280M. If Pharma Company pays Generic Company $125M to stay out of the market, both parties appear to win: Generics Company receives more profit than it would have with competition and Pharma Company obtains profits of $400M less $125M i.e. $275M which is more than the $180M it would have received in competition with the generic.

It appears to be the perfect business solution on paper i.e. by working together the companies have maintained a $400M market rather than reduced it to a $280M one.

Ah …. but where does the $120M in value that was "created" by co-operation come from? The FTC and the critics say the answer is that it is generated from the consumers who must now continue to pay more for the drug than they would if a generic was available. They argue that there has been no value creation only a transfer of value from consumers to producers, therefore it is "parasitic value creation."

Note: the above explanation comes from Sally Church's *Pharma Strategy Blog* which we constantly use as source on what's happening in the pharma industry.

The FTC considers "pay for delay" agreements to be an unreasonable restraint of trade that attempts to monopolize the market, and has brought antitrust law suits against companies, with mixed success. Earlier this year the FTC published a report "Pay-for-Delay": How Drug Company Pay-Offs Cost Consumers Billions" (*click here*). The report explains how legal decisions starting in 2005 have led to 63 settlements which delay generic drugs for an average of 17 months. The report estimates, using a very conservative analysis, that these settlements are costing American consumers $3.5 billion per year — $35 billion over the next ten years. Other legal experts have previously estimated that these agreements are costing $7.5 billion a year.

Earlier this year the European Commission launched its own probe over "pay-to-delay" patent settlements made between drug companies and generics manufacturers and whether their use is preventing consumers from accessing cheaper medicines. While the Commission did not name the parties involved, several key market players came forward and said they have been approached, including the UK-based majors AstraZeneca and GlaxoSmithKline, Switzerland's Novartis and Roche, and France's Sanofi-Aventis. Generics manufacturers also approached include Niche Generics (part of Unichem) and Israel's Teva. The Commission also revealed it is investigating Denmark's Lundbeck.

The Commission published a report last year entitled "Pharmaceutical Sector Inquiry" which provides a good background on what is happening in Europe (for that report *click here*).

The idea of formally banning "pay to delay" agreements through legislation would solve a lot of issues. The deals, also known as reverse payments, are currently not presumed to be anticompetitive on their face. That would be changed under the House measure, with the exception of deals in which both parties could clearly demonstrate that the pro-competitive benefits of the deal outweigh any potential anti-competitive effects.

Exceptions would also be made for patent infringement claim settlements if the only considerations made by the brand-name company are to give the filer the right to market the generic alternative in the U.S. prior to the original patent's expiration, a payment for reasonable litigation expenses under $7.5 million and a deal not to sue on any future infringement claims for that patent. The measure would also nix the 180-day exclusivity period for generic-drug marketing if the FTC or a federal court finds that an agreement violates the rules. It would give the FTC and courts authority to assess civil penalties for companies that break the rules.

A similar measure was added, then scrapped, from the comprehensive health care reform legislation that passed earlier this year. The war funding bill that this provision is tacked onto heads to the Senate for final passage and that will most likely occur after the July Fourth recess.

But not without a fight. The Generic Pharmaceutical Association and the Pharmaceutical Research and Manufacturers of America both say a ban on the pay-for-delay deals could stymie proconsumer deals that can actually help speed generic drugs onto the market before the original patents expire.

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