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Pay-for-delay deals aren't all bad, says Katherine Neville of Marshall, Gerstein & Borun

Do pay-for-delay deals threaten competition in the pharmaceutical industry?

So-called pay-for-delay settlements do not threaten the pharmaceutical industry, and have almost become an economic driver in the industry after the enactment of the Hatch-Waxman Act and the way that generic drugs are allowed to enter the market. In typical pharmaceutical patent disputes, the accused infringer would pay a settlement to end the litigation, however, in this situation the brand manufacturer is in a position to pay the accused infringer money to end the litigation and a reverse settlement is born.

Certain industry organisations, including the Generic Pharmaceutical Association (GPhA), consider these pay-for-delay settlements pro-competitive, not anti-competitive. The GPhA supported a whitepaper study that showed generic manufacturers resolved litigation by settlement in 64 percent of cases, and that when lawsuits between generics and brand manufacturers were allowed to go to judgement, the generic lost the case two out of three times, delaying generic entry until after patent expiration.

A 2011 report by the same organisation reported that 16 of 22 generic drugs that were supposed to launch in 2011 were able to launch due to reverse settlement agreements.

An independent study from RBC Capital Markets has shown that in 76 percent of patent settlement cases between branded and generic companies, generic versions of the pioneer drug are introduced an average of five years before the patent expiration date.

These types of settlements also do not threaten the industry, but in fact help the industry continue to develop and market new innovative drugs.

The cost of litigation and the uncertainty of how a court will decide a case encourages brand drug manufacturers to weigh the costs of litigation and other adverse consequences against the cost of an agreement with the generic drug to enter the market prior to expiration of the patent at issue in litigation. Often, this cost benefit analysis weighs in favour of settlement.

What about benefits to generic manufacturers?

This type of settlement is also beneficial to the generic as it is guaranteed entry into the market at a set time, which may not occur if the litigation is seen through and the generic gets an adverse decision and must then wait until the expiration of the patent. The generic manufacturer can then better plan its budget and future direction with the certainty of market entry in hand. This give and take between the branded manufacturer and the generic manufacturer allows the brand manufacturer to recoup the astronomical cost of fostering a drug candidate from development through gaining Food and Drug Administration approval for the drug while still allowing competition onto the market.

This monetary gain for both the brand and generic manufacturer is then reinvested in new research and development that may not otherwise occur. Putting an end to pay-for-delay deals could therefore have the unintended consequences of delaying, and even preventing, development of new therapeutics to benefit the public.

If this is the case, what keeps concerning competition authorities?

There seems to be an assumption with all of the arguments against reverse settlements that the generic could have prevailed in a litigation against a patent holder and therefore been on the market much sooner than the date of patent expiration. As the GPhA-supported whitepaper showed, when litigation goes to final judgement, the generic loses two out of three times, and therefore the assumption that the generic would have reached the market but for this settlement agreement is misleading.

Since 2005, all Hatch-Waxman settlement agreements are subject to Federal Trade Commission (FTC) review for anti-trust violations, and many of the agreements currently in litigation were at one time approved by the FTC. There are probably provisions in certain agreements that could be seen as anti-competitive, but those are likely a small percentage of those settlement agreements that are finalised and approved by the FTC.

On the whole, these reverse settlements benefit the pharmaceutical company by reducing uncertainty in the day to day activity and budgeting of the company.

They benefit the generic manufacturer because the majority of the generics are allowed to launch prior to patent expiration, and benefit the consumer because the generic is often launched prior to patent expiration and therefore the consumer benefits with reduced drug prices earlier than they might **IPPro**

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