Important Hearings on Pharmaceutical Patent Settlements

By David A. Balto

As many of you know yesterday the Senate Judiciary Committee held hearing on pharmaceutical patent settlement titled: "Paying off generics to prevent competition with brand named drugs: should it be prohibited?" The speakers were FTC Commissioner Jon Leibowitz, Bruce Downey the CEO of Barr Labs, Billy Tauzin of Phrma, Mike Wroblewski of Consumers Union and Merril Hirsh a private antitrust lawyer.

Here are some of the highlights of the testimony. Senators Leahy, Schumer, Grassley and Kohl came out in support of legislation which would prohibit so called "exclusion payments" of cash or some other form of consideration from a branded to generic firm which leads to a delay in generic entry. The two Senators who raised the most significant concerns about the legislation were Senators Spector and Hatch. Senator Spector emphasized the complexity of the issues and especially the apparent conflicting legal standards that had been articulated by the courts. He also observed that if the FTC thought these agreements were per se illegal why did they not act upon them. He also highlighted that from his perspective the burden was on the parties to explain why these settlements were procompetitive.

Senator Leahy in a statement emphasized that this legislation will be a significant priority. Many speakers and the Senator emphasized how generic drugs result in substantial cost savings. Leahy noted that a one percent increase in the use of generic drugs saves over four billions dollars annually. He said that the legislation sought to make any payment unlawful and that there should "zero tolerance" for efforts by big drug companies to pay off generics to keep them off the market.

Senator Spector on a couple of occasions observed that a more appropriate solution would be to have a court assess whether a settlement raised antitrust concerns before approving the settlement. Senator Hatch also seemed to be interested in that proposal. There were concerns raised by some members of the panel that a patent judge might not be an antitrust expert and be able to make an assessment of the antitrust issues. In addition, Wroblewski observed that with the current state of the law the results might be any different in anticompetitive settlements still might be the result. Leibowitz commented that that would be an interesting approach.

Spector raised concerns about a legislative approach that would make any form of compensation per se illegal. He observed that Congress only intervenes with per se rules only where there were unambiguous anticompetitive effects. But these are very complex cases, how he questioned was it appropriate to make a sweeping generalization that these were illegal settlements. Moreover, Spector questioned what the current legal standard was. What was the meaning of "that the settlement had to exceed the exclusionary power of the patent?".

Senator Hatch, like Senator Spector emphasized the complex issues that exist in this situation. He focused on whether or not there was some more refined amendment to the Hatch-Waxman Act that might make sense. Two possible alternatives would be eliminating 180 day exclusivity if the generic firm settlement the litigation or reinstating the successful defense rule. Hatch asked each speaker why a bright line rule was preferable to case by case analysis.

Some highlights from some of the witnesses testimony included:

> Wroblewski observed that legislation was necessary because courts would not fix this problem in a timely manner. He noted that the recent court decisions were based on two faulty premises: that a generic firm must prove that a patent was invalid or not infringed to hold a settlement invalid. And in addition courts gave settlements and the need for settlements with too much deference.
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> Merril Hirsch focused on the fact that reverse payments really did not lead to anything that procompetitive. In fact, he suggested that the availability of reverse payments just leads to unnecessary litigation that are brought for the purpose of securing reverse payments.
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> Bruce Downey talked about settlements which Barr had entered into. He noted that in approximately the 30 patent challenges, Barr settled approximately half. Almost all of those led to entry prior to the expiration of the patent. He noted that in both Tamoxifen and Prozac the ultimate consumer savings from early entry were just under two billion dollars.
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> Downey emphasized the fact that without the availability of a broad range of settlement options settlements would not occur. In litigation they are frequently differences between the parties' assessment of the likelihood of success and some form of compensation may help bridge that gap between the perceptions of success.
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> Senator Hatch asked why money cannot be translated into simply an earlier entry date and Downey replied that was unlikely because the parties would have different views of the success of litigation. Hatch emphasized his discomfort with making this a per se violation and his trouble with taking a one size fits all approach.