

Senate Drug Price Bill May Alter 180-Day Exclusivity Awards

Sen. Bill Nelson (D-Fla.) has introduced the Drug Price Competition Act of 2009, which may affect how generic-drug makers are awarded 180-day exclusivity for their ANDAs.

Currently, the first applicant is defined as the drugmaker that submits and lawfully maintains a substantially complete application containing a Paragraph IV certification on the first day that such an application may be filed.

Nelson's bill, introduced this week, would allow a subsequent filer to qualify as a first applicant and trigger 180-exclusivity if the company submits an ANDA with a Paragraph IV certification "on the first day on which a substantially complete application containing such a certification was submitted."

If the brand-drug maker doesn't file a patent infringement lawsuit or a court has ruled the patent is invalid or not infringed, the subsequent filer could trigger the 180 days of exclusivity for it and other first filers, according to the bill.

If the bill becomes law, subsequent filers "can share in the exclusivity period with the original first filer or actually be on the market by themselves if the first applicant isn't on the market," Chad Landmon, a partner with the law firm Axinn, Veltrop & Harkrider LLP, told *D/D*.

"Ultimately, I think a bill like this will certainly devalue the exclusivity period while at the same time providing opportunities for certain later filers," Landmon said. "Overall, it will create a lot more uncertainty in the industry. While reaping the benefits of the first filer rights has always been pretty uncertain, this legislation would provide even greater risk to first applicants."

The bill also could result in more patent litigation because the brand company "will almost be forced to sue all later filers to ensure that their new 'first applicant rights' don't kick in," Landmon added. "Because this legislation will present opportunities for later filers to become first applicants by obtaining a favorable court decision, we will likely see more later filers willing to litigate with the brand company."

Nelson's bill, S. 1315, has been referred to the Senate's Committee on Health, Education, Labor and Pensions and is available at frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:s1315is.txt.pdf. — Elizabeth Jones