Bipartisan Drug-Patent Bills Ready for Senate Vote

Efforts Directed at Speeding Up Introduction of Generics

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The legal tactics that pharmaceutical manufacturers use to extend drug patents—thus delaying the introduction of cheaper generics—have been probably the biggest impediment to lower drug prices and to substantial Congressional action on drug pricing. Until now, that is. The Senate Judiciary Committee passed four bills at the end of June that would stifle brand-name manufacturers’ use of patents, perfectly legal in some cases but a major hindrance to the introduction of cheaper generic copies.

Despite the (relatively) big price advantage offered by generics, their introduction has been stymied in some instances by patent holders’ use of a number of delaying tactics, some of which are addressed by the four Senate bills. For the top 12 drugs in America, drug companies filed an average of 125 patent applications, averaging 38 years of market exclusivity—nearly double the guaranteed term, according to statistics cited by Senator Richard Blumenthal (D-CT). That said, Congress has previously failed to address these often legal (but to many minds abusive) patent moves by brand-name manufacturers.

The four bills address issues such as “patent thickets,” “patent hopping,” “pay for delay,” and “citizen petitions.” At hearings in the Senate Judiciary Committee in early May, Senator Richard Durbin (D-IL), the number two Democrat in the Senate, said, “There is more innovation among patent lawyers than among drug companies.” Durbin is a member of the Judiciary Committee and he joined other Democrats and Republicans on the committee in sending these four bills to the Senate floor for a vote:

- S. 1227, Prescription Pricing for the People Act of 2019, would require the Federal Trade Commission (FTC) to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with policy recommendations.
- S. 440, PACED Act, would block patent owners from asserting sovereign immunity claims in the process of requesting drug patents.
- S. 1224, Stop STALLING Act, would aid the FTC in blocking individuals or entities from bad faith interference in the approval of competing generic drugs or biosimilars.
- S. 1416, Affordable Prescriptions for Patients Act of 2019, would prohibit anticompetitive behavior by drug product manufacturers.

The last bill seeks to limit “patent hopping,” a situation in which a pharmaceutical developer creates a formulation of a drug and uses the market approval process under the Food and Drug Administration (FDA) to prevent generic substitutions tied to the old formulation from entering the market. The bill also targets “patent thicketing,” the obtaining of large patent portfolios covering manufacturing methods, uses, formulations, and so on, for a single drug. The poster child for the last abuse is the world’s biggest-selling drug, Humira, for which AbbVie has secured more than 100 patents and is currently blocking a biosimilar competitor in the U.S.

Karin Hessler, Assistant General Counsel at the Association for Accessible Medicines (AAM), the generic industry trade group, says some aspects of the bills are a step in the right direction in addressing drug pricing, but that “some aspects could be refined and improved.” She mentions S. 1416, which is intended to address the Humira situation. The amended bill that’s now on the Senate floor allows patent holders to assert as many as 20 patents when a biosimilar company seeks to enter the market. “From our perspective, 20 is a high cap,” states Hessler. “Federal district courts around the country have imposed much more limited patent caps, including restricting patent holders in biologics patent litigation to 8–10 asserted patents, with additional limits on the number of asserted patent claims.” Also, under the legislation, some patents, such as those on “methods of use,” are not subject to the cap. This means that branded companies could assert far more than 20 patents, which would ultimately increase the burden on the courts overseeing the cases and raise the cost of litigation for biosimilar companies.

The Senate is far ahead of the House in terms of moving drug-patent legislation. The House Judiciary Committee has considered a bill on the filing of citizen petitions by brand-name companies, but none of the other alleged problems that the other Senate bills are aiming at.

At hearings in the Senate Judiciary Committee in May, James Stansel, Executive Vice President and General Counsel of the Pharmaceutical Research and Manufacturers Association (PhRMA), walked a fine line in his answers, generally appealing sympathetic but explaining away some of the patent tactics as legal and failing to offer outright support for any of the bills. “As long as they encourage competition, we are happy to work with the committee on those types of issues,” he said, in answer to the questions posed by Senator Lindsey Graham (R-SC) as to whether he supported “pay for delay” legislation. Stansel defended those deals, saying, “Nothing nefarious is going on.”

On the use of citizen petitions by branded drug companies to tie up the FDA’s generic approval process, Stansel continued on page 533.
Letters to the Editor

Prescription: Washington

continued from page 516

explained that “the characterization of it hasn’t been correct.” He added later, “We wouldn’t oppose reasonable legislation on product hopping.” PhRMA did not respond to an e-mail enquiring about its position on the four bills currently on the Senate floor.

Senator John Neely Kennedy (R-LA) told Stansel at the hearings that the present situation makes the United States “look like a bunch of chumps.” He added, “Sooner or later, the U.S. Congress is going to act, and I don’t think your clients are going to like what we do.”