

Cornyn, Running for Re-Election, Gets in Pharma's Crosshairs

By Shira Stein

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- Hearing with AbbVie executive alarmed Cornyn
- Texas Republican pushing for more aggressive patent reform

A prominent Republican senator has broken with his party to push for aggressive drug patent reforms as he faces constituents during his re-election campaign.

Sen. John Cornyn (R-Texas) has been active in trying to reform the patent system since 2007, but observers have been surprised at how bold his legislation (S. 1416), cosponsored by Sen. Richard Blumenthal (D-Conn.), is.

The legislation would give the Federal Trade Commission more ability to go after pharmaceutical companies that file many patents on a drug or shift consumers onto slightly different, separately patented brand-name drugs when older patents run out, keeping prices and profits high.

Cornyn and consultants in the space say this issue has become a priority because of unsatisfying testimony from the CEO of AbbVie Inc. in March, a focus from both sides of Capitol Hill on drug pricing, and pressure from voters to lower drug prices.

"We're hearing a lot more from our constituents who are concerned about out-of-pocket costs when it comes to drugs," Cornyn said in an interview.

Blumenthal said his partnership with Cornyn on the bill started with comments they both made in a Senate Judiciary Committee hearing about concerns that current patent policies could be causing high prescription drug prices.

Bill Targets Drug Patents

Cornyn has introduced multiple patent reform bills with bipartisan support over the past 12 years, but S. 1416 is his first specifically targeting the pharmaceutical industry's abuse of patents. His previous focus on patent rights issues has been more in the tech space, said Michael Kades, director of markets and competition policy at the Washington Center for Equitable Growth.

"Cornyn clearly recognizes that this is a long overdue problem that requires bipartisan leadership and we appreciate his efforts to take on a powerful and well-funded industry in order to protect patient access to life-saving medicines," Matthew Lane, executive director for the Coalition Against Patent Abuse, said in a statement.

Another pending bill, the CREATES Act (S. 340), would make it easier for generic companies to sue brand-name companies for blocking access to the samples needed to create copies of existing drugs. Cornyn has voted against that bill in the past due to concerns about opportunities for frivolous patent lawsuits.

He also has opposed legislation addressing pay-for-delay settlements. Those are legal agreements between a brand-name drug manufacturer and a generic competitor in which the generic competitor agrees to wait to market a generic drug, typically in exchange for a payment from the brand-name manufacturer.

Cornyn and Blumenthal's bill is more aggressive than the CREATES Act and pay-for-delay legislation because it addresses conduct that's more commonplace in the drug industry, like patent thickening and product hopping, Kades said.

Patent thickening is a tactic where companies own overlapping intellectual property rights, while product hopping forces consumers onto slightly different, separately patented brand-name drugs when older patents run out.

Cornyn could have done the bare minimum on drug pricing reform by voting to pass other senator's bills, but he's going all in on this effort, a former Senate aide said. Four other GOP senator have joined Cornyn, Blumenthal, and a number of Democrats in cosponsoring the bill.

The leading drug industry lobby was critical of the bill.

"This legislation fails to appreciate the role and importance of medical advances post-FDA approval to patients, competition and the health care system," a spokesperson for the Pharmaceutical Research and Manufacturers of American said in a statement.

"Virtually any innovation made after filing of an original new drug application or biologics license application would be presumed to be anti-competitive and could be subject to significant new and existing penalties under the FTC Act," the representative said.

Frustration From Testimony

With drug prices a central issue in Congress, Cornyn has seen the same thing that many members of his party have: that some legislation to lower prescription drug prices is an inevitability, and voters want to see Congress take action.

Many observers said a Senate Finance Committee hearing in February appeared to be the cause of Cornyn's plan to take action on drug patents. Cornyn pointedly asked the CEO of AbbVie, Richard Gonzalez, if the company thinks it should have a monopoly on Humira, which treats arthritis, plaque psoriasis, ankylosing spondylitis, Crohn's disease, and ulcerative colitis. The company has 136 patents and 61 patent applications for the drug.

The price of the drug has been climbing. Medicare spent twice times as much per dose on Humira in 2017 than in 2013—up to an average of \$2,229 from \$1,150, according to a Bloomberg Law analysis of Medicare Part D data released by the Centers for Medicare & Medicaid Services.

Gonzalez's testimony "jumped out as a potential problem" with the number of patents AbbVie has to protect their exclusive access to produce Humira for a period beyond what Congress intended, Cornyn said in an interview.

Political Calculations

The bill and focus on drug pricing is a calculated move for Cornyn, said Maura Calsyn, managing director at the Center for American Progress Action Fund, a left-leaning organization.

The Texas Republican is facing a potentially tough re-election, and although the bill goes after real abuses by pharmaceutical companies, it won't meaningfully lower the prices of many drugs, she said.

Inside Elections, a nonpartisan Washington-based political newsletter, rated the 2020 Texas Senate race as "Solid Republican" as of last month. President Donald Trump in 2016 and Sen. Ted Cruz (R) in 2018 won the state by reduced margins compared with other recent elections in which Republicans have been dominant statewide.

Cornyn's most prominent Democratic challenger to date is MJ Hegar, an Air Force veteran who came within 3 percentage points of unseating Rep. John Carter (R) in 2018.

Cornyn's legislation is a necessary step, but several bills by Democrats in the Senate would go further by requiring the government to produce generic drugs, permitting it to directly negotiate drug prices, or allowing it to license drugs to companies' competitors when their prices aren't reasonable, Calsyn said.

Cornyn could face targeting by pharmaceutical companies in his re-election campaign as a result of his efforts to push this bill, and he could be concerned about patient groups that want to see effort on drug pricing from lawmakers. Advocacy group Patients for Affordable Drugs spent at least \$450,000 against Rep. Pete Sessions (R-Texas) in his 2018 reelection bid.

So far, however, Cornyn is still getting support from at least some corners of pharma.

He received \$14,500 from branded pharmaceutical companies in March, less than a month after the Finance hearing. He also received \$1,000 from the American Intellectual Property Law Association PAC, \$5,000 from generic drugmaker Mylan's PAC, and \$2,500 from CVS Health PAC, which owns a pharmacy benefit manager, in March.

Even if Cornyn weren't running for reelection, the former Senate aide said, the veteran lawmaker would likely have gotten involved in trying to prevent patent abuses by drug companies.

Anyone running for public office at federal level who is not paying attention to drug pricing reform is committing something close to political suicide, the former aide said.

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