

***Senate Judiciary: “Executive Business Meeting”
June 27, 2019***

Executive Summary

- S. 1227, returned to the floor favorably as amended
- S. 1224, returned to the floor favorably as amended
- S. 1416, returned to the floor favorably as amended
- S. 440, returned to the floor favorably as amended

The Committee discussed four bills aiming to lower drug prices, three of which - S. 1227, S. 1224, S. 1416 - passed easily with bipartisan support and little discussion. The final bill, S. 440, which aims to prohibit the patent holder from claiming sovereign immunity from administrative review, was met with opposition from committee Democrats. They fear the language is too broad and would severely limit the sovereignty of Native American Tribes. The bill passed on party lines.

Member Statements

Chairman Lindsey Graham (R-SC)

S. 1227 studies the role of the middleman in drug pricing. Some argue that having a middleman is good, while others argue they harm consumers. We are going to have the FTC study that issue.

S. 440 is Sen. Ernst’s legislation. This is a very important issue. Apparently, the pharmaceutical company Allergan sold patents to a New York Indian tribe, who claimed the review process did not apply because the Indian tribe owned the patent. This bill would stop this practice in the future.

S. 1224 is the citizens petition bill. There have been circumstances where petitions are filed to slow down the review process. We are going to stop this to prevent unnecessary delay.

S. 1416 deals with the gaming of the nation’s regulatory system by branded pharmaceutical companies who engage in product shopping to avoid competition from generics. It also ensures that patent thickening is not tolerated when it is abused. The idea of having the same drug but changing the composition of the needle multiple times to keep it from going to the generic market is an abuse that needs to stop. I intend to support this.

Ranking Member Dianne Feinstein (D-CA)

Three of the bills today are bipartisan, and I look forward to supporting them. The PACED Act, however, does not have bipartisan support and I will vote against it. I am concerned that this legislation is seeking to address a problem that has already been solved, and I am concerned the bill is overly broad and will weaken the sovereign immunity of Native American tribes.

The PACED Act was intended to respond to Allergan’s tactic of selling the patent for its drug Restasis to the Mohawk tribe, and then renting the rights back. This tactic is egregious, but it has

already been addressed. Last year, the patent office denied the tribes motion to dismiss administrative review on the basis of immunity. That decision was affirmed by the circuit, and the Supreme Court later denied a petition to review. The legal process worked, and this bill is not necessary.

The bill is too broad. Under the bill, if a tribally-owned company applied for and secured a patent for a new life saving medical device it would not have the same protections as state-owned universities do. Not only is this unfair, but the action is unnecessary. If this bill were to pass, it would weaken sovereign immunity for every Native American tribe. It is not limited to pharmaceutical companies.

S. 1227, Prescription Pricing for the People Act of 2019

- Manager's Amendment adopted by consent; bill reported to the floor

S. 440, PACED Act

Sen. Joni Ernst (R-IA)

The PACED Act will provide greater access to generic drugs across the country. The bill restores the power of the patent and trade office, federal courts, and the Federal Trade Commission (FTC) to review patents regardless of sovereign immunity claims made as part of sham transactions. This bill will codify the result of the recent trial that Sen. Feinstein mentioned by removing a loophole in the patent issuing process which allows manipulators to pay Native Americans to take ownership of their patents. The Manager's Amendment is narrow and clarifies that public universities are not captured by the scope of this bill. Some argue that this bill is unnecessary due to the court decision; I reject that statement. Failure to act could incentivize other industries to use similar tactics to prevent the production of generics.

Sen. Dick Durbin (D-IL)

The Senate Committee on Indian Affairs had bipartisan opposition to this bill. We need to take that into account. This bill is unnecessary as the issue has already been decided in federal court. This bill would prevent any patent holder, including Native American tribes, from asserting sovereign immunity to administrative review.

Ranking Member Feinstein

The bill is overly broad and unnecessary.

Chairman Graham

This is a reasoned and targeted approach and I support it.

- Manager's Amendment adopted by consent; bill reported to the floor

S. 1224, Stop STALLING Act

Sen. Chuck Grassley (R-IA)

Bill will help stop delay tactics to FDA approval of generics or biosimilars.

- Manager's Amendment adopted by consent; bill reported to the floor

S. 1416, Affordable Prescriptions for Patients Act of 2019

Sen. John Cornyn (R-TX)

The bill is designed to target and stop practices that create monopolies on high priced drugs. Targets product hopping and gaming of the patent system.

Sen. Richard Blumenthal (D-CT)

This bill will eliminate tactics that are used to limit competition and will help lower drug prices.

- Manager's Amendment adopted by consent; bill reported to the floor