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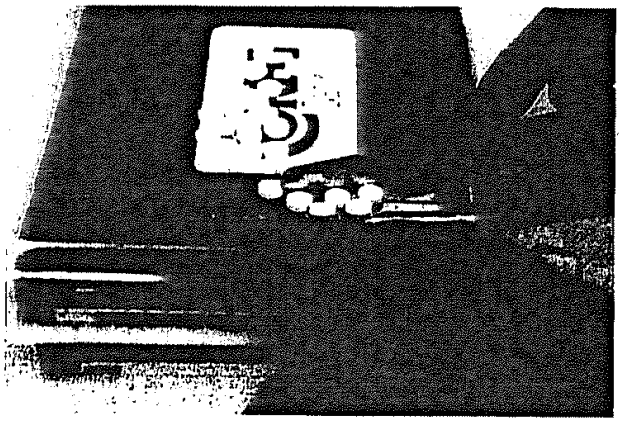
BUSINESS

# Drug-Industry Rule Would Raise Medicare Costs

**Congressional Budget Office estimates $1.3 billion increase in federal health-care costs over a decade**



A new estimate suggests federal health-care spending would rise $1.3 billion over 10 years if a drug-industry backed proposal to exempt brand-name drug patents from certain challenges takes effect. *PHOTO: ERICA YOON/THE ROANOKE TIMES/ASSOCIATED PRESS*



By JOSEPH WALKER
Aug. 31, 2015 7:20 p.m. ET

A patent law change sought by the pharmaceutical industry could cost federal health-care programs $1.3 billion over a decade by delaying new generic medicines, an analysis by the Congressional Budget Office found this summer, according to people familiar with the matter.

Pharmaceutical trade groups are asking Congress to exempt drug patents from being challenged through an administrative process that is cheaper and faster than the federal courts. The procedure has become popular with generic-drug companies looking to sell copies of brand-name products.

Drug makers say hedge-fund manager Kyle Bass used the procedure to challenge companies whose shares he is betting against, or selling short. The Coalition for Affordable Drugs, a group created by Mr. Bass, has this year challenged more than 20 patents held by companies including Biogen Inc., Celgene Corp. , and Jazz Pharmaceuticals PLC.

The Pharmaceutical Research and Manufacturers of America, also known as PhRMA, and the Biotechnology Industry Organization, or BIO, say brand-name pharmaceutical patents should be excluded from the procedure, called Inter Partes Review, or IPR, through patent legislation that Congress is considering.

"Our solution," said Mit Spears, general counsel at trade group PhRMA, "is to essentially exempt [pharmaceutical] products" from IPR challenges.

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The potential for such an exemption to increase drug spending has intensified opposition from some lawmakers, health insurers, and consumer advocates alarmed by rising drug costs. This summer, Rep. Mimi Walters (R., Calif.) withdrew her proposal to include an exemption in a U.S. House of Representatives' patent bill after it was opposed by Rep. Bob Goodlatte (R., Va.), the bill's lead sponsor and chairman of the House Judiciary Committee.

The IPR system went into effect in September 2012 with the support of many technology companies, which saw it as a way to combat patent trolls—nonoperating companies that profit by accusing companies of patent infringement. Under IPR, judges employed by the U.S. Patent and Trademark Office evaluate patent challenges that would be heard in lengthier court proceedings.

Several U.S. senators, including John Cornyn (R., Texas) and Chuck Schumer (D., N.Y.), asked the CBO this summer to estimate how much a pharmaceutical exemption for IPR would cost, according to congressional aides. The CBO's conclusion, communicated orally to Senate staffers in July, was that federal spending would increase by $1.3 billion over 10 years because the exemption would delay the launch of certain generic products, the aides said.

Generic drugs can cost 90% less than their brand-name equivalents.

The CBO, a nonpartisan federal research agency, provides "thousands" of preliminary analyses each year to Congress as early drafts of new laws are hashed out, according to the CBO's website. A CBO spokeswoman declined to comment.

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*'We won't have any new drugs come along at all if we don't support the investment that's needed... '*

—Bart Newland, Biogen counsel

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Some senators backing the broader patent law are open to the idea of an IPR exemption for drug patents and to finding ways that offset the projected increase in drug costs, congressional aides said. In July, 79 House members called for exempting drug patents in a letter to congressional leadership.

Tom DiLenge, BIO's general counsel, said the trade group is aware of the CBO estimate and disagrees with it because the IPR system is unlikely to lead to faster generic approvals. Mr. Spears of PhRMA also said he was aware of the CBO estimate.

Drug makers say the IPR process, in which judges employed by the U.S. Patent and Trademark Office evaluate challenges, is being used to circumvent a decades-old system for settling patent disputes between generic and brand-name drug companies. That system, created by a 1984 law, requires the FDA to wait 30 months, or 2.5 years, before approving generic versions of medicines whose patents are being challenged in court.

IPR challenges are usually decided within 15 to 18 months, using a different legal standard than what is used in the federal courts, and which legal experts and drug makers say is less favorable to patent owners. Patents can be challenged through the IPR system and in the federal courts simultaneously, forcing drug makers to defend themselves on two fronts.

"We agreed on a system 30 years ago for how generic drugs should be litigated," said Mr. DiLenge. "Now we're seeing generic drug companies trying to skirt those rules."

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*'Generally speaking it seems easier to invalidate patents in IPR than in federal courts.'*

—Jacob S. Sherkow, New York Law School

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Individual drug companies, including Amgen Inc., AbbVie Inc. and Biogen, have lobbied lawmakers about changes to the IPR system, according to federal disclosure documents. Companies say IPR challenges have created new uncertainty as they evaluate which experimental drugs to invest in.

"I understand people being concerned about drug prices, but we won't have any new drugs come along at all if we don't support the investment that's needed to make them happen," Bart Newland, chief counsel for intellectual property at Biogen, said in an interview.

But opponents of the exemption, such as the health insurance industry, say drug makers often use the slow pace of the federal courts to delay generic launches. The IPR system "is a critical consumer protection," said Matthew Eyles, executive vice president of policy and regulatory affairs at America's Health Insurance Plans, say: "An exemption would be really bad for consumers and really bad for the system."

Other groups opposing an exemption include AARP, an advocacy group for retirees, insurers represented by the Blue Cross and Blue Shield Association, and the Pharmaceutical Care Management Association, an industry group for pharmacy-benefit managers.

Mylan NV, a generic drug maker, has filed more than a dozen IPR challenges against brand-name drug patents and has lobbied against the exemption, according to federal disclosure documents. IPR challenges "could eliminate a lot of these patents that are frivolous, which would allow more access to affordable medicines," Mylan Chief Executive Heather Bresch said in an interview.

It is too soon to say if the IPR system will significantly alter the industry. Many challenges to technology patents have been successful, but most pharmaceutical cases haven't been decided yet, said Jacob S. Sherkow, an associate law professor at New York Law School. Among pharmaceutical challenges that have been decided, the patent office has upheld most of them, he said.

In August, the patent office declined to review the first of Mr. Bass's challenges against patents for Acorda Therapeutics Inc. 's multiple sclerosis treatment Ampyra, but agreed to consider a challenge brought by Mylan against Teva Pharmaceutical Industries Ltd. 's drug Copaxone.

"Generally speaking it seems easier to invalidate patents in IPR than in federal courts," Mr. Sherkow said. "For pharma patents, the jury is still out."

*—Andrea Fuller contributed to this article.*

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