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New Drug Patent Proposal Sparks Worry Over Gov't Overstep

By **Kelly Lienhard**

Law360 (December 8, 2023, 8:55 PM EST) -- The Biden administration's proposal to seize drug patents if the prices of the medicines are deemed unreasonable is expected to face significant legal pushback, and the potential effects on the pharmaceutical industry may not be what the administration had in mind, experts say.

On Thursday, the White House announced a proposed rule on the exercise of so-called march-in rights that would allow the government to seize the patents of drugs found to be too expensive and lease them to other entities. However, some legal experts told Law360 that the new framework is a clear case of government overreach and will spur legal challenges.

The government has never attempted to use the so-called march-in rights before, and if the proposal takes effect, pharmaceutical companies are expected to fight back.

The proposed framework is a mistake that would deter both the biotech industry from collaborating with federal agencies and universities from using government grants, according to Nick Matich, principal in McKool Smith's intellectual property practice group and former acting general counsel of the U.S. Patent and Trademark Office.

"During COVID, we saw what an asset the American biotech industry is to the world, and it is unfortunate that the Biden administration would threaten patent rights as a means to control drug prices," Matich said.

Any litigation spawned by the rule would attract the attention of the U.S. Supreme Court, since there are so many undecided legal issues involved, according to Robin Feldman, a professor at University of California College of the Law, San Francisco.

"This is a relatively new set of Supreme Court justices," Feldman said. "They will want to put their stamp on these issues."

The framework is a surprising reach of federal authority, according to Matt Wetzel, a partner in Goodwin Procter's life sciences regulatory and compliance practice.

"I look at it almost like it's a first step towards nationalizing an industry. … This sort of excessive government authority is troubling on some level and needs to be watched," Wetzel said.

Both drug and medical device manufacturers should be thinking about their strategies for getting to market

if they choose to accept federal funding, according to Wetzel.

"There's nothing that would prohibit an agency from also applying the same frameworks to medical devices too, so I think the whole sort of medical products — drugs, devices, biologics — those industries really do need to be paying close attention to what happens next," Wetzel said.

The University and Small Business Patent Procedures Act of 1980, also known as the Bayh-Dole Act, enables the government to force a manufacturer receiving federal funding to grant a patent license to another party in specific circumstances. No agency has ever exercised this right, according to the proposed framework.

The Department of Commerce and the National Institute of Standards and Technology jointly released the proposed framework Friday and are asking the public to weigh in on how the administration can promote access to taxpayer-funded treatments without stifling innovation.

If the proposal moves forward and the government starts seizing patents, pharmaceutical companies are expected to file claims in court that the government is wrongfully taking their property, but those arguments would be incorrect, according to Steven Knievel, an access to medicines advocate at consumer rights advocacy group Public Citizen.

Bayh-Dole gave the government the right to march in and involuntarily license patents under certain conditions, and it's "indisputable" those conditions would include price, according to Knievel.

"It's a bit ridiculous to argue otherwise," Knievel said. "The administration is finally beginning to formally recognize that."

Whether the government's proposal would help drive down high drug costs wasn't exactly clear yet.

Charles Silver, professor at the University of Texas School of Law, said the legal provenance for the proposal is "questionable," but added that if the rule is implemented at all, there would likely be very little effect on regulating costs.

March-in rights were not intended to be a means of price regulation, according to Silver.

The problem with the Biden administration's proposal is that without tying the right to be the second manufacturer with a cap on prices, companies that license a patent from the government will just follow the original manufacturer's lead on pricing, according to the law professor.

"There's no reason to expect the second company to do anything other than maximize its profits. That's what pharmaceutical companies do," Silver said. "And presumably, whatever the first pharmaceutical company is doing in the way of distributing the product, the product is profit maximizing, but there's a shortage, right? So, if the second company is also profit maximizing, then it's playing follow the leader with the first company and presumably the same shortage that advantages it."

When drugs go off patent, oftentimes generic makers either don't enter the market, or if they do, they start charging the same prices as the patent holder charged, so consumers aren't better off, according to Silver.

The proposed framework appeared to be the government "flexing its muscles" against the pharmaceutical industry as part of Medicare negotiations, according to Feldman of UC Law San Francisco.

"In other words, the government can say, 'Play nicely or we will do something you'd like even less,'" Feldman told Law360.

Some groups wasted no time voicing their opposition to the proposal.

The suggested framework is a "bureaucratic mess" and a "death knell" to smaller drug manufacturers, according to Joe Allen, the executive director of the Bayh-Dole Coalition, a group whose members include drug industry groups like the Pharmaceutical Research and Manufacturers of America and the Biotechnology Innovation Organization.

"The march-in rights are there to make sure that people are commercializing something in good faith and making it available for sale," Allen told Law360. "[The Biden administration] added all this other subjective criteria. … It's just mind-boggling."

Venture capitalists want to know what the rules are surrounding federal funding before investing in smaller manufacturers that have received money from the government before they invest, but the framework throws that into uncertainty and lowers the odds of smaller pharma companies and researchers making any money at all, according to Allen.

"Small companies take risks that big companies won't, and they're the people that are going to suffer from this mess," Allen said. "The big companies can walk away."

The proposal wouldn't necessarily discourage biotech companies and universities from accepting public funding, Knievel said. He pointed out that drug companies made the same arguments around the Inflation Reduction Act, but data has been showing that drug companies are continuing to spend the same amounts on research and development as before.

"There's still plenty of room even within this guidance for drug companies to make lots and lots of money. … I think this is another instance in which they're crying wolf, like anytime that anything threatens their bottom line or their ability to sort of exploit monopoly," Knievel added.

The Biden administration's proposal actually may not go far enough, according to Public Citizen in a Thursday statement.

The administration should revise the proposed framework to recommend using march-in rights whenever taxpayer-funded medicines are overpriced, according to Peter Maybarduk, Public Citizen's access to medicines director.

Maybarduk said the Biden administration's proposal could give federal agencies permission to continue allowing unreasonable prices, as few drugs will seem unreasonably priced because most drugs prices are already "egregious."

Instead, it should include criteria for what would qualify as an unreasonable price, as well as include recommendations for using march-in rights when pharmaceutical companies use their monopoly power to charge individuals in the U.S. more than those living in other countries.