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'Government Patent Use': A Legal Approach To Reducing Drug Spending

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ABSTRACT The high cost of patent-protected brand-name drugs can strain budgets and curb the widespread use of new medicines. An example is the case of direct-acting antiviral drugs for the treatment of hepatitis C. While prices for these drugs have come down in recent months, they still create barriers to treatment. Additionally, prescribing restrictions imposed by insurers put patients at increased risk of medical complications and contribute to transmission of the hepatitis C virus. We propose that the federal government invoke its power under an existing “government patent use” law to reduce excessive prices for important patent-protected medicines. Using this law would permit the government to procure generic versions of patented drugs and in exchange pay the patent-holding companies reasonable royalties to compensate them for research and development. This would allow patients in federal programs, and perhaps beyond, to be treated with inexpensive generic medicines according to clinical need—meaning that many more patients could be reached for no more, and perhaps far less, money than is currently spent. Another benefit would be a reduction in the opportunity for companies to extract monopoly profits that far exceed their risk-adjusted costs of research and development.

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In the past decade, Medicare Part D and the Affordable Care Act (ACA) have radically increased the number of patients who have insurance to help pay for their prescription drugs.^{1,2} Spending on prescription drugs by government payers continues to rise largely because of the use of costly brand-name drugs.³ In response to high drug prices, Part D plans and state Medicaid programs use various mechanisms to restrict prescribing.⁴ These programs have generated controversy in the recent context of direct-acting antiviral agents to treat hepatitis C, which appear to be superior to other treatment options but which are also much more expensive—with launch prices reaching \$1,000 per pill⁵ or more.⁶

A recent survey of forty-two states' Medicaid programs found that almost all of them imposed

sobriety requirements, and three-quarters required advanced liver fibrosis, before patients could receive a direct-acting antiviral.⁷ As one extreme example, Illinois's Medicaid program has twenty-five criteria that patients must meet, including some with no clear evidentiary basis.⁸

Rationing is a predictable response to high drug prices. Notably, though, new medicines such as Sovaldi are expensive not because they are expensive to manufacture but because they are protected by patents, which allow companies to bar competition and act as the sole supplier of a new medicine. (Sovaldi is produced by generic manufacturers in India under license from Gilead for around \$1,000 for a course of treatment.) Because patents permit companies to charge profit-maximizing prices, they reduce the uptake of patented medicines, generating a

social cost that economists call deadweight loss.

However, a little-known law, codified at 28 U.S.C. section 1498, could allow the federal government to substantially lower prices for high-cost drugs.⁹ This law gives the government the right to use patented inventions without permission, while paying the patent holder “reasonable and entire compensation.” In the case of pharmaceuticals, a patent gives a company the right to prevent others from making, selling, using, or importing a covered medicine. The “government use” provision is a form of governmental immunity from patent claims: Under it, patent holders can demand royalties but cannot stop the government from producing the medicine or allowing others (in this case, generic manufacturers) to produce or import the medicine. There have been prominent calls for the Department of Veterans Affairs to invoke its powers under section 1498 to address the funding shortfall that has resulted from the high demand for, and high cost of, direct-acting antivirals, despite the significant discounts that the department already enjoys.¹⁰

In this review we assess the potential for the federal government to invoke section 1498 to make important new high-cost therapies widely available to patients who need them. We argue that such an approach need not undermine incentives to innovate and could result in net gains from an economic as well as a health perspective. Most prominently, the approach should be considered whenever there is evidence of excessive pricing as measured against the risk-adjusted costs of research and development, and whenever substantial population-level benefits could be realized.

The Problem Of High-Cost Essential Medicines

In the United States there are 3–5 million people infected with hepatitis C virus, and over 16,000 deaths are reported annually from complications related to the virus—including hepatic cancer or fatal cirrhosis.¹¹ This chronic infectious disease was poorly treated by available drugs until 2013, when the direct-acting antivirals simeprevir (Olysio) and sofosbuvir (Sofaldi) were approved by the Food and Drug Administration (FDA). In 2014 Gilead, the manufacturer of sofosbuvir, marketed the follow-on combination drug sofosbuvir/ledipasvir (Harvoni), and AbbVie marketed a four-drug combination regimen that consisted of ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak). This class of drugs has demonstrated sustained virologic response rates of greater than 95 percent for some genotypes in clinical trials.¹²

Yet these drugs are also extremely expensive. Sofosbuvir has been priced at \$84,000 for a standard twelve-week course of therapy. Sofosbuvir/ledipasvir and the four-drug combination regimen have been priced similarly. Together, the products contributed to a 12.2 percent increase in US prescription drug spending in 2014.¹³ In just twenty-one months, Gilead reported \$26.6 billion in sales for its new hepatitis C virus drugs.¹⁴ Competition from AbbVie’s product has allowed some payers to negotiate discounts of over 40 percent, but cost pressures from these drugs continue to burden payers—particularly state Medicaid programs and federal prison systems.

Medicaid programs, for example, are entitled to a mandatory rebate of the greater of 23.1 percent of the average manufacturer price or the difference between the average manufacturer price and the best price (the lowest price offered to any purchaser of that product, with a few exceptions), and the programs can also negotiate supplemental rebates with manufacturers. But a recent Senate investigation found that only five states reported reaching supplemental rebate agreements with Gilead and that the vast majority of states rejected Gilead’s offers as unacceptable.¹⁴

The same report expressed concern that only 2.4 percent of Medicaid patients with hepatitis C were being treated, which reflects the restrictions states imposed on prescribing in response to the price of these medicines. Federal prisons responded much the same way as Medicaid programs and as a result are treating fewer patients for hepatitis C than they were before the new drugs were approved. In 2015 only 222 federal prisoners were treated for hepatitis C, at an average cost of approximately \$61,000 per patient.¹⁴

The direct-acting antivirals are the most prominent recent example of essential medicines being priced at high levels. However, the extraordinary cost of these drugs is a function not of their manufacturing expense or their research and development costs,¹⁵ but of companies’ pricing powers protected by patents and other market exclusivities. As noted above, in India sofosbuvir is produced competitively and sells for \$1,000 for a twelve-week course of treatment. One recent study estimated that competition could drive prices as low as \$100–\$250 for a twelve-week course of treatment.¹⁶ At such prices, drugs with transformative public health potential would reach more patients. In the case of hepatitis C virus, this would be because the government and private insurers would no doubt develop radically different prescribing guidelines.

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Government Patent Use For High-Cost Essential Medicines

One way for the federal government to address the high costs of certain essential medicines would be the “government use” strategy. As explained above, under section 1498, the federal government can use inventions covered by patents as long as it provides “reasonable and entire compensation” to the patent holder. The Department of Defense has relied on the provision to purchase night-vision goggles and lead-free bullets that violate patents,^{17,18} and the Department of the Treasury has relied on it to purchase software without regard to patents.¹⁹ Royalties are commonly set at 10 percent of sales or less.^{17,20}

When section 1498 is invoked, patentees may not stop the government from procuring the patented goods but are entitled to reasonable compensation. Government patent use is akin to the government power of “eminent domain” over land, which allows the government to take property for public uses while paying fair market rates. When the federal railroad system was mapped, without eminent domain, anyone holding property along the rail line could have extracted payments far in excess of the appropriate valuation of the land.²¹ Railroad construction was thus dependent on eminent domain.

Important patented medicines such as sofosbuvir are similar to plots of land along the rail line: Government health programs must move through these medicines to address the risks associated with health problems such as the hepatitis C virus. Patents permit their holders to extract as much revenue as possible, setting prices without regard to the cost of research and development or drug manufacturing—as we know occurred with the new hepatitis C virus medicines.¹⁵

Courts typically set compensation under section 1498 by determining a reasonable royalty rate.^{22,23} The government could argue that reasonableness should be keyed to the amount invested in the relevant drug, adjusted for the risk

of failure and to permit companies to earn reasonable or average profits. This approach would permit royalty awards that were sufficiently robust to induce the development of new medicines, because companies could be assured of compensation for their investment. But it would also produce more efficient prices.

Our approach would, of course, diminish the profits earned by pharmaceutical companies in cases when the government use provision is deployed. In this sense, the approach might be said to reduce financial returns on manufacturers’ investments in research and development. But it still would ensure a reasonable return on investment, as long as there were no sizable errors in the estimates of risk or of research and development costs. Notably, courts can compel disclosure of information on research and development costs and risks, which can be used to fine-tune the amount of awarded royalties. If the risk of error can be estimated, allowed profit margins could also be increased to compensate for it. Finally, even if our approach diminished incentives for research to some degree, the efficiency gains might still be large if the access gains were substantial. In addition, reduced incentives might improve research efficiency if existing profits are too high and induce wasteful “racing”—in which multiple companies chase similar compounds, dissipating resources that could be dedicated to other worthy unmet medical needs.

We use sofosbuvir to provide an illustration of the benefits of this approach, based on publicly available information. Senate investigators estimated the outlay for research and development for sofosbuvir at between \$942.4 million (a price based on Gilead reports, which are an overestimate because they include research and development for all regimens that include sofosbuvir) and \$125.6 million (the amount projected by the parent company that sold sofosbuvir to Gilead).¹⁴ With current sofosbuvir sales exceeding \$26 billion, Gilead clearly has recouped its investment and has earned returns that are more than adequate to compensate it for its risk of failure and the time invested in developing the drug.

Under these circumstances, even a very modest royalty, akin to the 10 percent common in the military context, would be reasonable. With these royalties (which could be levied per treatment or calculated as a lump sum based on the projected number of patients reached), the government would pay far less than even Gilead’s discounted prices. For example, assuming a price of \$1,000 per course of treatment and royalties of 10 percent, the government could treat four million people at a cost of \$4.4 billion, which is less than federal programs now spend in one year to treat a

much smaller patient population. Treating four million people would cost \$180 billion if government paid Gilead's lowest published US price of approximately \$45,000 per course of treatment.

The government no doubt would be concerned about the upper bound of its potential liability in any court case. In theory, courts can award companies "lost profits" under section 1498, but courts have held that this method of calculating damages is rarely appropriate in this context.²⁴ Under a lost-profits theory, a company might argue that it should be awarded the equivalent of the full price on each unit procured by the government. But even if a court accepted this measure, the company still would have to show that it was reasonably likely to accrue the profits it claimed.^{25,26}

The government could make a strong argument that likely company profits would have been capped by payers' prescribing restrictions as well as more recent price discounts. Even in the worst-case scenario, the result would be damages in the amount the government currently expects to spend. Of course, such an outcome would still lead to the ability to prescribe the drug for anyone for whom it is warranted, which would lead to greater public health benefit than current prescribing guidelines permit.

STRENGTHS AND LIMITATIONS One advantage of government patent use is that it can apply to any patent. Under the Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act), patents granted on inventions developed with the use of government funds can be exclusively licensed to promote their commercialization, but the government retains the ability to "march in" if the patented technology is not made available to the public on reasonable terms.²⁷ Although some legislators have recently pressed for more active use of march-in rights, this option is relevant in the pharmaceutical context only if there is a formal government interest in all of the relevant FDA-listed patents. In addition, the National Institutes of Health has been averse to exercising march-in rights on the ground of drug pricing, arguing that reasonable terms cover only product availability. Government patent use would avoid this historical resistance.

However, the government's authority is limited to federal use of the patent. The legal limits of federal use under section 1498 have not been resolved. But at a minimum, federal programs such as Medicare and Medicaid would be included, as would programs for which the government directly procures medicines—such as the Veterans Affairs system and the Department of Defense.

The government would also have to address

To our knowledge, the government has only once sought to use section 1498 in the drug context.

any regulatory exclusivity barriers to registering versions of the unpatented sofosbuvir product made by generic manufacturers. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), generic manufacturers must wait five years before submitting an Abbreviated New Drug Application for a bioequivalent version, although that time is reduced to four years when there is a patent challenge.

NEGOTIATING PATENT BUYOUT To our knowledge, the government has only once sought to use section 1498 in the drug context. In 2001 the threat of widespread domestic use of anthrax as a chemical weapon led the United States to seek to stockpile the antibiotic ciprofloxacin (Cipro) as treatment. Bayer, Cipro's manufacturer, initially resisted raising production levels and refused to provide a reasonable price for the drug to the US government. In response, Tommy Thompson, then the health and human services secretary, raised the specter of importing generic versions under section 1498 and secured from Bayer a guarantee of an adequate supply of ciprofloxacin and a 50 percent discount in the price.²⁸

As happened in the ciprofloxacin case, one positive outcome from the federal government's use of its power under section 1498 to lower the price of sofosbuvir might be to bring pharmaceutical manufacturers to the table to work out a voluntary patent buyout that covered the entire US marketplace, instead of just federal programs. Patent buyouts have a long history: In 1839 the French government purchased the patents covering the daguerreotype photography method. The inventors received generous annual payments, and the public received access to the technology, which led to widespread uptake and subsequent improvement of the method. A voluntary patent buyout (or a lump sum ex ante payment in exchange for use of the relevant patents) could be structured to benefit all payers, including state prisons, Medicaid programs, and private insurers. Allowing generic manufacturers to enter the market before the end of

Asserting government rights may encourage companies to establish lower launch prices.

the regulatory exclusivity period, perhaps as producers of authorized generics under the original New Drug Application, might also be part of the deal.

The price that could be achieved in patent buy-out negotiations would depend on many particulars, including the covered providers, credibility of the government's intent to use section 1498 as an alternative, and any competition that might be triggered between manufacturers (such as between Gilead and AbbVie). Potential weaknesses in the patents would also add to the government's negotiating leverage, because if a company sued the government for compensation under section 1498, the government would be entitled to challenge the validity of any patent asserted against it.

Sofosbuvir patents are being challenged around the world. One was being recently rejected on a preliminary basis in India,²⁹ and another was recently denied in China.³⁰ Patent invalidation would immediately open up private as well as public markets to generic competition.

Ultimately, the federal government's power to act in a nonvoluntary fashion would surely result in its paying less than is currently contemplated. Though patent-holding companies might nonetheless stand to earn substantial profits from such a deal, discounts could mean access for many more patients—and especially for vulnerable patients such as prisoners, who are unable to exert significant political pressure on payers and so obtain very little treatment at current costs.

OBJECTIONS AND EXTENSIONS Innovator companies would likely complain that the use of section 1498 interferes with their incentives to invest in innovation, but such incentives would remain robust if the government royalties were sufficient to compensate the companies for research and development costs, adjusted for risk of failure and margins of error in calculations made by a court or agency. Other adjustments might also be appropriate—for example, to reflect the share of research and development costs attributable to the US market or to provide a

bounty for particularly important innovations.

However, we do not suggest that governments should set payments for medicines through this mechanism according to cost-effectiveness thresholds. Sofosbuvir, for example, has been considered cost-effective when compared to existing treatments. These thresholds are disconnected both from the cost of research and development—the true measure of appropriate reward, if the aim is to induce efficient investment—and from budgetary realities. Because cost-effectiveness tools are not empirically based on assessments of how much governments are able or willing to spend on health, they can sometimes recommend the use of interventions that are unsustainable from a fiscal perspective and that could be obtained at a much lower price, without sacrificing incentives for research and development.

Fine-tuning of appropriate compensation under section 1498 could happen in courts or in the executive branch over time. No one should expect these parties to make no errors in their assessments. Instead, the costs of possible errors must be weighed against the very substantial benefits of government use as a strategy to lower drug costs and improve access to medicines. Of course, these benefits are especially substantial where communicable and life-threatening diseases—such as hepatitis C—are concerned.

Another potential source of criticism of our approach stems from the fact that direct-acting antivirals are approved on the basis of surrogate markers (such as sustained virologic response) for which long-term outcomes are uncertain.³¹ Is it prudent for the government to significantly scale up treatment with drugs that may prove, after additional experience, to be unsafe or less effective than originally believed? Further evidence of long-term effects of these drugs is certainly needed, but the short-term restrictions being imposed are not the result of reasoned debate about the best form of patient care or the best approach to managing hepatitis C from a public health standpoint.

Conclusion

New direct-acting antivirals represent the first serious opportunity to treat hepatitis C, one of the most widespread infections in the United States, but public payers face short-term budgetary problems because of the drugs' high prices. Pharmacological tools make it possible to eliminate hepatitis C. But policy tools are needed to make a public health approach to these new medicines possible. Invocation of the government's power under section 1498 is a policy solution of precisely this sort.

We recommend, therefore, that the government consider invoking its power under section 1498, at least when the following two criteria are met: First, there appears to be a large disconnect between the risk-adjusted costs of research and development and the price a patent holder is commanding, and second, substantial public health benefits could accrue from the use of section 1498.

Used either directly, to cover patients in federal programs, or as a source of leverage for a broader strategy of patent buyout, this approach could vastly expand the impact of these new drugs while sustaining incentives for drug development. The government patent use approach could also be exercised at the discretion of the executive branch, while legislative solutions to high drug prices are less likely because they would have to emerge from a closely divided

Congress. More work would be needed to operationalize the plan described in this article and to map out the optimal approach to treating hepatitis C once costs are not so prohibitive. However, there may be few better opportunities to make substantial progress in fighting a serious disease.

Finally, asserting government rights may encourage companies to establish lower launch prices. With major new drug approvals on the horizon that could result in debilitating costs to public health care budgets,³² acting decisively in the case of hepatitis C could save the government billions of dollars in expenditures on other new medicines in the future. Used wisely, this power could help diminish the inefficiencies and health impact of the current pricing paradigm, at least for federal programs and possibly beyond. ■

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