Realizing Public Rights Through Government Patent Use

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Abstract: A substantial portion of biomedical R&D is publicly funded. But resulting medicines are typically covered by patents held by private firms, and priced without regard to the public's investment. The Bayh-Dole Act provides a possible remedy, but its scope is limited.

The novel coronavirus that emerged in 2020 has led to extraordinary social and economic dislocation. By late September, it had caused an estimated one million deaths around the world.[1] Governments are taking unprecedented steps to try to accelerate the development of effective therapies and vaccines, and in a matter of months have allocated almost $9 billion in research funding toward this end, much of it to private companies.[2] As of early August, an estimated 150 therapeutics were under clinical investigation worldwide, and 27 vaccine candidates were in clinical trials.[3] But only one anti-viral drug had yet shown some efficacy: remdesivir.

Patented and sold by Gilead Sciences, remdesivir is far from a game-changer. No peer reviewed studies have yet shown a mortality benefit. But the drug has been shown to reduce hospitalization time,[4] and it has become the standard of care in the US for many of those hospitalized with COVID-19.[5] However, there are significant questions about whether Gilead has priced it appropriately and will be able to provide adequate supply.

The price of remdesivir in the US was set at $2340 to $3120 for a five-day course.[6] However, generic prices today are $320 or less, and the cost of manufacturing has been estimated at far less, at $5 for a five day course.[7] A leading independent non-profit that performs technology assessments in the US, ICER, determined that a fair price for the medicine could be as little as $10-600 if only covering marginal manufacturing cost, or $1010 to $1600, accepting the company's forecasted development costs.[8] These prices, it assumed, may be appropriate because any past company R&D costs appear to have been recovered, since the line of research that resulted in remdesivir also yielded Gilead's lucrative Hepatitis C medicines.[9] ICER also estimated that, using traditional, cost-effectiveness analysis, the appropriate price would be below the current US price unless the medicine was

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shown to have a mortality benefit, which has yet to be shown.[10]

Additionally, over the summer, shortages of remdesivir have emerged in hotspots around the United States. An independent analysis found that shortages were reported in 38 hospitals around the country, and in 12 states.[11] This is so even as Gilead had directed almost all its available worldwide supply to the US.[12]

Given these concerns, it is notable that remdesivir benefitted from substantial public sector funding and research collaboration.[13] The US government funded and helped design the phase III trial for remdesivir and also was significantly involved in the earlier period of the medicine's development.[14] The early clinical research of remdesivir as a possible treatment for Ebola was funded by the US government.[15] Government researchers with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Centers for Disease Control and Prevention (CDC) in fact appear to have contributed to the discovery of remdesivir's anti-viral properties, and perhaps even to the selection of it as a candidate to treat SARS-CoV2.[16] An independent analysis suggests on this basis that the US government may be legally entitled to claim co-ownership over key patents.[17] No such rights have to date been recognized or asserted. Gilead alone appears to hold the patents, which give it a general entitlement to prevent all other companies from making, using, selling, or importing the compound into the United States. Despite the substantial investment made by taxpayers, then, the public exerts no direct control over the price or supply of the medicine.

This is in fact commonplace. The US government invests billions of dollars in research each year, research that one study showed underpinned the development of all of the drugs approved from 2010 to 2016.[18] The Bayh-Dole Act reserves the US government "march-in" rights, which allow it to give any company the right (or a "license") to make an invention covered by a patent, even against the wishes of the patent-holding firm.[19] It also gives the government the right to make or use the invention without permission, for its own benefit.[20] These rights only attach where the government's funding meets certain restrictive criteria, however. They only reach inventions very proximately developed with government funding, namely inventions "conceived or first actually reduced to practice in the performance of work under a funding agreement."[21] A great deal of government funding supports drug development, for example by identifying biomarkers or clarifying the nature of a disease, that does not result in Bayh-Dole rights because these grants did not directly fund the development of the marketable technology. The NIH and HHS have also taken the contested view that these rights can only be used in very limited ways. The law states that the government can march-in on patents if the action is "necessary to alleviate health or safety needs."[22] But some have argued that this does not cover the problem of excessive pricing, but only reaches problems like failure to commercialize.[23] No march-in petition has ever, in fact, been formally granted.[24] In addition, the agency leading the allocation of COVID-19 research funding, BARDA, has used contracts that seem to eliminate even these limited obligations for recipients of its funding.[25]

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Remdesivir shows the limits of the Bayh-Dole approach. It is not clear that Bayh-Dole rights attach to the relevant patents, despite the significant public investment in the drug.[26] In addition, the BARDA contracts might restrict the government's march-in rights — even assuming NIH would be inclined to use them.

Is there a way to recognize government funding more comprehensively than through the limited means of government patenting and Bayh-Dole rights? The question is likely to present itself urgently as more effective COVID-19 therapies and vaccines come online. Given the government's major investment in research in ordinary times, and the acknowledged impact of high drug prices on patients and

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health in the United States, the question also has broader importance.

Any system of fair pricing passed by Congress could include, as a factor in the definition of fair price, an accounting of public sector contributions. Some leading proposals for drug price reform in the US have this design. The proposed Medicare Negotiation and Competitive Licensing Act (H.R. 1046 [2019]), for example, would treat private sector research and development expenditures as one consideration, which incorporates public funding indirectly (because public funding will diminish private expenditures). Public funding could also be directly considered to reduce the price that the company could command in negotiations. Such an approach makes sense: if government investment has reduced the research and development (R&D) cost and risk of a drug's development, then as a matter of both fairness and efficiency, the price should reflect this input.

Existing law also provides an ex post procedure that can be deployed to a similar end. In the United States, patent holders have never been entitled to prevent the federal government from using, making, or importing a patented technology — instead, it can use the technology freely, paying only a royalty. Initially, this right of "government patent use" was an outworking of the organization of courts and the logic of sovereign immunity. The right has also been likened to eminent domain, a process that allows government to take private land for public use in exchange for fair compensation. This right permits the government to avoid situations where private rightsholders can hold up the public for more than reasonable compensation, as might happen, for example, where an owner holds the last plot of land needed to complete a new railroad line.

The government patent use right works similarly: it permits the federal government to override a patent and purchase a product competitively. The law has been extensively used by the federal government, for example to procure equipment for defense at fair prices and without the complexity of evaluating patent claims when assessing responses to a government bid.[27] Section 1498 was also used repeatedly by the Department of Defense and other agencies in the 1960s and 1970s to procure generic medicines such as tetracycline hydrochloride.[28] It was also invoked in 2001, after the government sought to procure surge supplies of an antibiotic in the aftermath of the anthrax attacks: in response, the patent-holding company agreed to cut the price in half and to ensure adequate supply.[29]

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Codified at 28 U.S.C. § 1498, this right immunizes not only federal agencies and programs but anyone acting "by or for" the US, including contractors and other state actors under certain circumstances.[30] Patent holders are entitled to compensation, although not, courts have suggested, the full replacement of anticipated profits.[31] Instead, caselaw suggests that courts should set royalties that take into account a variety of factors, including existing license terms (if there are any), and investments into R&D by the patent-holder.[32]

Practically, government patent use is a straightforward process: federal procurement agents are entitled to accept bids to contracts regardless of patent status, and patent holders cannot prevent their effort.[33] Their only remedy available to rightsholders is a suit for compensation, beginning in the Court of Federal Claims. Drug regulatory requirements can create additional complexity. The FDA does have some enforcement

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flexibility to permit unapproved medicines into the US, and the government can seek to expedite the process of generic drug approval by asserting its government use rights in proceedings brought by drug companies to try to prevent approval, for example under procedures set out in the Hatch-Waxman Act.[34] If a drug is new and enjoys data exclusivity, which prevents for a period of time the registration of generic versions that rely on the originator's data, generics face a significant but not insurmountable barrier to entry.[35] Particularly in a pandemic, emergency use authorization — the process under which Gilead was permitted to market remdesivir absent new drug approval — may permit use with limited data and avoid any barrier of data exclusivity. (Drugs issued an EUA also are not awarded data or market exclusivity for the use, which attaches only to approvals.) Government agencies may also possess data needed to approve a drug. In the remdesivir case, for example, the trial that showed efficacy was conducted by the NIH.[36] This normally would allow the government to give such data to third parties or even make such data public, as long as they have not promised companies involved in the trial that they will keep the data confidential.

How might government patent use work in practice to help ensure taxpayers receive the benefits of their investment? Remdesivir provides an example. Suppliers of generic remdesivir exist in India, Bangladesh, and China. The Department of Health and Human Services, which is distributing the existing supply, could put out a competitive tender to seek additional competitive bids for high quality remdesivir, and accept any bids that appeared advantageous, on the condition that they seek an EUA or approval. Gilead would be able to request compensation, and the government could negotiate a fair royalty, taking into account both the government's investment, and Gilead's. If no agreement was made, Gilead could seek compensation in the Court of Federal Claims, and a court could determine compensation using a similar means. Because the fair price, when accounting for research and development costs, may well be significantly below Gilead's price, the government might well also save substantially by invoking section 1498.[37] Even if the government were to pay Gilead the same as it currently is, the public would still have the benefit of adequate and more reliable supply — a significant one, particularly in pandemic times.

Critics of Bayh-Dole often argue that fair-pricing clauses will distort investment away from drug candidates that emerge from federal funding. An ex post or ex ante system for negotiating drug prices would not trigger such concerns, and has the additional benefit that it can be deployed to ensure fair prices for medicines that are not substantially funded by the federal government. Finally, invoking the ex post remedy of government patent use is especially attractive in a case where there is urgent public health need a substantial public investment, as in remdesivir — it may create the urgency needed to set precedents for the administrative and judicial treatment of this approach, that can assist in decision-making in more ordinary times. The knowledge that the remedy can and will be used may help discipline drug makers seeking excessive returns on their products in the future.

Note

The author has no conflicts to disclose.

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