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Patent (and public health) pending

by Philip A. Perry, MSJ

Kesselheim AS, Avorn J. Biomedical patents and the public health. Is there a role for eminent domain? *JAMA*. 2006;295:434-437.

In a health crisis, such as a flu pandemic, prompt medical intervention by physicians and the public health community may save lives. Sometimes, however, the curative drugs are too expensive or there's just not enough to go around. Furthermore, physicians can't act when laws that protect the patent rights of pharmaceutical companies conflict with other laws that promote public health. Is there a mechanism that can resolve the conflict? Seeking a creative solution, the authors of this article—physician-lawyer Aaron S. Kesselheim, MD, JD, a clinical fellow in the Department of Medicine and Harvard School of Public Health and an associate physician at Brigham and Women's Hospital, and Jerry Avorn, MD, professor of medicine at Harvard Medical School and chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's—propose that the government's powers of eminent domain can and should be applied for the public good in serious health crises.

Eminent domain powers allow governments (local, state or federal) to buy property or take other actions in the name of the public good. The idea of just compensation for the exercise of eminent domain is written into the U.S. Constitution [1]. But while it has often been applied to real estate law, for example to build roads while compensating landowners for the sale (coerced or otherwise) of their property, eminent domain has not been a common legal instrument in the health care business.

A legal precedent retooled for health care

As the authors point out, however, the concept of eminent domain has broadened throughout U.S. legal history [2]. Eminent domain was used in 1948 to gain access to patented processes when that use of governmental power was established through the U.S. judicial code [3]. But it was a power seldom exercised, partly because of the weight of the free enterprise tradition that honored patents and innovation in U.S. commerce. In the tradition of hard bargaining, the power has been held in reserve, as a kind of ultimate weapon, while a favorable deal was cut between the patent holder and governmental authorities.

Kesselheim and Avorn propose that we apply the principle of eminent domain to the purchase of pharmaceutical or vaccine patents from private industry. In their scheme, a set of standards would be developed to determine when to invoke eminent domain. Possibly a standing committee of the U.S. Department of Health and Human Services would review requests for invoking the power and would try to work out a fair compensation deal for the patent owner. In some cases, a compromise might easily be reached with the company or individuals who hold the patent and intellectual property rights to a drug or device that's suddenly in demand. When time is money, or a matter of life or death, it's important to make sure that the mechanism for reaching a fair decision works quickly.

Eminent domain law requires fair compensation, so the public will eventually have to pay in some measure for what it needs. Economists have tried to estimate the cost of taking a drug patent and compensating the patent owner. In 1995, two Indiana State University economists, Robert C. Guell and Marvin Fischbaum, developed a fairly detailed theory involving a "market appeal" of commercial sales for a limited time to calculate just compensation prior to a government takeover [4]. Critics will probably object that there would not always be time for a market appeal, if, for example, an investigational drug proved useful against a pandemic that hit unexpectedly.

Kesselheim and Avorn make a good case that we need some kind of legal construct to protect the public in medical emergencies. Some have questioned whether it would be wise, or even constitutional, to invest the power of eminent domain in a committee of the Department of Health and Human Services, an agency of the executive branch. Legal challenges might tie up the courts for quite a while. And it certainly stacks the deck in favor of the government's side of the case.

Real world solutions hard to find

Real world experience demonstrates that the problem is a difficult one to solve. Both the AIDS epidemic and the more recent avian flu scare provide sobering examples. Pharmaceutical companies were assailed for their inhumanity in withholding drugs from needy patients, and governments were urged to force the companies to provide the AIDS cocktail free to the world's growing population of indigent patients, otherwise doomed. Avian flu raises the specter of deaths due to vaccine shortages or logistical failures of drug production.

During the anthrax scare, proposals in Congress floated the idea of government control of drug production by overriding patents on Bayer Corporation's antibiotic Cipro (ciprofloxacin hydrochloride) [5]. But the matter was dropped when the crisis passed with only a few serious cases. In the avian flu controversy of 2005, patent holder Roche did agree to allow generic Tamiflu to be produced by other companies during talks with U.S. lawmakers [6], but the agreement came only after considerable pressure was applied. Roche executives estimated that it would take generic manufacturers three years to gear up for any production, indicating that there's still a severe, unavoidable supply problem in a flu pandemic situation [7].

Meeting peak demand, corporate planners say, would require huge investments with an unacceptable risk of loss. Some sort of government guarantee as well as compulsory licensing might be necessary to build a big enough national stockpile of vaccine.

A Washington, D.C., councilman proposed an ordinance that would allow the city to take a drug company patent using its own powers of eminent domain. The reaction from a top drug industry lawyer was that it would never work. “Unwise, unworkable and unconstitutional,” said David Remes of Covington and Burling, an expert on patent law and an attorney representing the Pharmaceutical Research and Manufacturers of America [8].

One other limitation of the authors’ proposed legal instrument is that it stops at the U.S. borders. A pandemic would require an international solution. And the authors don’t really address the problem, which several other articles have raised, that the flu drugs are patented—and distributed—in only a handful of developed countries, so even if all were to nationalize the drug patents in an emergency many countries could still be without access to the drugs they needed [9]. One study, however, concluded that patents were not a serious barrier in Africa with reference to AIDS medications. Poverty and lack of public health infrastructure were much the greater problems [10].

Clearly, some compromise between commerce, government, and the public health is a prerequisite to successful medical interventions in these situations, whether local, national or international in scope. Yet eminent domain may be too disruptive. In legal theory, the knowledge that some “just compensation” is going to be forthcoming mitigates the disincentive to do research into and produce needed medications. But just compensation cannot match entrepreneurial returns from an exclusive patented blockbuster drug. If drug company innovation were to slow, then some other mechanism—such as increased government aid to drug company research and development efforts or guaranteed government contracts—would be needed to compensate for the inability of the private sector to meet a particular health threat. A current example is Washington’s \$1 billion support of manufacturers to accelerate their development of cell-based flu vaccine technology [11]. Application of eminent domain alone can’t be expected to meet all the possible competing needs of drug production and public health in an epidemic.

Ethics of denial of care

The market place has in effect denied care to many patients by pricing drugs out of their reach. The permanent solutions to this problem that have been proposed so far have been rejected—national health care, a group purchasing plan based on the federal government’s purchasing power, AIDS drug giveaways and so on. An awkward silence ensues for physicians, bioethicists and policy makers who take medical ethics seriously.

In their conclusion the authors note that it's difficult to decide when competing public goods have a claim on our sense of fairness. In this case, it's laid out as the good of "new drug development" versus the good of "access to lifesaving medicine." In so many cases the good of new drug development has seemingly won out, but the consequent inequities seem great. At what point does the fact that so many people cannot afford life-saving medications constitute an emergency in which the government should intervene for the good of the public?

Paradoxically, the more success there is in new drug development, the greater is the problem for the drug industry. William B. Schwartz, MD, pointed this out in "Life Without Disease," predicting that "a widening gap between what is medically possible and what is medically customary will create widespread conflicts between patients and health care providers, which will ultimately require resolution in legislatures and the courts" [12]. Constant demands for access and the lack of medications for indigent patients erode the image of medicine and the pharmaceutical industry. In the wake of the AIDS epidemic and in the face of avian flu and various threats real and imagined, pressure to find a better solution mounts.

Entering the courts on a case-by-case basis is not the most satisfactory alternative for the parties involved. If not eminent domain then some better, comprehensive legislative solution would seem to be the only road to a compromise that will balance competing commercial interests with urgent public health needs. All the more wonder that the situation the authors describe has been in stalemate for so long.

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