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PERSPECTIVE

Pharmaceutical Patents and Economic Inequality

THOMAS POGGE

A human right is realized when all persons have secure access to its object, to what this right is a right to. States and particularly governments have a responsibility to make this happen—principally by not taking measures that prevent such secure access. Governments currently award and enforce 20-year product patents on pharmaceuticals in accordance with the TRIPS Agreement they included in the 1995 founding treaty of the World Trade Organization.[1] Patent enforcement involves preventing generic manufacturers from offering patented medicines at competitive prices. So protected from competition, patented medicines are often sold with exorbitant monopoly markups that effectively deprive many poor patients of access to them.

It is true that governments, in their 2001 Doha Declaration, explicitly declared that their "Agreement can and should be interpreted and implemented in a manner supportive of [World Trade Organization] members' right to protect public health and, in particular, to promote access to medicines for all."[2] But these words did not result in universal access to important new medicines—far from it.

In 2013, an important hepatitis C drug, sofosbuvir, was introduced by Gilead Sciences in the United States at a price roughly 3,000 times its variable cost of production—US$84,000 per course of treatment—and at lower but similarly unaffordable prices in poorer countries.[3] Five years after its introduction, only about 7% of the 71 million persons living with hepatitis C had been treated.[4] The others continued to suffer—and to spread the disease. Many who catch hepatitis C nowadays would not have done so if the new drug had reached a larger percentage of the relevant patient population. Insofar as patients suffer or die because willing and able generic manufacturers are prevented by law from selling them the medicines they need for their grave diseases, the governments that adopt and enforce these laws are arguably violating the patients' human rights.[5]

It is true that Egypt could and did reject Gilead's patent application, finding that sofosbuvir lacks novelty and inventiveness. It is true that Malaysia could and did issue a compulsory license permitting generic production of sofosbuvir for domestic consumption. It is true that the world's "least developed

Thomas Pogge is Leitner Professor of Philosophy and International Affairs and founding director of the Yale Global Justice Program, New Haven, United States.

Please address correspondence to the author. Email: thomas.pogge@yale.edu.

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countries" are not required to grant patents on new pharmaceuticals and, lacking domestic manufacturing capacity as they do, may ask a capable state to issue a compulsory license for export to them—though the required process is so cumbersome that it has been used only once in the last 20 years, when Canada licensed its firm Apotex to deliver three batches of anti-HIV/AIDS combination therapies to Rwanda.[6]

While the so-called TRIPS flexibilities *could* be used to substantially improve access by poor people to new medicines, they are not in fact so used. One key reason for this is that weaker states are reluctant to risk sanctions imposed upon them by powerful pharmaceutical firms and their even more powerful governments. For example, the Office of the US Trade Representative issues *Special 301 Reports* that place states on a Priority Watch List if they are deemed insufficiently supportive of US firms' legitimate business interests, prominently including their intellectual property rights.[7]

It should also be mentioned that some pharmaceutical firms have licensed important new pharmaceuticals for generic production in some poorer countries. Gilead has done this with sofosbuvir. But understandably, these voluntary licenses do not include "the majority of middle-income countries, where most of the hepatitis C burden lies. For example, Argentina, Brazil, China, Georgia, Iran, Mexico, Peru, Turkey, and Ukraine are all excluded from Gilead's voluntary license."[8]

That poor people overwhelmingly lack access to new medicines is a foreseeable effect of our globalized innovation regime, which makes innovators reliant on monopoly markups and therefore highly motivated to prevent low-priced sales of their proprietary pharmaceuticals. Originators plausibly fear that such sales would undermine their income from selling their product to the rich and well insured at hundreds, even thousands, of times the cost of production. And they have no chance to earn meaningful profits from sales to the poor, seeing that 42% of the human population—well over three billion people—are so poor that they cannot even afford a healthy diet valued at the purchasing-power equivalent of US$3.66 per person per day on average.[9]

In the case of infectious diseases, patents provide an additional incentive to price medicines out of the reach of less affluent patients, as doing so keeps the target disease alive, thereby ensuring future demand. If sofosbuvir were universally accessible, the incidence of hepatitis C, and hence demand for its cure, would dwindle fast. Thus, a patent-holding firm profits even from those who cannot afford its product, as they infect others who can. That pharmaceutical firms have this incentive is not a criticism of them. It is an indictment of the innovation regime our governments are upholding in our names. This regime is not merely unjust by excluding the poor but also counterproductive by undermining population-level strategies to contain, suppress, and eradicate infectious diseases.

It is worth noting that patent incentives would work poorly in the pharmaceutical sector even if extreme poverty were eradicated. In ordinary markets, as people become more affluent, more of what they need is supplied by competing producers and sellers at prices near the variable cost of production—diets improve. With an important patented medicine, by contrast, the single seller finds it profitable to raise the price in response to rising ability to pay, ensuring continued exclusion of the less affluent. Here the proportion of patients that it is optimal to exclude depends on the shape of the demand curve. If a minority is much richer than the rest, this demand curve can be highly convex and the profit-maximizing price may then exclude a large majority of the patient population, as happened with sofosbuvir. The patentee rationally sacrifices sales to most potential buyers because lowering its sales price would entail an earnings loss from reduced markup exceeding the earnings gain from increased sales volume. Given large financial

inequalities, both globally and in most countries, patented medicines routinely exclude most of the patients who need them. These inequalities would continue to aggravate the human rights impact of pharmaceutical patents even if all incomes worldwide were to double or quadruple. Even in an affluent population, patents on an important product that has no close substitute will exclude the hindmost—in sharp opposition to the "Leave No One Behind" motto of the Sustainable Development Goals. As pharmaceutical patents deepen the impact of financial inequality by cutting many patients off from the medicines they need, so greater financial inequality—reflected in a more convex demand curve—broadens exclusion from patented medicines.

Replacing patents with impact rewards

Universal access to new medicines could be achieved through a global buyers' alliance—including national health systems and insurers—which would tell each originator how much it can charge various kinds of buyers for its product. Such an alliance could effectively dictate prices, as the originator's sole alternative would be to take a loss on its entire R&D investment. But such a monopsony would greatly reduce pharmaceutical R&D: investors would not spend billions on developing important new medicines if their return were wholly at that alliance's discretion. Is there a feasible regime that would ensure the profitability of pharmaceutical R&D without the massive human rights denials entailed by monopoly patents?

Years ago, Aidan Hollis and I proposed that a coalition of willing countries should institute a Health Impact Fund as an optional scheme of impact rewards, to be paid through preannounced large annual disbursements divided among important new medicines according to health gains achieved with them in the preceding year.[10] Each invention would partake in 10 such distributions and then go generic in its 11th year. The number of new pharmaceuticals entering the scheme each year would depend on the size of the annual disbursements. With, say, 12 pharmaceuticals entering the scheme each year, replacing a similar number exiting at the end of their reward period, the scheme would consistently support about 120 important new medicines with each disbursement. In such a scheme, important new medicines would be instantly available at competitive or even lower prices. Yet pharmaceutical R&D would still be reliably incentivized—and more broadly than at present: by valuing the health and survival of all human beings equally, the scheme would finally create strong incentives to develop remedies against the heretofore neglected diseases concentrated among the poor, such as tuberculosis, malaria, hepatitis, HIV/AIDS, pneumonia, meningitis, diarrhea, and many tropical diseases.

Though such an impact reward scheme might eventually be financed from its own endowment, it would require substantial state funding in its early years. But it would also generate large cost savings for taxpayers through much lower drug prices and much better health around the world. If pharmaceutical firms were paid for achieved reductions in disease incidence, they would be highly motivated to include even the poorest people in a population-level strategy of fighting diseases to extinction. Thus, Gilead Sciences would have found it profitable to invest in diagnostic efforts to identify hepatitis C patients around the world and to ensure they have access to a full course of treatment with proper instructions and adherence support to forestall the emergence of drug resistance.

Because it would largely avoid the wasteful expenditures now typical of the pharmaceutical sector—costs for patenting and associated litigation, economic deadweight losses, and costs arising from corrupt marketing practices and counterfeiting—an impact reward scheme would not require increased fund flows into the pharmaceutical

sector. But it would greatly raise the share of such funding devoted to R&D and effective delivery and—partly thereby—greatly improve this sector's efficiency and human rights record.

The described impact reward scheme improves in five main ways upon innovation prizes and other pull mechanisms, such as advance market commitments.[11] It constitutes a structural reform, establishing stable and predictable long-term innovation incentives. It lets innovators, who know their own capacities best, decide which innovations to pursue across the whole range of disease areas. It avoids having to specify a precise "finish line," which is difficult to get right in advance, and instead rewards each registered innovation according to the benefits produced with its deployments. It avoids having to specify a reward-for-benefit rate, which instead evolves endogenously through market forces. It gives innovators strong incentives also to promote (through information, training, technical assistance, discounts, and so on) the fast, wide, effective diffusion of their registered innovations.

Two ways in which an impact reward scheme would help realize human rights are distinctly egalitarian. By ensuring that important new medicines are immediately available at competitive prices and that their effective delivery is well rewarded, it would ensure that even impoverished and remote populations have access to such treatments. And by rewarding health gains regardless of patient finances, it would greatly intensify investments in combating the heretofore neglected diseases of poverty.

In addition, an impact reward scheme would massively reduce the overall disease burden by incentivizing pharmaceutical firms to fight diseases at the population level, aiming for their containment and extinction. Finally, it would also avoid the destructive effects of exorbitant monopoly markups, such as massive efforts at regulatory capture toward preserving and extending the flow of monopoly rents (exemplified by efforts to stall US Food and Drug Administration action on Vioxx), widespread misprescribing induced by kickbacks to health care professionals, and intense efforts to sell unsuitable drugs to vulnerable populations (as evidenced in the US opioid crisis which—fueled by high markups that would disappear if profits were proportioned to health gains achieved—is now killing some 100,000 people annually).[12]

Understanding economic inequality

It is noteworthy that the two egalitarian advantages of impact rewards are invisible in conventional economists' understanding of economic inequality. According to this understanding, any measure of economic inequality must be based on information solely about the distribution of income and wealth—including non-money items such as real estate, home-grown foodstuffs, and public services, all valued at local prices. A general change in prices or product availabilities does not affect economic inequality; such data are excluded from the informational base of inequality measures. Thus, if an important medicine goes off-patent, becoming much cheaper, inequality remains unchanged because purchasing power is deemed irrelevant to measuring economic inequality based on income or wealth.

Though the conventional economists' view seems self-evident, it can be challenged with this highly simplified example involving two persons and two commodities. The rich person has $1,000 a month and spends $200 on necessaries and $800 on discretionaries. The poor person has $100 a month and spends $80 on necessaries and $20 on discretionaries. Now necessaries become 25% more expensive and discretionaries 20% cheaper. The rich person can consume as before, spending $50 more on necessaries and $160 less on discretionaries, for new monthly savings of $110. The poor person must adjust—for example, by spending $92 on necessaries and $8 on discretionaries (reducing

consumption by 8% and 50%, respectively). It seems that the rich person has become economically better off because she can consume the same amount of both necessaries and discretionaries and actually saves $110 under the new price scheme, while the poor person has become worse off because she must consume fewer necessaries and fewer discretionaries. This would imply that economic inequality between them has widened.

Conventional economists refute this conclusion by insisting that income inequality has remained unchanged at 10-to-1: what matters is not what people happen to buy but what they *can* buy, their option space. For any basket of necessaries and discretionaries the rich person can buy, the poor person can buy a corresponding basket one-tenth its size. The price changes leave this fact unchanged.

This reasoning ignores, however, that some consumption patterns are feasible for the rich but infeasible—indeed fatal—for the poor person. The latter must maintain a certain minimum consumption of necessaries to ensure survival, the most basic imperative of *homo oeconomicus*. What seems paradoxical to conventional economist doctrine is then true nonetheless: a drop in the price of necessaries reduces not merely poverty (by increasing the purchasing power of money) but also economic inequality.

While I have presented the argument in diachronic terms, it can be restated in synchronic terms to show how prices can be relevant to comparing economic inequality across two populations or indeed two possible futures of the same population. If our governments had established impact rewards rather than monopoly markups as rewards for important pharmaceutical innovations, global and national economic inequality would be substantially lower even if the distribution of (monetized) income and wealth were exactly what it is now. To be sure, that better choice would in fact have resulted in more egalitarian distributions of income and wealth, as well as a much smaller global disease burden with consequent higher income and wealth across the board.

Self-reinforcing economic inequality

How then did we end up with such a toxic regime for rewarding important pharmaceutical innovations, one that persistently harms and kills millions of people around the world?

Before TRIPS, poorer states generally imposed only weak patent protections. India was the "pharmacy of the world" because its ingenious generic manufacturers could typically, by finding a different way of making a newly patented drug, invent around its Indian seven-year process patent and then supply it legally to patients in India and in other developing countries with similarly permissive patent laws. By adopting a globally uniform regime of strong 20-year product patents, governments ended this life-saving opportunity, enabling pharmaceutical innovators to collect substantial monopoly rents from affluent patients in the Global South with the foreseeable side effect of excluding much larger numbers of patients from patented medicines altogether.

The TRIPS revolution thus highlights the following two further links of patents to economic inequality. In the pharmaceutical sector especially, innovations require substantial investments. Rich people and organizations therefore have a large advantage in reaching important innovations first. Strong patents enable them to charge road tolls from others. TRIPS globalizes these road tolls, creating substantial financial flows from poorer to richer countries and thereby entrenching and exacerbating international inequality.

Why then did developing countries sign up to TRIPS? World Trade Organization membership offered them "most favored" access to the much larger markets of the richer countries. The affluent states used the greatly superior bargaining power

derived from their much greater wealth to extract a concession, TRIPS, that would help them stay ahead. The highly inegalitarian TRIPS Agreement bears the imprint of, and perpetuates, an extreme international disparity of economic power that was unjustly accumulated through a period of extreme violence, with enslavement, genocide, and colonialism.

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