Chapter 10: Global Poverty

Case Study: Pharmaceutical Patent Reform

Millions of people die each year from curable diseases. More than half of all deaths in low-income countries in 2016 were caused by what are known as 'Group I' conditions, which include communicable diseases, maternal and perinatal conditions, and nutritional deficiencies.[1] Seven of the top ten causes of death in such countries are Group I, including respiratory infections, diarrhoeal diseases, HIV/AIDS, malaria, and tuberculosis. Most of these deaths are preventable, as can be seen from the fact that less than 7 per cent of deaths in high-income countries were due to Group I conditions. Further, hundreds of millions more people experience increased morbidity as a result of these conditions. Extreme poverty is a leading determinant of ill health, and ill health in turn hampers the ability of individuals to meet even the basic needs of themselves and their families. These facts seem strikingly at odds with the idea of a human right to health, as found in a number of key human rights documents. For instance, article 25 of the Universal Declaration of Human Rights (United Nations, 1948) states: 'Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care.' Article 12 of the International Covenant on Economic, Social and Cultural Rights (United Nations, 1966), meanwhile, refers to 'the right of everyone to the highest attainable standard of physical and mental health', and requires of states that they ensure 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases' and bring about 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness.'

One key reason for global ill health is lack of access in the developing world to essential medicines. This case study examines an international institution— namely the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement—which, according to its critics, has contributed to millions of deaths, both by making it the case that needed drugs are priced out of the reach of developing countries, and by skewing the priorities of pharmaceutical innovators, such that they devote insufficient attention to developing cures for the world's biggest killer diseases. If these charges are well-founded then we should surely demand the replacement of TRIPS as an urgent priority. One prominent proposal for how to do this is via a 'Health Impact Fund', which would direct funding in ways that encourage the development and dissemination of vital new drugs to the developing world. We will examine this proposal later on. First, however, let us consider TRIPS, and what, according to its critics, is so desperately wrong with it.

TRIPS: history and impact

Following successful lobbying by the United States, the European Union, and other developed countries, the TRIPS Agreement was negotiated in 1994, during the Uruguay Round of the

[1] http://www.who.int/en/news-room/fact-sheets/detail/the-top-10-causes-of-death.

General Agreement on Tariffs and Trade (GATT), which paved the way for the establishment of the World Trade Organization (WTO). TRIPS requires of signatories that they establish laws affording robust protection to intellectual property rights—including, crucially, those held by pharmaceutical companies in respect of their innovations. Assent to the TRIPS agreement is now a condition of WTO membership. As such, developing countries seeking access to lucrative western markets have found themselves compelled to sign up.

TRIPS vests patent-holding pharmaceutical companies with monopolies over their innovations lasting for a minimum of 20 years, and allows them to maximize their revenues during that period by selling their drugs at prices greatly in excess of production costs. This arrangement, however, while conducive to the interests of the pharmaceutical giants and their shareholders, effectively excludes poor countries from accessing vaccines, cures, and palliatives urgently required by their citizens. Countries who violate pharmaceutical patents by manufacturing generic copies of medicines, or by allowing them to be imported from elsewhere, are charged, in effect, with piracy, can be vigorously pursued through the dispute resolutions process specified under TRIPS, and may be subject to economic sanctions.

TRIPS: is it unjust?

On what grounds might the existing regime of patent protection be defended? Some—and in particular libertarians—would no doubt argue that pharmaceutical researchers have a right to control access to their innovations, no matter how urgently others might need them. For many, however, it will be far from clear why researchers' interests in having such control should take priority over the interests of the global poor in getting affordable medicines. TRIPS is not a natural fact, or an inevitable and immutable way to allocate property rights. It is an institution designed by humans that seemingly has the predictable result of preventing medicines from getting into the hands of those that need them most. In this sense, it seems plausible to suggest that TRIPS causes premature deaths. If so, there is a strong case for reform, in order to remedy this harm.

A better defence of the current regime seeks to show that it does not cause the harm that its critics claim, by arguing that intellectual property rights are in fact beneficial not only to the drug companies, but to all, *including* the global poor. This argument begins by noting that researching and developing a new medical treatment is a costly and risky enterprise, as there are no guarantees as to whether the research will be successful in yielding an effective product, or how quickly. Because of the costs and uncertainties associated with pharmaceutical research, the argument continues, companies would not commit the necessary investment unless they had good grounds for thinking that they would benefit in the long run. And, of course, if they did not invest, we would all be denied many necessary drugs. As it is, the promise that one will be able to patent one's pharmaceutical inventions, and thereby recoup expenses and make a profit stimulates and incentivizes life-saving research. And while the poorest nations may be excluded from purchasing the treatments developed in the early years of their availability, the argument concludes that they will in

time (after the expiry of the patent) benefit more than they would under a system that did not recognize patents at all.

Critics of TRIPS, however, reject this argument from mutual benefit. First, they reply that the research programmes of the pharmaceutical corporations are inadequately aligned with health priorities in the developing world. For if the poorest nations will not be able to afford the drugs developed, then there is little incentive to cater to their particular needs. Thus, a disproportionate amount of money is channelled into treatments for relatively minor complaints, such as erectile dysfunction or male pattern baldness, rather than, say, for the big three killer diseases (AIDS, malaria, and tuberculosis) that afflict developing countries across swathes of Africa and elsewhere. Second, opponents of TRIPS will be unsatisfied with the prospect of developing countries acquiring access to pharmaceuticals only twenty or more years down the line, given the suffering caused by treatable diseases in these countries every day. The benefits generated by the current intellectual property regime seem small compared to the harms that are caused. Third, fatal diseases are themselves innovators: crucially, by the time a patent expires and a given treatment reaches the developing world, the disease it addresses may have mutated, rendering the drug obsolete.

<A>Compulsory licensing arrangements

The above-cited problems with patent protection for live-saving medicines have led many to conclude that developing countries would be morally justified in disregarding intellectual property rights, and producing or importing generic copies of branded drugs wherever necessary to meet the healthcare needs of their people (see, e.g., Brock, 2001). However, there is in fact a provision within the terms of the existing TRIPS Agreement that appears to give developing countries some leeway to do so legally. To elaborate: TRIPS allows a country's government to grant a 'compulsory license' for the domestic manufacture of generic copies of patented medicines, subject to their paying a royalty (generally of under 10 per cent) to the patent holder. The situation on compulsory licensing was clarified in the 2001 Doha Ministerial Declaration on TRIPS and Public Health, which emphasized that TRIPS ought not to be seen as an impediment to a country's taking the steps needed to protect public health. The Declaration also allowed countries to grant compulsory licences for the manufacture of generic drugs intended for foreign (as opposed to domestic) consumption, so as to make room for cases in which a country is in need of a medicine, but lacks the capacity to produce it internally.

The system of compulsory licensing, then, appears to go some way to addressing the health needs of developing countries, and allaying concerns about the effects of TRIPS. However, according to its critics it is limited in several key respects (Hollis and Pogge, 2008, 99-100). First, although states are allowed under compulsory licensing arrangements to manufacture generic drugs for export to a country that needs them, the costs of their doing so are borne by the manufacturing country itself, rather than the intended beneficiary. Moreover, the procedure is frustratingly bureaucratic. For these reasons, then, it is difficult for poor

countries which are in need of generic drugs but unable to manufacture them to enlist other countries to help with production. Second, although discretion as to when granting a compulsory licence is warranted rests in the hands of individual states, the pharmaceutical industry uses its considerable power to try to restrict their use as far as possible. Countries tend, then, to be extremely cautious about issuing compulsory licences, in case they attract political reprisals. Third, and perhaps most importantly, compulsory licensing does not address the problem of research priorities being slanted in favour of the needs of the developed world. Indeed, there are good grounds for thinking that, if developing countries are sometimes entitled to bypass product patents, pharmaceutical companies will have even more reason to concentrate on satisfying the health priorities of wealthy consumers in the developed world, rather than tackling the major killer diseases.

<A>The 'Health Impact Fund'

Various schemes for addressing these problems have been developed. Some of these focus on seeking to incentivize research and development through prize funds and grants, such as those provided by the Gates Foundation. While helpful, these do not directly address the issue of ensuring that people in developing countries can actually access the medicines (Hassoun 2014, p. 234). Nicole Hassoun (2014) proposes a rating system for pharmaceutical companies, based on their drugs' impact in improving global health. Hassoun suggests that the best companies could be issued a Global Health Impact label to use on all of their products, including cosmetics etc., which would then attract customers. This would encourage companies to both invest in research into drugs that greatly improve global health and to ensure that those drugs, and indeed existing medicines, reach the people who need them most.

A distinct, more ambitious proposal, seeks to more directly change the financial rewards to pharmaceutical companies. This is the 'Health Impact Fund', an idea that has been refined in recent years by a number of academics, including several prominent political theorists (see https://healthimpactfund.org). It aims to incentivize the development of treatments and cures for the world's most pressing healthcare needs, and would work roughly as follows (see Hollis and Pogge, 2008). First, pharmaceutical innovators embarking on research into a new drug would be offered a choice between taking out a patent of the conventional sort, and taking out a new alternative type of patent. Those taking the second option would *not* be granted exclusive rights to sell their product at a profit. On the contrary, they would be required to allow the reproduction of the drug by generic drug manufacturers, and its sale at cost price. Instead of making money through sales, innovators would be given financial rewards out of a Health Impact Fund, paid for by national governments, at a level reflecting the contribution made by the drug to alleviating global health problems. In other words, researchers would receive more money from the Fund depending on how many people are helped by their product, and the severity of the illness that it tackles. Note that, because the proposed new species of patent would sit alongside the conventional patent system, pharmaceutical companies would still have the option of spending their time on developing

medicines for the relatively trivial complaints, like baldness, that affluent consumers in the developed world are prepared to pay large sums of money to get. However, they would also have a second financially viable option, namely that of developing new drugs to solve urgent global health problems. In short, the Health Impact Fund is intended to create greater harmony between the currently antagonistic interests of the big pharmaceutical companies and the global poor.

Of course, as we have just noted, the Health Impact Fund would require a financial commitment by national governments—ideally, in proportion to their respective levels of affluence. In order to be effective the Fund would need to be large; its advocates hope that it will initially be around $6 billion. It would thus be expensive to create. Hassoun (2014, p. 235) mentions that one of the key comparative advantages of her rating system proposal is that it would be much cheaper to implement. Thomas Pogge (2005) has argued, however, that financing the Health Impact Fund is not only the morally indicated course of action for wealthy nations, but also in their self-interest. For, in contributing to the scheme they will not only earn the goodwill of poorer countries, but also benefit from reductions in the prices of drugs that their own citizens will often need (for instance, treatments for HIV), and reductions in the cost of the latter's medical insurance. Promisingly enough, the Health Impact Fund idea does now appear to be gaining some political support. The Social Democratic Party of Germany has endorsed it, calling on the German government to support a pilot scheme. And the World Health Organization Expert Working Group on Research and Development Financing has said that the idea merits further consideration. Whether or not the Health Impact Fund ultimately sees the light of day remains to be seen. It is, however, already a prime example of how ideas from political theory can gain political traction in the real world.

References

Brock, D. (2001) 'Some Questions about the Moral Responsibilities of Drug Companies', *Developing World Bioethics* 1: 33–7.

Hassoun, N. (2014) 'Globalization, Global Justice, and Global Health Impact', *Public Affairs Quarterly* 28: 231–58.

Hollis, A. and Pogge, T. (2008) *The Health Impact Fund: Making New Medicines Accessible for All*, New Haven, CT: Incentives for Global Health.

Pogge, T. (2005) 'A New Approach to Pharmaceutical Innovations', *Online Opinion*, http://www.onlineopinion.com.au/view.asp?article=3559.

United Nations (1948) *Universal Declaration of Human Rights*, General Assembly Resolution 217A (III).

United Nations (1966) *International Covenant on Economic, Social and Cultural Rights*, General Assembly Resolution 2200A (XXI).