

## Trade agreements and health in developing countries



Politicians champion free trade for bringing an era of high and stable growth, although the evidence supporting such claims is ambiguous. Studies that associate increases in trade with increases in gross domestic product often leave open questions of causality: high growth, the result for instance of strong industrial policies, typically leads to more trade. China and India's growth spurts preceded trade liberalisation. A study by UN Development Programme showed little relation between trade liberalisation and growth.<sup>1</sup>

But trade liberalisation is associated with growing inequality in most countries of the world (although there are other contributing factors). Especially in conjunction with liberalisation in capital and financial markets, trade liberalisation has brought unprecedented instability, even in countries with otherwise sound economic policies. Moreover, trade liberalisation has deprived developing countries, which are heavily dependent on tariffs, of needed revenues. The resulting combination of increases in poverty and social stress with decreased public spending is a prescription for decreases in health status. Even a relatively short episode of malnutrition from a severe downturn, of the kind that became all too common during the global financial crisis of 1997–98, can have lifelong consequences.<sup>2</sup>

But perhaps the most adverse consequences for health arise from provisions in trade agreements that are designed to restrict access to generic medicines. These include the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property) provisions of the Uruguay Round Agreement of 1994 (as discussed by Richard Smith and colleagues in a paper in this Series<sup>3</sup>) and the data exclusivity provisions that have become a standard part of US<sup>4</sup> and European<sup>5</sup> bilateral trade agreements.

The fundamental problem with the intellectual property (patent) system is simple: it is based on restricting the use of knowledge.<sup>6</sup> There is no extra cost associated with an additional person gaining the benefits of knowledge. Restricting knowledge is thus inefficient, but the patent system also grants (temporary) monopoly power, which gives rise to enormous economic inefficiencies. In the USA, high prices make drugs particularly costly for people without

insurance; in the developing world, people cannot afford brand-name drugs, but might be able to afford generics. Generic versions of first-line AIDS drugs, for instance, have reduced the cost of treatment by 99% since 2000, from US\$10 000 to \$130 per year.<sup>7</sup>

Advocates of intellectual property argue that such protection is necessary to provide incentives for research. But drug companies spend far more money on advertising and marketing than on research, far more on research for lifestyle drugs than on life-saving drugs, and almost no money on diseases afflicting the poor countries, such as malaria. The reason is economics: companies direct their research where the money is, regardless of the value to society. Poor people cannot pay for drugs, so there is little research on their diseases, no matter what the costs to society.

There is, moreover, little relation between private rewards and social returns. A me-too drug can be highly profitable, even if its value to society is limited. Similarly, companies raced to beat the human genome

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**Mariam Sabo has her own cotton field, independent of those of her husband and family, in Burkina Faso**

She cannot make money despite good yields because cotton prices are below production costs. Burkina Faso produces some of the world's highest quality, low-cost cotton, but huge American and European cotton subsidies are destroying the industry.

project to obtain patents on genes, such as *BRCA1* and *BRCA2* in breast cancer. The value of these efforts was minimal: the knowledge was produced a little sooner than it would have been otherwise. But the cost to society was enormous, encompassing far more than the wasted duplication of research. In the USA, the high price that Myriad Genetics, the holder of the *BRCA* patents, will charge for genetic tests—over \$2500—means that many women, who could otherwise have been tested, discovered that they were at risk, and taken appropriate remediation, might die instead.<sup>8</sup>

Trade advocates claim that in the World Trade Organization (WTO) there are built-in flexibilities that allow access to life-saving drugs through compulsory licensing. But these provisions were designed to make it difficult for countries to issue such licences. If they wanted developing countries to have access to essential drugs, they should have allowed automatic licences for all drugs except those that are not essential. When Thailand or Brazil proposed to issue compulsory licences, enormous pressure came from the USA not to do so.<sup>9</sup> To further discourage governments from setting standards for granting patents that balance the social benefits and costs, these trade agreements allow private parties to sue governments at the WTO. (In most other arenas, only governments can bring action in the WTO.)

The data-exclusivity provisions of the bilateral trade agreements are, in some respects, even worse. They restrict the use of drug-company data (even when generated by publicly funded research and/or published) to validate safety and efficacy. Some of the trade agreements seem to restrict use of bioequivalency. If a generic drug can be shown to be equivalent to a drug that has been approved, why should it not be approved as well? Moreover, if a drug has been proven safe and effective, there are ethical problems in testing an equivalent generic against placebo. Data exclusivity (with other related

provisions) can thus extend the effective life of a patent by as much as 10 years.

But unlike patents, challenges to claims of data exclusivity in court seem impossible, and there are worries that data exclusivity may even prevent valid patent challenges from occurring before the period expires.

These adverse effects of trade liberalisation, and trade agreements on health are not inevitable. They are the result of how we have managed trade—to enhance profits of the drug companies, not to enhance the health of those in the developing countries. As I,<sup>6</sup> and Richard Smith and other colleagues in another paper in this Series,<sup>10</sup> have proposed, we can reform our trade regimes and the way we finance and encourage research into drugs so as to improve health—and even lower costs.<sup>6,10</sup>

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