Access to Global Disease Innovation

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The health needs of the world’s poorest people are not being adequately served by market-driven health systems. Some health care goods and services are produced globally, but the poor lack resources to create and sustain the attention of global markets. Two salient examples for the IGWG are global markets for biomedical R&D and pharmaceutical intellectual property (IP) rights.

In wealthy economies, the pharmaceutical IP system works tolerably well, especially when supported by generous government grants (such as the US National Institutes of Health) and tax subsidies (such as R&D tax credits and the Orphan Drug tax credit). In wealthy countries, access issues from IP-induced higher prices are ameliorated by government-subsidized insurance and other social mechanisms. These subsidies total hundreds of billions of dollars in OECD member countries. The pharmaceutical IP system works in wealthy countries because massive subsidies and social insurance compensate for its weaknesses.

Poorer countries lack the resources to provide these subsidies and social insurance mechanisms. Poorer countries cannot afford multi-billion dollar NIH-style grant programs to focus attention on local health conditions. They cannot subsidize the cost of patented medicines to the point where they are affordable in a practical way to their citizens in dire need. The pharmaceutical IP system simply doesn’t work for the world’s poorest people, a message which has been clearly articulated for many years by leading advocates for equitable access to medicines.

The mission of the IGWG is to find solutions that work for all WHO member countries, both in biomedical R&D and in access to patented health technologies.

Neglected & Global Diseases

Much attention has been focused over the past decade upon ‘neglected’ or ‘tropical’ diseases, conditions largely overlooked by global pharmaceutical research companies. (Type III diseases) (WHO 2006c). Examples include onchocerciasis (river blindness), leishmaniasis (kala-azar), Chagas disease, and African sleeping sickness. In the past few years, donors have created several significant initiatives to direct R&D towards these neglected diseases. While these are significant diseases, we should note that total global deaths from the tropical-disease cluster in 2001 were only 128,000 people. (Mathers, Lopez & Murray 2006, Table 3B.1).

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The neglected disease literature tends to overlook the fact that chronic conditions in the high-income and low-income worlds are converging. Non-communicable disease accounted for 47% of the global burden of disease in 2001 (WHO 2004b) and about 49% of the global DALYs in 2001. (Mathers, Lopez & Murray 2006, Annex 3C).

It is the poor themselves who are neglected, rather than just their diseases. Global diseases\(^2\) (Type I and II) are conditions which affect patients in both rich and poor countries. The global disease list includes many of the major chronic conditions associated with wealthy countries — including cardiovascular disease, stroke, mental illness, diabetes, and arthritis. These wealthy country diseases are also the leading causes of adult disease burdens throughout the world. (WHO 2006c; WHO 2004; Outterson 2005a, at 244-46).

Many of these conditions disproportionately affect the poor. Take the example of cervical cancer. In high-income countries, deaths from cervical cancer are relatively rare due to expensive population screening and treatment. Deaths from cervical cancer in low- and middle-income countries totalled 218,000 in 2001, exceeding the deaths from all diseases in the tropical-disease cluster. (Mathers, Lopez & Murray 2006, Table 3B.1) A highly effective vaccine is now available to prevent most cases of cervical cancer (Harper, Franco, Wheeler, Moscicki, Romanowski, et al. 2006), but the price – US$360 per person – exceeds the per capita annual health budgets for most of the women worldwide who need it. (Outterson 2006b).

R&D Incentives for Neglected Diseases

Several recent proposals attempt to correct the neglected disease market failure by creating mechanisms such as purchase commitments and prize funds (Kremer & Glennerster 2004, Hollis 2004). Many public-private partnerships have accelerated neglected disease research (Moran, et al. 2005). Others look to non-market incentives such as grants and government-sponsored research (Love 2003a-b, Hubbard 2003, but see DiMasi & Grabowski 2004). Occasionally proposals are coupled with an expansion of IP rights in poor countries (Sykes 2002), but expanded IP rights are an unnecessary and unwelcome addition. Expansion of IP rights will not create incentives in the absence of money to buy the product. These diseases are neglected due to the poverty of the afflicted, not the lack of IP rights (Outterson 2005a, at 241-46).

\(^2\) Herein, the term global disease refers to conditions for which a therapeutic market exists in high-income countries, and the condition is also endemic to the low or middle income world. The definition of global disease is not static. Malaria was once a global disease, but is now largely eradicated in high-income countries, rendering it potentially neglected were it not for research for military and tourist markets. Tuberculosis remains a significant condition in OECD markets, even though its disease burden falls heavily on the poor. For a fuller discussion on global diseases in this context, see Bradly Condon & Tapen Sinha, *Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries*, NW. J. INT’L L. & BUS. 1, 25-28 (2005); Outterson 2005a, at 244-250. The WHO Commission preferred the Type I, II and III terminology. (WHO 2006c).
R&D Incentives for Global Diseases

Global diseases (Types I and II) afflict both rich and poor. For global diseases, innovation is assured by demand in wealthy OECD countries. Collection of IP royalties from low-income populations is not important for global disease innovation. These drugs could be provided generically to the poorest without undermining optimal innovation. The deaths of less than 17,000 women per year in wealthy countries offered sufficient financial rewards to prompt both Merck and GlaxoSmithKline to spend hundreds of millions of dollars to bring HPV vaccines to market. The deaths of more than 222,000 poor women per year may have provided moral, scientific or humanitarian incentives to create HPV vaccines, but the potential financial rewards were modest, since these women can’t afford an expensive vaccine. (Outterson 2006b).

Pharmaceutical rent extraction is best accomplished in high-income populations, among people who can afford expensive patented drugs. The burden of supporting innovation should rest upon those with the ability to afford expensive medicines. This principle has been embraced by pharmaceutical companies and major Western governments. Price discrimination based upon ability to pay underlies all voluntary differential pricing programs, as well as the recent Canadian legislation to permit export of compulsory licensed pharmaceuticals for low-income populations. In the Canadian program, the royalty varies with the poverty of the target country (The Jean Chretien Pledge to Africa Act 2004). The United States Department of Commerce followed suit in December 2004 when it calculated pharmaceutical free riding by various OECD countries, with adjustments for per-capita GDP (US Department of Commerce 2004, fig. 5). High-income individuals typically have low demand elasticities for patented pharmaceuticals, permitting both high prices and relatively modest access externalities. In such situations, both clinical needs and innovation goals can be met simultaneously.

Access to Global Disease Innovation

Global disease innovation can be offered to low- and medium-income countries without damaging innovation. One mechanism could be to purchase the non-OECD patent licenses from pharmaceutical companies at a price which reflects the foregone R&D cost recovery in those markets. Since a relatively small proportion of global pharmaceutical profits come from the poorer countries, the price of this buyout would be relatively modest. For cervical cancer vaccines, the indicated buyout price might be a low at $30 million per year until patent expiry. The purchased patents could be contributed to a nonprofit patent pool, or otherwise made available for royalty-free licensing to legitimate companies, exclusively for the targeted geographic areas. (Outterson 2006b).

While diversion, theft and arbitrage from low-income to high-income markets is a potential threat, companies and governments possess many tools to block pharmaceutical arbitrage, and empirical evidence of significant dysfunctional arbitrage is limited. (Outterson 2005a)
The much more significant threat to high-income country patent rents – and to public health – comes from counterfeit pharmaceuticals, which are greatly encouraged by the high price discrimination ratios made possible by IP law. (Outterson 2005a & 2006a). Counterfeit pharmaceuticals are a grave threat to health in the developing world, (WHO 2006b) and the US drug supply chain itself appears remarkably vulnerable. (Eban 2005). One important ancillary advantage of generic pricing is the virtual elimination of the incentive to counterfeit drugs in low- and medium-income countries: with artificial price discrimination stripped away, the vast majority of the economic incentive to create a counterfeit disappears. (Outterson 2005a).

Conclusion

The pharmaceutical IP system works well in high-income countries able to afford government subsidies and social insurance. It does not work for the poor in low- and middle-income countries. For global diseases (Types I and II), innovation is assured by high-income country markets alone, permitting an accommodation for the poor in low- and medium-income countries such as a patent buyout or other access programs which support equitable access without damaging optimal innovation incentives.

References:


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