Arguably the most controversial aspect of the World Trade Organization’s Agreement on Trade-related Aspects of International Property Rights (TRIPS) is over the issue of patents for pharmaceutical drugs. To their proponents, patent rights are essential to encourage innovation, as the virtual monopoly they create allows firms to extract greater profits from drugs that they invent. Opponents, however, point out that patents result in higher prices, making essential medicines less affordable. In this paper, I address the issues of health access and medical research in turn. I first examine how implementation of the TRIPS agreement restricted health access in developing countries and assesses whether these concerns have been subsequently addressed. It then examines the effects of patents on stimulating medical research, and discusses cases of market inefficiencies and failure. It goes on to consider several approaches that attempt to fix some of these shortcomings, and concludes by suggesting six points essential to a comprehensive strategy in tackling these issues.

**Barriers to Distribution**

**Background: The TRIPS agreement**

The TRIPS agreement was brought into effect on January 1, 1995. The agreement unambiguously extended the scope of intellectual property rights, declaring in Article 27 that “patents shall be available for any inventions, whether products or processes, in all fields of technology.” Moreover, patent rights would be “enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

These provisions were in part a response to the lack of protection for pharmaceutical products in countries such as India, whose 1970 Act of Parliament granted “patent rights only to manufacturing processes, rather than to the end products themselves,” allowing Indian firms to ‘reverse-engineer’ the production process and manufacture generic copies of drugs. Pharmaceutical companies in the US and EU had campaigned in favor of the agreement, as the provisions ensured that any company that invented a drug would have exclusive rights over its production and distribution for the duration of the patent. However, by preventing cheap generic copies of a drug under patent from being produced, the TRIPS agreement had serious ramifications for public health. The ability of patents to restrict access to treatments for diseases became glaringly evident with the rapid spread of HIV/AIDS.

**The AIDS pandemic**

The first cases of Acquired ImmuneDeficiencySyndrome (AIDS) were documented in 1981 in the US and UK. By 1997, UNAIDS reported that 30 million people were infected with HIV. There were estimated to be 3 million cases of HIV/AIDS in India alone. In Sub-Saharan Africa,
the effects were far worse; already, the region accounted for more than half the HIV/AIDS cases worldwide.\(^8\) That ratio has scarcely improved since.\(^9\)

The development of antiretroviral (ARV) treatments for HIV/AIDS appeared “to be a remarkable success story, with more than 20 highly effective medicines developed in the past 17 years.”\(^10\) However, the average yearly cost of antiretroviral treatment using patented drugs is $10,000-15,000 per person.\(^11\) Of the population of developing countries, roughly one billion people live under a dollar a day.\(^12\) Given that per capita health expenditures in low income developing countries average $23 per year, only a fraction of those infected with AIDS in Third World countries could afford such treatment.\(^13\)

**South Africa authorizes generics**

Responding to the alarming growth of HIV infections in the country, South Africa passed a law in 1997 giving the government “blanket powers to...produce or import cheap alternatives to the brand-name drugs for HIV and other diseases.”\(^14\) Since producers of generics do not need to invest money in research, they can sell at a fraction of the cost of patented drugs. As Appendix A shows, this fraction can be as little as six percent.

Thirty-nine pharmaceutical companies raised a court challenge to prevent South Africa from implementing the law. John Barton, former chair of the UK Commission on Intellectual Property Rights, observes that this move “became a public relations debacle for the industry.”\(^15\) A multitude of NGOs, including Oxfam and Medecins Sans Frontieres (MSF), sharply criticized the pharmaceutical companies for attempting to restrict health access. With pressure mounting, the companies eventually dropped their challenge, “after threats that the amount of public support for the development of the relevant drugs would be publicized in the hearings.”\(^16\) Despite the victory, the South African government has been criticized for moving too slowly on resolving its AIDS epidemic since then.\(^17\)

**Brazil’s fight against AIDS**

In 1996, the Brazilian government began offering free ARV therapy to people with AIDS. As the costs of this program grew, the government expanded its health budget and increased its production and import of generics. Brazil also used the threat of compulsory licensing – authorizing companies to produce generic copies of patented drugs – to force patent-holders to cut prices.\(^18\) As a result, drug prices in Brazil are much lower than other countries and the government has succeeded in cutting AIDS mortality rates by 50 percent.\(^19\)

In response to Brazil’s actions, the US filed a complaint with the WTO in early 2001, accusing the government of violating TRIPS. As in the case of South Africa, the move backfired. In April 2001, all members of the UN Human Rights Commission except the US supported a Brazilian resolution asking nations not to “deny or limit equal access for all persons to preventive, curative or palliative pharmaceutical or medical technologies used to treat pandemics such as HIV/AIDS.”\(^20\) The US withdrew the complaint in June 2001, saying it would pursue the issue in bilateral talks.

**Doha and the August decision**

The spread of the AIDS pandemic, along with highly publicized cases such as Brazil and South Africa, contributed to increased awareness on an international level that patents threatened to severely restrict access to health in developing countries. This awareness contributed to the outcome at Doha in November 2001, hailed as the development round of the WTO. In response to the issue of patents on pharmaceutical drugs, the conference released the “Declaration on the TRIPS agreement and public health” on November 14. The declaration did not offer any substantial revisions to TRIPS; rather, it recognized flexibilities that already exist in the agreement, such as Article 31, which establishes the procedures by which a compulsory license may be granted. According to 31(f), a compulsory license must be “predominantly for the supply of the domestic market of the Member authorizing such use.”\(^21\)

The Doha declaration stressed that TRIPS “should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”\(^22\) Moreover, “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”\(^23\) Recognizing that due to Article 31(f), countries lacking sufficient drug manufacturing capacity would have difficulty employing the compulsory licensing clause, the agreement referred this issue to the Council for TRIPS to resolve by the end of 2002. The decision, eventually made on August 30, 2003, allowed all least-developed countries (LDCs), as well as any other member that provided prior notification, to import generics from abroad by issuing a
compulsory license. The requirements of 31(f) would be waived for this purpose.\textsuperscript{24}

\textit{An imperfect solution}

With the conclusion of these agreements, the world is moving towards a consensus that differential pricing – making the costs of medicine cheaper for people in developing countries than in developed countries – is a solution to the issues of health access raised by patents. The argument makes economic sense, as developing world markets provide minimal incentive for research; “the total market of the poorest countries...is on the order of 1 percent of the global pharmaceutical market.”\textsuperscript{25} Moreover, the logic of patents is that they allow prices to be artificially high on the understanding that increased profits will be fuelled back into research. As John Barton observes, “It seems reasonable that the burden of these costs, which benefit all of humanity, should fall more heavily on the wealthy than on the poor.”\textsuperscript{26} Nonetheless, while the Doha agreements were an important step towards promoting health access, several issues remain.

The pharmaceutical industry is correct to point out that patents are not the only obstacle to health access. There is a range of causes including poor health infrastructure, lack of sanitation, and shortage of funding for even generic drugs. Any comprehensive approach to tackling the problem will need to address all of these factors.

Moreover, despite the Doha agreements, patents still have the potential to restrict health access. A key concern is whether the production of generics will decrease as a number of developing countries fall under the patents regime on January 1, 2005. The Commission on Intellectual Property Rights notes:

“There will be no incentive, as now, for manufacturers in these countries to reverse engineer newly patented drugs and take the other steps necessary for manufacture and sale (including obtaining regulatory approval), because the domestic market would be closed. Thus the ready supply of generic substitutes for patented drugs now available will gradually disappear. Potential compulsory licensees would therefore have to charge a price closer to full economic cost (including start-up and manufacturing costs) as compared to the possibility of providing off-the-shelf generics at prices where start-up costs have already been amortised to some extent on the domestic market. Moreover, if the necessary investment is only triggered by the availability of a compulsory licence, there will inevitably be long delays before the drug actually reaches the intended patients.”\textsuperscript{27}

Addressing the economic question is as important as addressing the legal one. MSF has been campaigning for an “Article 30 exception” that would allow countries like India that manufacture generics to continue exporting to countries that need them.\textsuperscript{28} When member countries of the WTO meet in Hong Kong in 2005, they would do well to ensure that any amendment to TRIPS, incorporating the August 30\textsuperscript{th} agreement, also addresses concerns that a supply of generics be readily available for developing countries.

\textbf{Incentives to Innovate}

The logic behind patents is a form of social contract between society and firms. Society agrees to grant patent-holders a temporary monopoly, thus allowing them to set prices at an artificially high level, on the understanding that doing so will provide a strong incentive for innovation. In the case of an industry constantly creating new products, such as the pharmaceutical industry, the assumption is that much of the increased profits will be fuelled back into research, resulting in new treatments for diseases being discovered.

There is a general consensus that patents on pharmaceutical drugs provide a very strong economic incentive for research. The R&D requirements of creating new drugs are significant, and the potential payoff that a patent grants encourages companies to make the necessary investments. However, while one must acknowledge these incentives, it is essential that an optimal balance be struck between the benefits to society from increased innovation and the costs of paying the patent derived price. There are certainly reasons to question whether such a balance currently exists.

\textbf{Inefficiency and waste}

Pharmaceutical companies argue that a new drug may cost $500-$800 million to develop, and that perhaps only 30 percent of these drugs may make a good return, though as the Commission on IPR observes, these figures are “contentious.”\textsuperscript{29} Still, there is no doubt that the industry is compensated well, having occupied
the top of the Fortune 500 list for most of the last two decades. And yet it is far from ideal in terms of developing new treatments for diseases. According to MSF, the industry spends twice as much on marketing as on R&D and “It is in any case a vastly wasteful mechanism for encouraging innovation, since only one tenth of drug sale profits is plugged back into R&D.” Moreover, as a study in The Lancet showed, “68 percent of all new chemical entities marketed worldwide in the last 25 years were ‘me-too’ products, representing little or no therapeutic gain.” As such, substantial resources may be diverted from meaningful innovation, without any significant drop in prices.

An ounce of cure is worth a pound of prevention

In addition to inefficiency, the market system can also be a source of research bias. According to the International AIDS Vaccine Initiative (2002), private industry HIV/AIDS vaccine R&D expenditure totaled a meager $50 – $70 million. By contrast, even conservative estimates put the cost of developing a single antiretroviral drug at $200 million. In a working paper for the Center of International Development (CID) at Harvard University, Michael Kremer and Christopher Snyder explain the gap in expenditure by presenting an economic model that predicts “drug revenue could exceed vaccine revenue by more than a factor of four” in the case of sexually transmitted diseases. This market bias carries disturbing implications for the prospect of developing vaccines for such diseases.

Neglected diseases: A clear case of market failure

However efficient research may be, patents cannot provide an incentive for R&D into treatments for diseases that do not have a market. The lack of a market does not imply a lack of customers; it implies an inability to pay. Treatments exist for AIDS, as pharmaceutical companies could be certain of recovering R&D expenditures in the developed market, regardless of whether poor nations purchased their drugs. There is no such guarantee for tuberculosis, pediatric AIDS, malaria and other tropical diseases that affect people primarily in poor nations. The Commission on IPR observed:

“So what role does IP protection play in stimulating R&D on diseases prevalent in developing countries? All the evidence we have examined suggests that it hardly plays any role at all, except for those diseases where there is a large market in the developed world...The heart of the problem is the lack of market demand sufficient to induce the private sector to commit resources to R&D.”

The Commission estimates that less than five percent of pharmaceutical R&D worldwide is spent on diseases that predominantly affect the developing world. The imbalance is shown in Figure 1.

Possible Solutions

Awareness of these shortcomings has contributed to the emergence of a number of alternative approaches that attempt to correct the shortcomings in the research system. Many of these initiatives however, came up only recently and have not yet been evaluated for effectiveness. Others remain under-funded; the pharmaceutical industry still funds most global R&D for health, estimated in total at $75 billion in 2002. A few of the most interesting initiatives

Figure 1: Global pharmaceutical market and disease R&D targets

A – Global Diseases (e.g. cancer, cardiovascular diseases) affect people everywhere and constitute the major focus of the R&D-based pharmaceutical industry.

B – Neglected Diseases (e.g. malaria, TB, HIV/AIDS) mainly affect people in poor countries, but a small market in wealthy countries prompts R&D efforts.

C – Most Neglected Diseases almost exclusively affect people in developing countries who are too poor to pay for treatment. They do not represent a viable market, and therefore fall outside the scope of the drug industry’s R&D efforts. Most neglected diseases include sleeping sickness, Chagas disease, Buruli ulcer, Dengue fever, leishmaniasis, leprosy, lymphatic filariasis and schistosomiasis.

Z – Pharmaceutical products that do not correspond to major public health problems (comfort and lifestyle).

follow:

The Global Fund to Fight AIDS, Tuberculosis and Malaria was created on the initiative of UN Secretary General Kofi Annan, governments of African countries and the G8, in 2001. The Fund is a partnership between governments, civil society, the private sector and affected communities. Its purpose is to “dramatically increase resources to fight three of the world’s most devastating diseases.” French President Jacques Chirac has called for a commitment of $3 billion a year to the Fund so that it is able to provide sufficient resources to the various initiatives it supports.

Public-private partnerships (PPPs) and not-for-profit drug development initiatives bolster research on neglected diseases by “matching existing capacity, expertise and resources in both the public and private sector on specific projects or diseases.” The Bill and Melinda Gates Foundation is a major contributor to PPPs focusing on neglected diseases.

In addition, many innovative approaches have been suggested but not yet initiated. Notable among these is the idea of establishing a vaccine purchase fund, as suggested by Jeffrey Sachs, noted economist and former Director of the CID at Harvard. In “The Case for a Vaccine Purchase Fund,” Sachs, et al. argue that while there exists significant evidence that development of vaccines for AIDS, tuberculosis and malaria is scientifically feasible, there is no economic incentive for pharmaceutical companies to invest in their development. Thus, the authors propose establishing an artificial market: governments contribute to the fund according to their means, but no actual expenditure is made until some firm develops a reliable vaccine. The fund would then purchase the vaccines to immunize children in low-income countries where these diseases are prevalent. The authors argue that there are two advantages to this approach that do not exist in public funding of research: there is a stronger incentive for researchers to focus on vaccine development, and the cost of failures is borne by firms rather than taxpayers. Sachs and his colleagues estimate that prices of $10 – $40 should provide sufficient incentive, resulting, if vaccines for all three diseases are discovered, in immunization of 160 million children per annum at a yearly cost of $1.6 – $6.4 billion to the fund. This they see as a modest cost for eradicating diseases that together account for nine percent of all deaths.

Conclusion: The Way Forward

Clearly, in the complex matters of health access and medical research, one cannot expect any single approach to work across all countries and all diseases. But turning ideas into results will require coordination and direction. At present the World Health Organization is the one entity capable of fostering the growth of such a global commitment. The WHO is in a unique position due to its status as the only organization legally mandated as responsible for global health issues. It has significant achievements to its credit in the past, such as the eradication of smallpox, efforts to improve sanitation in developing countries, and establishment of biological standards for food and drugs. Recently, the WHO helped coordinate an “unprecedented” international effort to contain the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003. Thus, the WHO should take on a leadership role, coordinating global health efforts with long-term vision, and a concrete but flexible plan for implementation. Details of such a plan are best left to the organization, but its success will rely on adherence to the following six principles.

First, the WHO should set an R&D agenda for the world, prioritizing diseases based on which ones constitute major global health concerns. This global research agenda should be dynamic, with the WHO periodically reassessing the burden imposed by diseases and adjusting priorities as necessary. Once the agenda is set, governments should promote research into diseases deemed high priority.

Second, the WHO should campaign for differential pricing between developed and developing countries to be established as routine in the case of essential drugs. Differential pricing could be arranged for by pharmaceutical companies or by the availability of generics, though developing countries should have the flexibility of both options. The organization should also lobby for an amendment to TRIPS in line with the waiver of Article 31(f), and it should stress the need to ensure a sufficient supply of generics, by amendment or other means.

Third, the WHO’s regional offices should continue to help developing countries work on infrastructure, availability of treatments, sanitation and other potential barriers to health access. It should pressure governments of these countries to increase health spending and match these efforts with commitments from developed countries to provide funds, transfer of technology, or skills and expertise. The WHO should also initiate programs
to facilitate the establishment of pharmaceutical manufacturing sectors in LDCs and other countries that lack such capability.

Fourth, the WHO should continually assess the efficacy of various initiatives by governments, NGOs, PPPs and other groups that aim to address some shortcoming in health care or the current system of research. The WHO can use its existing Civil Society Initiative (CSI), set up in June 2001, for this purpose. CSI teams should assess the effects of such initiatives on a yearly basis, bringing to public attention the best practices for experience sharing, and as projects for donor funding. CSI should also recommend approaches that are especially effective and that the WHO could expand to a wider scope of problems or regions than originally envisioned.

Fifth, the WHO will have to continually review the impact of patents on global health. The World Health Assembly established the Commission on Intellectual Property, Innovation and Public Health in 2003. The Commission should be made into a permanent body, capable of carrying out its mandate through required financial and legislative support. Patents are not an inalienable right, but a means towards striking the best balance between innovation and cost. To determine that balance, countries must be able to assess the efficiency of the system. Thus, it would be in the interest of developed nations to assist the Commission with its investigations.

Sixth, the WHO should promote technology transfer and sharing of research outcomes in order to ‘fast-track’ innovation. Where revealing research outcomes may conflict with R&D incentives, the WHO should ask the Commission to determine the ideal balance.

In conclusion, successfully combating disease requires a willingness to put significant resources into efforts. In this age of globalization we must recognize a global responsibility. The HIV/AIDS epidemic, the SARS outbreak; these serve as poignant reminders of the need for concerted action. No single country is capable of eradicating diseases that know no national boundaries, and no single country can hope to remain insulated indefinitely from the world’s problems. As we see major shortcomings in the market-oriented system of medical research, we should increasingly move towards the recognition that global disease cure and prevention is, in simple economic terms, a public good. Only through a sustained and substantial public-sector effort to complement the current privately funded research can a realistic solution be found.

Appendix A: Tables and Data

Section A1: Comparison between cost of patented drugs and Brazilian generics

ANTIRETROVIRAL DRUG PRICES
Difference between proprietary company offers and generic producer prices

Price of AZT/3TC:
- GlaxoSmithKline (proprietary company), special discount price: US$ 2 per day
- FarManguinhos (generic): US$0.96 per day (52% cheaper)

Price of Nevirapine:
- Boehringer Ingelheim (proprietary company): US$1.19 per day (3)
- FarManguinhos (generic): US$0.59 per day (50% cheaper)

Price of AZT:
- GlaxoSmithKline (proprietary company): US$1.6 per day
- FarManguinhos (generic): US$0.09 per day (94% cheaper)

Price of 3TC:
- GlaxoSmithKline (proprietary company): US$0.64 per day
- FarManguinhos (generic): US$0.41 per day (36% cheaper)

From Medecins Sans Frontieres, “Brazilian Generic ARV Drugs in South Africa – the Backgound,” 29th November, 2002
Section A2: Regional statistics for HIV/AIDS end of 2004

![Map of global HIV/AIDS prevalence](image)


Endnotes

1 World Trade Organization, Uruguay Round, 15th April, 1994, Annex 1C (TRIPS), Part II, Section 5, Article 27, Para 1, [http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5](http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#5)
2 Ibid.
4 Typically a period of twenty years.
5 AVERT, “The history of AIDS up to 1986,” [http://www.avert.org/his81_86.htm](http://www.avert.org/his81_86.htm)
7 Ibid.
8 Ibid.
11 Ibid.
16 Ibid.
17 AIDS drugs have been more expensive in South Africa than in Brazil, and the government took until April 2004 to make free antiretroviral therapy available to its citizens. IRIN, UN Office for the Coordination of Humanitarian Affairs, “South Africa: Slow start of ARV rollout,” 1st April, 2004, http://www.irinnews.org/report.asp?ReportID=40383&SelectRegion=Southern_Africa&SelectCountry=SOUTH_AFRICA (Note IRIN’s views do not necessarily reflect those of the UN or its offices.)
18 Supra n. 17.
19 Appendix C shows how much cheaper several antiretroviral drugs are in Brazil. Also see Brazilian Ministry of Health AIDS Drugs Policy, http://www.aids.gov.br/assistencia/aids_drugs_policy.htm
21 Supra n. 1, Article 31(f).
23 Ibid.
24 The resolution was delayed due to demands by the US, and initially the EU, that any exceptions be limited to a predefined set of diseases. These demands were eventually dropped on the condition that the Chair of the WTO General Council read out a parallel statement indicating that the agreement would only be used in good faith, for the purposes for which it was intended. Supra n. 15.
25 Supra n. 15.
26 Ibid.
27 Supra n. 13.
According to Article 30 of the TRIPS agreement, “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”
29 Supra n. 13.
30 Supra n. 10.
31 Ibid.
32 Supra n. 10.
34 Ibid, p. 3.
35 Supra n. 13.
36 Ibid. Or, to put it another way, only 13-16 of 1393 drugs developed between 1975-1999 were aimed at tropical diseases, which account for 10% of the global disease burden.
Supra n. 10.

Examples of PPPs include the Medicines for Malaria Venture (MMV), the Global Alliance for TB Drug Development (TB Alliance), the International AIDS Vaccine Initiative (IAVI), the Institute for One World Health (IOWH), and the Global Alliance for Vaccines and Immunization (GAVI). The Drugs for Neglected Diseases Initiative (DNDi) is a not-for-profit initiative created in 2003 to carry out R&D into new drugs for neglected diseases, such as sleeping sickness, Chagas disease and leishmaniasis.


Since firms are used to taking such risks when they invest in R&D, they would have ample incentive to develop vaccines, provided that the artificial market is large enough.

Supra n. 41, p. 1.

Supra n. 10.

Ibid.

Supra n. 10.

Governments could do so by increased direct R&D funding, providing funds to firms or other organizations, or guaranteeing a market for research output. Governments could also consider imposing disincentives, such as increased taxes, on firms that pour resources into areas of little therapeutic worth.

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