
Managing the hydra: The herculean task of ensuring access to essential medicines

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It is one thing to describe the Augean stables - another thing to clean them

Myres S. McDougal

I. The concept of essential medicines

The task of ensuring access to essential medicines presents a complex and embedded set of problems that will remain a persistent feature of the international governance landscape for the foreseeable future. According to the definition provided by the World Health Organization (WHO):

Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.¹

The WHO's recommended list of essential medicines has been developed with a view to aiding procurement authorities in determining the supplies needed to treat local populations. The price of medicines is a significant factor in determining what should be included on the list since there is small utility in recommending expensive therapies that are not affordable. As the WHO observes:

In developing countries, newer combination antimalarial medicines may be 30–200 times more expensive than chloroquine; medicines to treat multi-drug resistant tuberculosis may cost 20–30 times more than the usual DOTS treatment; and treatment of HIV/AIDS with anti-retroviral medicines may cost between \$400–2500 per year.

Most medicines budgets in developing countries are below \$30 per person per year, with 38 countries having less than \$2 per person per year.²

Nonetheless, the most recent WHO Essential Medicines list includes a significant number of antiretroviral medicines (ARVs) that are under patent.³ These drugs may not be affordable for many HIV-positive individuals, even

¹ Introduction to World Health Organization's (WHO) 12th Model List of Essential Medicines, *available at* <http://www.who.int/medicines>.

² The Selection of Essential Medicines, WHO Policy Perspectives on Medicines No. 4 (June 2002), *available at* <http://www.who.int/medicines>.

³ The following antiretroviral (ARVs) medicines are included on the 12th Model List: Nucleoside reverse transcriptase inhibitors (1) Abacavir (ABC) (2) Didanosine (ddI) (3) Lamivudine (3TC) (4) Stavudine (d4T) (5) Zidovudine (ZDV or AZT); Non-nucleoside reverse transcriptase inhibitors (1) Efavirenz (EFV or EFZ) (2) Nevirapine (NVP); Protease inhibitors (1) Indinavir (IDV) (2) Ritonavir (3) Lopinavir + Ritonavir (LPV/r) (4) Nelfinavir saquinavir (SQV) (NFV). The Model List is revised periodically.

taking into account recent price declines, unless public health budgets in developing countries are supplemented by international assistance.

The world community is presently confronted with tremendous public health challenges due to HIV/AIDS, malaria and tuberculosis. Yet, populations around the world, and especially in developing and least-developed countries, face heavy public health burdens from many sources, including other infectious diseases, diarrheal diseases, cancer, diabetes, heart and circulatory disease, and other conditions.⁴ While HIV/AIDS is the most immediate problem, it is not enough to address only this scourge.

Although there has been considerable public debate concerning the effect of patents on access to medicines, ensuring adequate supplies involves an extensive regulatory framework encompassing a multiplicity of factors. These include:

- Research and Development
- Safety and Efficacy (including Liability)
- Manufacturing Systems and Controls (Good Manufacturing Practices)
- Intellectual Property
- Procurement, Distribution and Dispensing
- Health Care Personnel and Infrastructure
- Financing

Each of these elements in the essential medicines supply chain can and does act as a roadblock. Yet, each element is present for a reason. It is not helpful to supply inexpensive medicines if they are not safe and effective, or if they are prescribed to treat the wrong condition.

II. Public goods, private markets and public finance

The supply of essential medicines is a “public goods” problem in the sense that the private market does not adequately address it. Health care systems throughout the world require an array of low-cost medicines - some under patent by originators, some not - for distribution through public hospitals and clinics. But the provision of health care services is not limited to the public sector, even in the lowest-income countries.

⁴ See Annex Table 3 of the World Health Organization, World Health Report 2002. In Africa, HIV/AIDS is the number one killer, with malaria, diarrheal disease and respiratory infections also major killers. Yet, cancer, cardiovascular disease and non-infectious respiratory disease are also major causes of premature death. In South-East Asia, cancer, cardiovascular disease and diabetes are major causes of premature death, along with HIV/AIDS, diarrheal diseases, TB and measles. Cardiovascular disease and cancer are major killers throughout the Americas. Many of the disease burdens disproportionately affect children.

A. *Public goods and private markets*

If the concept of “public goods” is limited to goods and services supplied by governments and non-governmental organization (NGOs), then the problem of providing access to essential medicines might be described as a mixed public goods-private market problem. Consumers of health care services from private doctors and pharmacists require low-cost medicines just as consumers using public providers.

B. *Pandemics and public finance*

Even if the private market might be adapted in the general case to address the demand for essential medicines, pandemic scale public health problems, such as HIV/AIDS are beyond the capacity of market mechanisms. Pandemic scale public health problems overwhelm the financial capacity of developing countries, and they require international cooperation and a multilateral financial response.

The establishment of the Global Fund, and the more recent adoption by the United States of legislation to substantially increase funding of efforts to treat the HIV/AIDS pandemic, are steps in the right direction. Nevertheless, even assuming that the United States fulfills its recent promises, the budgeted amounts fall far short of that needed for a comprehensive response.

C. *The political dimension*

At the heart of the essential medicines problem is the lack of political will to address it. Whether the question is one of increasing public funding or adapting private market mechanisms to better accommodate the needs of individuals in differing economic circumstances, change cannot take place without the support of decision-makers in control of national governments and multilateral institutions.

1. *The question of leadership*

Within each nation, the public health budget competes with other governmental interests for priority. This reality prevails not only in countries that lack resources, but also in countries where there are substantial resources that are not directed toward the goals of disease prevention and treatment.

The problem of delivering treatment for the HIV/AIDS pandemic, while perhaps atypical among global public health problems, helps illustrate the political difficulties in ensuring access. Because the need to address HIV/AIDS is so apparent, the failure of political leadership to act calls attention to the difficulties affecting less striking problems.

ii. At the national level

It is useful to compare and contrast leadership issues in the very different contexts of developed and developing countries.

1. Developed country side

Using the United States to illustrate the developed country side, the government provides massive medicines research funding through its National Institutes of Health (NIH), the bulk of which is directed to addressing disease problems in the United States.⁵ Since many diseases, including HIV/AIDS, affect both the U.S. and developing countries, the NIH funding does indeed create “potential” public goods that are useful to developing countries. Yet, the medicines that result from NIH-funded research are patented (directly or indirectly) by pharmaceutical enterprises, and the pricing practices of these enterprises determine the level of access to them in developing countries.⁶

The U.S. Congress in early 2003 approved legislation authorizing a substantial increase in funds for treatment of HIV/AIDS in selected developing countries.⁷ This may reflect a turning point in the formation of political will on the developed country side, but at least until now, budget allocations have been far too low to meaningfully address HIV/AIDS, let alone the other public health problems affecting developing countries.

The U.S. faces budgeting and resource constraints. Although these constraints may differ in scale from those affecting developing countries, they are nevertheless real. A decision to allocate a significant portion of the U.S. budget to aid for developing-country public health problems requires the support of local constituencies that are in a position to make competing resource demands.

Critical decisions concerning public health policy outside the United States are typically relegated to executive agencies concerned with commercial affairs,

⁵ “The NIH, of course, is the focal point for American health research, spending about \$28 billion a year pursuing basic research into cancer, heart disease, diabetes, AIDS and other life-threatening diseases. Most of the U.S. advances in health in the past 30 years have come from the agency that Dr. Zerhouni now heads.” Moderator: Tammy Lytle, National Press Club President, Biomedical Challenges, National Press Club Luncheon with Dr. Elias Zerhouni, Director, National Institutes of Health (6 Mar. 2003). The Director of NIH, Dr. Elias Zerhouni, was recently quoted as follows:

There’s no doubt that NIH has been a terrific federal investment. It has been at the basis, if you will, of most of the discoveries made in the past 50 years that have advanced our health. Of over 100 Nobel prizes, half of all the American Nobel prizes have been trained or funded, developed with NIH’s help. *Id.*

⁶ See below discussion of NIH policies.

⁷ Amy Goldstein & Dan Morgan, *Bush Signs \$15 Billion AIDS Bill; Funding Questioned*, WASH. POST, 28 May 2003, at A2.

rather than health. External medicines policy has been determined principally by the U.S. Trade Representative (USTR), who has consistently represented the interests of the U.S. research-based pharmaceutical sector.⁸ There has been little practical consideration given to the question of access to medicines in developing countries. There is a minimal voting constituency with an interest in external patents policy. The only counterbalance to a strictly commercially-oriented external policy is provided by NGOs. This contrasts with growing interest among U.S. consumers in domestic medicines patent policy, particularly as it affects pricing and access.

The problems arising from the ability of the external commercial trade apparatus to exercise control over medicines policy is becoming increasingly serious, because the United States has decided to override the flexibilities built into the TRIPS Agreement by negotiating high patent protection terms in bilateral and regional agreements.⁹ This forum-shifting policy threatens to undermine progress that developing countries may otherwise make in obtaining lower-priced access to medicines through use of those flexibilities.

Secretary of State Colin Powell recently has begun to take a more visible role on HIV/AIDS questions, particularly with respect to Africa.¹⁰ This is a positive

⁸ The USTR is responsible for negotiating U.S. trade agreements, and as such is responsible for the drafting of provisions concerning protection of intellectual property rights (IPRs), data protection and related regulatory issues. The principal U.S. industry lobbying group for the domestic R & D based pharmaceutical industry is PhRMA (the Pharmaceutical Research and Manufacturers of America), see <http://www.phrma.org>. The President of PhRMA, Allen Holmer, is a former senior USTR official. PhRMA submits an annual Special 301 report to USTR setting out its objective on protection of IPRs (posted *id.*). USTR positions at the WTO on medicines issues typically restate positions developed and published by PhRMA, and USTR has recently advised developing country delegates in TRIPS negotiations that they should deal directly with the pharmaceutical industry to satisfy their concerns. See, e.g., *U.S. Wants Resolution to TRIPS, Public Health Debate Before Cancun*, INSIDE U.S. TRADE, 4 Apr. 2003.

⁹ See Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, CIPR Background Paper 8, (CIPR 2002) (published in 5 J. WORLD INTELL. PROP. 765 (Sept. 2002)).

¹⁰ For example, a recent article reports the following news:

Powell, in a round of interviews on postwar Iraq, has been mentioning the issue frequently, saying that Bush will push even harder to advance the AIDS initiative.

"Why? Because it's the biggest killer on the face of the earth, more so than any army, any regional instability, or anything anybody can imagine a weapon of mass destruction can do," Powell told US News & World Report. "The greatest weapon of mass destruction today on the face of the earth is the HIV virus, and it is a destroyer of people, families, nations, societies, and hopes in the poorest parts of the world. And it is spreading."

John Donnelly, *Bush to Seek Action on \$15b AIDS Plan*, BOSTON GLOBE, 29 Apr. 2003, at A8.

development on the political side in the sense that it should facilitate additional financial support for treatment. However, the extent to which the State Department will broadly support access to medicines for developing countries remains an open question. The State Department was very active in the campaign the U.S. waged against South Africa over implementation of the Medicines Amendment Act,¹¹ and it has been an ardent supporter of pharmaceutical industry interests.

As regards financial support, the United States has done more than Europe to support access to medicines in developing countries, so it is not a matter of singling out the former. The European Commission is nearly as aggressive as USTR in representing the interests of the EU pharmaceutical sector,¹² and one of the reasons it can act in a somewhat more balanced way in multilateral forums is that it knows the U.S. will do some of its work for it. Since the European Commission and the EU member states are tough in their dealings with pharmaceutical companies at home (demanding strong price controls and other concessions), there is perhaps an even starker contrast between domestic and foreign policy in the EU than in the United States.

2. Developing country side

The need for and importance of political leadership is perhaps even more apparent when viewing the developing countries. To take HIV/AIDS as an example once again, only a few developing country governments have made treatment a national priority, such as Botswana, Brazil, Thailand and Uganda.¹³ Others, such as China, India, Russia and South Africa, have not

¹¹ See, e.g., Letter of Barbara Larkin, Assistant Secretary, Legislative Affairs, U.S. Dep't of State (5 June 1999) (enclosing Report on U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(C) of the South African Medicines and Related Substances Act of 1965), *quoted in* Frederick M. Abbott, *The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO*, in *THE POLITICAL ECONOMY OF INTERNATIONAL TRADE: ESSAYS IN HONOR OF ROBERT E. HUDEC* 311, fn. 20 (Daniel L.M. Kennedy & James D. Southwick eds. Cambridge University Press 2002).

¹² The European Commission, for example, joined the United States in aggressively threatening South Africa for its adoption of the Medicines and Related Substances Control Amendments Act, Act 90 of 1997.

¹³ The extent of success of these national programs differs, and depends on the level of financial resources available to address the problems. Brazil is a high income developing country that has instituted a program of universal access to public treatment for HIV/AIDS, and it has engaged in tough bargaining with the pharmaceutical industry over medicines prices (including the threat of compulsory licensing). Uganda has expressed strong political commitment to solutions, but is far more constrained by its budget. See, e.g., Tina Rosenberg, *Look at Brazil*, N.Y. TIMES MAGAZINE, 28 Jan. 2001, at 26; Geoff Dyer & Amy Kazmin, *Thai Agency will Begin Production of Drug for AIDS*, FIN. TIMES, 17 Oct. 2002, at 12; *Lessons from Uganda's AIDS Success Story*, DAILY NEWS (HARARE), 26 Feb. 2003; Sudarsan Raghavan, *Botswana Wages Struggle Against AIDS*, KNIGHT RIDDER/TRIB. BUS. NEWS, 8 July 2003.

made comparable commitments, even though the budgets of these countries would allow them to do considerably more.¹⁴

Each national political situation is different, and there is no question that for many countries dealing with HIV/AIDS, treatment will constitute a major financial burden. Even so, the difficulties of establishing a treatment program hardly excuse failing to do whatever lies within the government's means.

Consider the case of South Africa. Although its President at some stage questioned the link between HIV and AIDS, the absence of a meaningful treatment program until now resulted from additional factors. There has been skepticism about the efficacy of ARV treatment among the top echelon of the ruling political party (ANC). The HIV/AIDS problem predominantly affects the black population, and the white minority population (which owns the vast preponderance of productive assets) placed little pressure on the government to address it, at least until it appeared that corporate earnings might be affected. The government initially viewed ARV treatment largely in terms of the ongoing costs of medicines, without factoring in the impact on the economy if treatment were not provided. The local Pharmaceutical Manufacturers Association (PMA) fights with the government over any steps taken to promote low-cost access, and uses its financial resources to hire the country's small pool of specialist lawyers.

The government is meanwhile attempting to pull off one of the most difficult economic and social transitions attempted in modern history. It seeks to empower a majority population that was systematically excluded from property ownership, wealth accumulation and higher education, while at the same time providing an environment that will encourage the privileged minority to remain. The human catastrophe in Zimbabwe is a continuing reminder of what might happen if the government gets it wrong.¹⁵

None of the complexities of South African politics excuses the government's failure to implement an adequate HIV/AIDS treatment program, but they do illustrate the roadblocks that must be overcome. In the first instance, however, it will be difficult to overcome these and other obstacles if governments do not view public health as a priority.

¹⁴ The failure of China, India, Russia and South Africa so far to implement effective treatment programs is well chronicled. See, e.g., Geoff Dyer, *CIA Warns of New Frontiers in AIDS Epidemic: US Intelligence Predicts Russia, China and India Will Head a New Wave of Nations Falling Victim to HIV Infection*, FIN. TIMES, 4 Oct. 2002, at 10; *Number of HIV Carriers Hit 850,000 in China*, XINHUA ECON. NEWS SERVICE, 12 Apr. 2002, LEXIS; Sam Vaknin, *Europe's New Plague*, UNITED PRESS INT'L, 3 Dec. 2002; Shefalee Vasudev with Suman K. Chakrabarti, Nidhi Taparia Rathi & Amarnath K. Menon, *AIDS: The Mess*, INDIA TODAY, 9 Dec. 2002, at 42.

¹⁵ Observations concerning South Africa are based on the author's experiences in that country and conversations with persons in and outside the government.

iii. At the multilateral level

Many multilateral institutions, as well as regional institutions, are responsible for addressing some aspect of the essential medicines problem. These include the World Health Organization (WHO), other parts of the United Nations system (including UNAIDS, the Global Fund, the UN High Commissioner for Human Rights, the United Nations Development Program (UNDP), the United Nations Conference on Trade and Development (UNCTAD) and the World Intellectual Property Organization (WIPO), the International Monetary Fund (IMF), World Bank and World Trade Organization (WTO). Taking as a starting point that multilateral institutions have not as yet provided an adequate response to the demand for essential medicines, a few of the problems affecting the multilateral governance structure may be considered.

Multilateral institutions have different priorities, and not infrequently they work at cross purposes. The mandate of the WHO is to promote access to medicines,¹⁶ and it pursues this objective by providing advice to developing countries regarding ways in which medicines can be obtained at lower prices. They also provide TRIPS-consistent legal advice regarding ways to overcome the obstacles posed by patent protection, including government use licensing and parallel importation.¹⁷ The mandate of WIPO is to promote intellectual property protection.¹⁸ WIPO representatives routinely encourage developing countries to adopt and maintain strict standards of IP protection and to avoid implementing or using the flexibilities recognized in the TRIPS Agreement. Two directly conflicting sets of advice can be given by WHO and WIPO to patent authorities and to trade and public health officials at the same meeting.¹⁹ Given the divergent

¹⁶ See e.g., Constitution of the World Health Organization, arts. 1, 2, at <http://www.who.int>.

¹⁷ See, e.g., *TRIPS, Globalization and Access to Essential Pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3. (Mar. 2001).

¹⁸ See Convention Establishing the World Intellectual Property Organization, 14 July 1967 (as amended on 28 Sept. 1979), 21 U.S.T. 1749, 828 U.N.T.S. 3, art. 3, providing:

The objectives of the Organization are:

(i) to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization.

¹⁹ The author represented WHO at the first WIPO-WTO joint workshop for least-developed countries on the implementation of the TRIPS Agreement, held in Tanzania, 22–25 April 2002. After the author presented the special flexibilities on patents incorporated into paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2 (14 Nov. 2001) [hereinafter Doha Declaration], the WIPO representative (Ms. Karen Lee) told the attendees that WIPO had been advised by friends in the pharmaceutical industry that they would cure AIDS within the next few years but only if strong patent protection was maintained, so the least-developed countries should not do anything that might weaken the protection afforded by patents.

perspectives of the various multilateral institutions, it perhaps is not surprising that their activities in respect of public health and medicines are not coordinated.

Multilateral institutions operate on instructions from national governments and have limited "independence." Although some secretariats, for example, the International Bureau at WIPO, play a significant role in policy formulation and execution, for the most part it is difficult for the secretariats to act without a clear mandate from national delegations. To the extent that the more economically and politically powerful delegations exercise significant control over the policies of the multilateral institutions, the latter's independence is further constrained. Part of this control emanates from the fact that powerful countries provide the preponderance of budgetary support for operations.

National governments appear substantially more susceptible to industry capture in their external relations dealings than in domestic affairs. In the United States, for example, the Office of the U.S. Trade Representative (USTR) appears to act almost exclusively at the behest of producer interests. This bias is particularly glaring in respect to the pharmaceutical sector and medicines issues where, in recent negotiations, the USTR has encouraged foreign governments to deal directly with the U.S. pharmaceutical industry to provide it an adequate level of comfort.²⁰ For the European Union as well, the disjunction between the way the pharmaceutical sector is treated as a matter of intra-Union regulation and the way it is promoted abroad is remarkable. At the intra-Union level the industry is heavily regulated, stringent price controls are imposed, and competition proceedings are initiated. Yet, as regards developing countries, the EU aggressively supports maximum protection and open market access for its pharmaceutical sector.

The economics-driven institutions, such as the International Monetary Fund (IMF) and WTO, carry more influence with national governments than "softer" institutions, such as WHO. The WTO, in particular, develops its rules on the basis of bargaining over trade concessions. The pharmaceutical industry in countries belonging to the Organization for Economic Cooperation and Development (OECD) may obtain higher standards of patent protection (as it did in the Uruguay Round) in exchange for the grant of increased market access for textiles. From the standpoint of world public health, this is a very questionable means for establishing policy.

The United States has in recent years pursued policies with respect to the protection of its pharmaceutical sector that threaten to further weaken the multilateral governance framework. In particular, it has negotiated and concluded bilateral and regional free trade agreements that use the standards of the

²⁰ See *U.S. Wants Resolution*, above n. 8 (referring to Geneva press conference of U.S. Deputy Trade Representative Peter Allgeier referencing efforts "to foster a dialogue between companies and governments so that they both feel more comfortable"). See also *Pharmaceutical Companies Close to New Joint Position on TRIPS*, INSIDE U.S. TRADE, 11 July 2003.

WTO/TRIPS Agreement as a baseline for protective IP rules, but tighten those rules with so-called “TRIPS-Plus” restrictions. The demands made by the United States in bilateral FTA negotiations go well beyond increased protection of patents, to impact directly on the ways in which countries operate their public health systems.²¹

D. Socio-cultural factors and political responses

Political inattention to essential medicines problems does not arise in a vacuum. Political leaders respond to constituent demands, and constituents are motivated by their social interests. The people affected by the lack of access to essential medicines are the poor, and particularly the poor living in developing countries. A sufficiently influential part of international society does not yet place a value on redressing imbalances between enfranchised and disenfranchised peoples so as to generate demands on the political leadership for action. Absent a change in this value equation, it is doubtful that pressures on political leadership will emerge.

Notwithstanding this bleak reality, opportunities arise precisely because political leaders remain in power by satisfying their constituencies, including voters (in democratic states), financial backers and/or, in some cases, the military. Voting constituencies may be persuaded by effective communicators with access to media. Financial supporters respond to success and failure in securing profits. Military leadership may be influenced by budget allocation and security concerns.

Multilateral institutions, such as the WHO and World Bank, may provide a focal point for developing and disseminating effective, authoritative communication that will influence public voting constituencies. The financial sector will be influenced by allocation of larger budgets, whether for R & D or procurement. Medicines producers may be stimulated by the promise of access to new markets. The opening up of competition may offend the monopolist, but it will encourage those outside its control.

If one is pessimistic concerning the prospects for social value reorientation, a plausible alternative is to seek to redefine the self-interest of the enfranchised part of the global population in terms of redressing gross imbalances; that is Alexis de Tocqueville’s “principle of self-interest rightly understood” as applied

²¹ See Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, QUNO Occasional Paper 14 (Apr. 2004), available at <http://www.quno.org>; and Peter Drahos et al., *The FTA and the PBS*, Submission to the Australian Senate Select Committee on the US – Australia Free Trade Agreement (2004). See also various requests to USTR from US PhRMA in its 2003 Special 301 submission on regulatory concerns, at <http://www.phrma.org> and <http://ustr.gov>.

to public health.²² Pointing to a threat to developed country public order based on developing country chaos would appear to be one avenue of persuasion. Yet, the self-interest of developed country individuals in developing country public health is less directly apparent than interests in military defense, and it is not clear that the public in developed countries is prepared to draw the self-interest connection.

The political dimension of the problem of providing access to essential medicines is not amenable to a neat formulaic solution. Designing and implementing solutions requires that political leaders give this a high priority. As noted at the outset, the problem of access is complex, embedded and will be persistent over time.

III. Regulatory obstacles and responses

The current international regulatory framework for medicines is characterized by segregated national and/or regional approval and registration authorities. This creates basic inefficiencies that delay the introduction of medicines into developed and developing country markets. Complex regulatory systems provide an extraordinary opportunity for legal “gaming” in the developed countries.²³ These gaming opportunities are magnified in the developing countries where regulatory systems are less well developed and transparent.

A. Regulatory streamlining

The proper focus of medicines regulatory systems must be to assure the quality, safety and efficacy of medicines, and not to act as a supplement to patent protection. Until recently, most countries have required that their public health regulatory authorities approve each medicine placed into circulation,

²² De Tocqueville observed:

The Americans, on the other hand, are fond of explaining almost all the actions of their lives by the principle of self-interest rightly understood; they show with complacency how an enlightened regard for themselves constantly prompts them to assist one another and inclines them willingly to sacrifice a portion of their time and property to the welfare of the state. In this respect I think they frequently fail to do themselves justice, for in the United States as well as elsewhere people are sometimes seen to give way to those disinterested and spontaneous impulses that are natural to man; but the Americans seldom admit that they yield to emotions of this kind; they are more anxious to do honor to their philosophy than to themselves. ALEXIS DE TOCQUEVILLE, *DEMOCRACY IN AMERICA*, bk. II, ch. 8

(From the Henry Reeve Translation, revised and corrected, 1839).

²³ See U.S. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (2002), <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> [hereinafter *FTC Orange Book Study*].

in some cases relying on decisions by foreign regulatory authorities. This situation imposes substantial burdens on registration authorities and creates inefficiencies that operate to the detriment of developing countries.

The WHO has initiated a program of prequalifying medicines with respect to quality, safety and efficacy, which includes certifying good manufacturing practices (GMP) of facilities producing them.²⁴ By relying on this WHO prequalification system, developing country regulators can avoid duplicating key medicines regulatory functions. However, the WHO prequalification program – while applauded by public health specialists for its role in accelerating access to HIV/AIDS treatments – has had difficulty obtaining the funding necessary to continue or expand its operation. While the program has drawn its regulators and inspectors from recognized European medicines authorities, the United States has so far indicated that only U.S. FDA approvals may be relied on in connection with the procurement of HIV/AIDS medicines with federal funds.²⁵

Any consolidation of regulatory authority at the multilateral level creates a risk of capture by enterprises based in countries that exert a high degree of authority at those institutions. The WHO is not immune from this phenomenon.

B. Intersection of regulatory review and patents

The United States has in place a complex legislative and regulatory system allowing for the review of generic medicines during the patent term of the originator.²⁶ The so-called “Bolar” exception²⁷ was coupled with patent term extension.²⁸ The patent term extension covers the period during which the originator medicine was subject to regulatory review, and the Bolar exception provides a counterbalance to the extended term by allowing generic producers to enter the market at the end of the term (in theory at least) without also being subject to a regulatory review delay.

²⁴ See website of the WHO Prequalification Project, <http://mednet3.who.int/prequal/default.htm>.

²⁵ See Jill Wechsler, *The not-approved-here syndrome: public health officials want to know: why is the United States opposed to the use of cheap generic AIDS drugs?*, PHARM. EXEC. (1 May 2004) (Lexis/Nexis); U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Guidance for Industry Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV (May 2004), CCH Research Network, Guideline, FD&C-ARD ¶ N41,499a.

²⁶ For a description, see FTC Orange Book Study, above n. 23.

²⁷ 35 USC § 271(e) (2000) (effectively reversing the decision of the Court of Appeals for the Federal Circuit rejecting a common law regulatory use exception argued as an experimental use defense). (See *Roche v. Bolar*, 733 F.2d 858 (Fed. Cir. 1984).

²⁸ 35 USC §156 (2000) (extension of patent term).

For developing countries that are required to comply with the patent provisions of the TRIPS Agreement, the adoption of a regulatory review exception is a necessary feature of domestic patent law, which would reduce the harmful effect of monopolies. Whether or not patent term extension is appropriate for the United States, where consumers may be able to afford expensive patented medicines, it is inappropriate for developing countries. These latter countries are not in a position to fund Pharma activities embedded in patented medicines, which include advertising and administrative costs.

Pharma research funds are not spent in developing countries. Neither is a significant portion of Pharma research devoted to diseases of special relevance to developing countries. Indeed, while the benefits of Pharma research in terms of new medicines flow to consumers in developing countries, the cost of such medicines should be kept within their budget capacities.

C. *Rights in data and solutions*

Rights asserted in data compiled for regulatory purposes are not encompassed within conventional notions of intellectual property,²⁹ yet they have become one of the main instruments for preventing market entry by generic producers. Perhaps the most significant recent trend in the behavior of Pharma towards developing countries involves the assertion of regulatory data protection claims. At the multilateral level, these claims are based on Article 39.3 of the TRIPS Agreement, which restricts the disclosure of certain data by regulatory authorities and authorizes the originators of “new chemical entities” (NCEs) in the pharmaceutical field to prevent “unfair commercial use” of data regarding those NCEs submitted for regulatory purposes.³⁰

The establishment of a multilateral regulatory approval authority under auspices of the WHO might serve to limit the possibility of asserting claims based on unfair commercial use of data submitted for regulatory purposes. If developing country governments allow medicines to be placed on the market by virtue of WHO approval process, there would hardly appear a basis for claiming that the governments or enterprises within their territories took unfair advantage of the relevant data.

²⁹ In 1996, however, the EU adopted a hybrid exclusive property right in noncopyrightable collections of data, which deviated from traditional IP concepts. See, e.g., J. H. Reichman, *Database Protection in a Global Economy*, 2002 REVUE INTERNATIONALE DE DROIT ECONOMIQUE 455–504.

³⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 Apr. 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1c, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND Vol. 31, 33 I.L.M. 81 (1994) [Hereinafter TRIPS Agreement], art 39.3. See also Carlos M. Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement* (South Centre & World Health Organization 2001)

Public procurement authorities in developing countries are often the purchasers and distributors of medicines for use in public hospitals and clinics, and new medicines that are registered for purchase by such procurement authorities should not be deemed subject to “commercial use.” The TRIPS Agreement does not require that registration authorities provide protection against the use of regulatory data for medicines that are procured for use in public health systems.

In other circumstances, the question of whether specific regulatory data may fall within the “unfair commercial use” provision of article 39.3 will depend on the facts. It would appear a rather stretched interpretation of “use” that mere reliance on the granting of registration in a foreign jurisdiction could constitute “use” of data, since there is no access to the data required.³¹

One reason for the shift by Pharma to assertion of claims based on rights in regulatory data is to cover the many situations in which local patents were not obtained on medicines. Without such claims, the introduction of generics could not be blocked under domestic patent law if the regulator’s product was unpatented or unpatentable.

The United States has negotiated provisions in free trade agreements specifically designed to block reliance on data submitted for foreign regulatory approvals.³² The effects of these provisions will vary with individual cases. Marketing approval is typically granted well before expiration of a patent term, so that if the originator of the data is a patent holder in the foreign market, there may be limited effect in extending the patent term. However, if the originator of the data does not hold a patent in the foreign market, then an approval-blocking mechanism in that foreign market will effectively act as a patent for the duration of the blocking term.

³¹ See, e.g., Correa above n. 29 (tracing legislative history of TRIPS Agreement, above n. 29, art. 39.3 to show that so broad an interpretation was not agreed to by the negotiations).

³² The U.S.- Singapore FTA provides:

Article 16.81:

...

2. If a Party provides a means of granting approval to market products specified in paragraph 1 on the basis of the grant of an approval for marketing of the same or similar product in another country, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product in the Party or in the other country, whichever is later. (available at <http://www.ustr.gov>)

IV. Intellectual property related obstacles and responses

Patents are in essence financial instruments that permit investors to earn comparatively high returns from the assumption of investment risk. Patent holder behavior can be explained as an effort to maximize the benefits from a financial instrument.³³ All of this is consistent with the observable behavior of the research-based pharmaceutical industry. We may be able to tinker with the patent system so as to improve its responsiveness to the problems of the poor, but this tinkering will not provide a comprehensive solution. The patent is a market-based instrument, and an industry dependent on that instrument cannot be expected to provide solutions to essential medicines problems that are non-market based.

A. Patents as obstacles

Patents provide their holders with rights to prevent others from making, using, selling, offering for sale and importing protected products. By preventing the entry onto the market of equivalent products, patents prevent the emergence of competition based on the reduction of production costs while encouraging the innovation that may lead to new competitive products.³⁴ Although many factors affect the extent to which people have access to essential medicines, it is obvious that each step in lowering the price would enable more people to enter the treatment market.

Patents are complex and non-transparent instruments that have generated extraordinary opportunities for using legal measures to improperly impede the introduction of competitive generic products. Patents are often granted for claims that do not truly satisfy the criteria of patentability,³⁵ in many countries without substantive examination, and in many (if not all) countries with inadequate

³³ Jean Pierre Garnier, the CEO of GlaxoSmithKline, has observed that he is not the head of a charitable institution, and the company he heads should not be expected to behave like one. Sarah Boseley, *Jean Pierre Garnier, Head of Glaxo*, Special AIDS Report, THE GUARDIAN, 18 Feb. 2002, <http://www.guardian.co.uk/aids>. In his book recounting the sequencing of the human genome, John Sulston remarks at his surprise at discovering the “venality” of the market. JOHN SULSTON & GEORGINA FERRY, *THE COMMON THREAD: A STORY OF SCIENCE, POLITICS, ETHICS AND THE HUMAN GENOME* (2002). The head of a major World Bank health program recently observed to me that pharmaceutical patent holder behavior is very predictable, and should be accepted for what it is.

³⁴ See, e.g., Lee Branstetter, *Do Stronger Patents Induce More Local Innovation?* [this volume]

³⁵ In the United States, where patents are subject to relatively rigorous examination and very few patent claims reach the trial phase, about 30–35% of patents brought to trial are found invalid or unenforceable. Kimberly A. Moore, *Judges, Juries, and Patent Cases - An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 392 (2002).

examination.³⁶ Very few patent offices have the expertise necessary to examine complex patent applications in the field of medicines, and those that have such capacity often are overburdened by the large number of applications received.

In the United States, invalid patents were routinely abused to prevent the introduction of generic medicines by listing the products at issue in the Food and Drug Administration's Orange Book.³⁷ Efforts to curtail these practices formed the basis of recent amendments to U.S. regulations governing the registration of generic medicines.³⁸ The U.S. is a heavily regulated market in which generic producers have substantial stakes in early entry to the market, and where NGOs monitor the pharmaceutical sector. Similar oversight is often weak or lacking in developing countries, where there is substantially less likelihood that abusive patent practices will be effectively controlled.

Medicines are often protected by multiple patents, and patent searching systems are not designed to identify medicines by their corresponding patents.³⁹ This creates a situation of legal insecurity for those contemplating the manufacture or procurement of new medicines.

Lawyers in developing countries with training to operate effectively in the patent environment are typically retained by established pharmaceutical enterprises. They do not have an incentive to challenge the validity of patents within their own legal systems.

Legal proceedings to challenge the validity of patents are costly and time-consuming. There are few individuals or enterprises with the incentives necessary to challenge the validity of patents, particularly when this entails confronting patent holders with substantial financial resources. (An incentive might, for example, be provided by a generic producer's prospect of securing a long-term government procurement contract.)

The patenting pattern in sub-Saharan Africa shows a high density of patents on critical ARVs in countries with the capacity to produce medicines and

³⁶ South Africa, for example, grants patents without substantive examination. The patent office of the African Regional Intellectual Property Office (ARIPO), as of 2001 had four patent examiners (presentation by ARIPO representative at Workshop on TRIPS and the Implementation of Its Safeguard in Relation to Pharmaceuticals in the WHO African Region, Harare, Zimbabwe, Aug. 2001).

³⁷ See U.S. Federal Trade Commission, above n. 23. This study found that patents had been grossly abused at the Food and Drug Administration to prevent the entry of generic drugs onto the U.S. market. A principal violator company has been the subject of consent injunction and has paid substantial fines. The U.S. market is subject to relative close monitoring by competition authorities and public interest groups. Yet potential competitive abuse of patents in foreign markets is not within the scope of U.S. antitrust law (absent a direct and substantial impact on the U.S. market), and equivalent capacities for monitoring and enforcement would be the exception in developing Members of the WTO.

³⁸ Food and Drug Administration Order, 68 Fed. Reg. 36676 (18 June 2003). Technical amendments, 69 Fed. Reg. 11309 (10 Mar. 2004).

³⁹ See Drug Patents under the Spotlight, Médecins Sans Frontières Report (22 May 2003), available at <http://www.accessmed-msf.org>.

comparatively high income. In South Africa, there are approximately twenty patents covering fourteen ARVs and fixed dose combinations.⁴⁰ In Zimbabwe, there are eleven patents covering seven ARVs and fixed dose combinations. In Kenya and Uganda there are eleven and ten patents, respectively, on seven and six ARVs and fixed dose combinations.⁴¹

The introduction of generic ARVs into the South African market has been substantially inhibited by patents. The U.S. and European Union, and their pharmaceutical enterprises, used strong-arm tactics to prevent the implementation of legislation intended to facilitate lower prices for patented medicines, and in doing so distorted the policies of the South African government.⁴² Although that government has not been a model of good practices in addressing HIV/AIDS, the clock cannot be turned back to see whether those practices might have been different had the government not been so aggressively attacked. The few South African corporations that have provided ARVs to their workers have paid high patent holder/originator prices, limiting the scope of the programs.⁴³ NGOs and regional procurement authorities in South Africa continue to be inhibited in purchasing from generic producers in India.⁴⁴

Moreover, despite public statements to the contrary, the research-based pharmaceutical companies are still asserting very strong pressure on South Africa to prevent it from obtaining lower-priced access to medicines. The 2003 Special 301 submission by U.S. PhMRA to USTR accused the South African government of a number of offenses against intellectual property interests.⁴⁵

There is an increasing tendency on the part of the U.S. and EU trade negotiators to demand "patent term extension" based on the period during which medicines were under regulatory review as a part of bilateral and regional trade agreements.⁴⁶ From the standpoint of developing countries, this represents nothing more than a demand for increased rent payments (i.e., higher medicines prices) with little in the way of countervailing benefits.

⁴⁰ *Id.* ⁴¹ *Id.*

⁴² For some details concerning the abusive character of the litigation brought by the PMA against the government of South Africa, see Frederick M. Abbott, WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries, United Kingdom Commission on Intellectual Property Rights Study Paper 2a (Feb. 2002).

⁴³ Henri E. Cauvin, *Mining Company to Offer H.I.V. Drugs to Employees*, NY TIMES, 7 Aug. 2002; Claire Bisseker, *AIDS in the workplace—Anglo, De Beers Take Risky Lead in Free Treatment*, FIN. MAIL (South Africa) (16 Aug. 2002).

⁴⁴ See, e.g., MÉDECINS SANS FRONTIÈRES/WORLD HEALTH ORGANIZATION, SURMOUNTING CHALLENGES: PROCUREMENT OF ANTIRETROVIRAL MEDICINES IN LOW- AND MIDDLE-INCOME COUNTRIES, § 4.8 (2003).

⁴⁵ See PhRMA Special 301 submission, above n. 21.

⁴⁶ See U.S.-Singapore, art. 16.8(4)(a) and U.S.-Chile FTA, art 17.10(2)(a), available at <http://www.ustr.gov>; each contain a provision extending the term of the patent if its granting is subject to "unreasonable" delay.

B. Solutions to the problems posed by patents

For developing countries seeking improved access to essential medicines, implementation of policies and legislation that would facilitate resort to compulsory and government use licensing provides the principal counterbalance to the adverse impact of patent monopolies.⁴⁷ Other strategies to consider include the use of waivers introduced by the Doha Declaration on TRIPS and Public Health, parallel trade, and differential pricing, all of which are briefly discussed below.

i. Compulsory licensing and government use

Compulsory licensing and government use serve several functions:

- They provide a favorable background for all price and licensing negotiations with patent holders;
- They serve as critical bargaining levers in specific negotiations (such as the U.S. Department of Health negotiations with Bayer concerning the price of Cipro and the Brazilian Health Ministry negotiations with Roche concerning the price of Viracept);
- They allow the realization of production by persons other than the patent holder.

The patent law of every country permits the government to use the patent for public purposes.⁴⁸ Even if a government use provision is not expressly written

⁴⁷ The author has addressed this subject in detail in Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, Quaker United Nations Office Occasional Paper 9 (Feb. 2002), available at <http://www.quno.org>, and in Abbot, above n. 41.

⁴⁸ The author is not aware of any patent law that prohibits the government from using patents, though the conditions under which such use is permitted vary. Brazil, South Africa, Switzerland, the United Kingdom and United States provide useful illustrations of the government use theme. For Brazil, see especially Presidential Decree No. 3,201 of 6 October 1999 implementing Article 71 of Law No. 9,279 of 14 May 1996. For South Africa, see Patents Act No. 57 of 1978 (as amended through 1997), which provides:

4. A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.

The Swiss Federal Law for Patents on Inventions (of 25 June 1954, as last amended on 24 March 1995) provides:

B. Expropriation of the Patent

Art. 32. – (1) If public interest so requires, the Federal Council may wholly or partially expropriate the patent.

into the patent legislation, all governments reserve the right to take property for public purposes, and patents are no special exception to this general principle.⁴⁹

No country facilitates government use of patents better than the United States. Under U.S. patent law, the government and its contractors are free to use any patent without notice to the patent holder, and the patent holder is precluded from obtaining an injunction against such use.⁵⁰ The patent holder

(2) The former owner of an expropriated patent shall be entitled to full compensation which, in case of dispute, shall be fixed by the Federal Court; the provisions of Chapter II of the Federal Law of June 20, 1930, on expropriation shall apply by analogy.

For the United Kingdom, see Patents Act 1977 (as last amended by the Copyright, Designs and Patents Act 1988), arts. 55–59, including “Special provisions as to Crown use during emergency,” providing *inter alia*:

59.–(1) During any period of emergency within the meaning of this section the powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 55 above shall include power to use the invention for any purpose which appears to the department necessary or expedient –

...

(b) for the maintenance of supplies and services essential to the life of the community;

(c) for securing a sufficiency of supplies and services essential to the well-being of the community;

For the United States, see below nn. 50–51 and accompanying text.

⁴⁹ For an examination of compulsory licensing grounded in public interest or government use provisions, with particular reference to North American law and practice, see generally J.H. REICHMAN WITH CATHERINE HASENZAHN, NONVOLUNTARY LICENSING OF PATENTED INVENTIONS, PART I, HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE UNITED STATES OF AMERICA, (UNCTAD/ICTSD 2002); PART II – THE CANADIAN EXPERIENCE (UNCTAD/ICTSD 2002); PART III – THE LAW AND PRACTICE OF THE UNITED STATES (UNCTAD/ICTSD, 2003) [hereinafter *LAW AND PRACTICE OF THE UNITED STATES*].

⁵⁰ U.S. legislation regulating the Court of Claims, 28 U.S.C. § 1498 (2000) provides:

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . .

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

is given the right to obtain compensation in a proceeding before the Federal Court of Claims. The U.S. essentially uses a liability rule; the government is allowed to use the patent without precondition and for any purpose, but is liable to the patent holder to pay compensation.⁵¹ The United Kingdom and Switzerland each grant the government sweeping authority to use patents.⁵²

In the public procurement context, government use licensing provides a good solution to addressing patent monopolies. Patent laws typically subject government use licensing to substantially fewer procedural obstacles than for private compulsory licensing. Often the matter is handled by a decision of the Minister responsible for maintaining the patent register. There is no reason, however, why such authority cannot equally well be delegated to the Health Minister and, through that Minister, to the procurement authority.⁵³

Compulsory and government use licensing can be used for importing medicines that are on-patent in the importing country and obtained lawfully outside the country, such as from a country that has not yet introduced pharmaceutical product patent protection. After January 1, 2005, when all developing countries are required to implement pharmaceutical product patent protection, the supply of new generic medicines will contract, and imported generic medicines will be more difficult to secure.

Negotiations at the WTO concerning Paragraph 6 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health⁵⁴ addressed the situation arising in 2005, in which countries needing to import medicines under compulsory (including government use) licenses may be unable to find sources of off-patent medicines.⁵⁵ On August 30, 2003, the General

⁵¹ For details, see REICHMAN WITH HASENZAH, *LAW AND PRACTICE OF THE UNITED STATES*, above n. 48, ch. V (“Government Use”).

⁵² See above n. 47.

⁵³ In the United States, for example, the “administrative and departmental agencies [that] also possess specific statutory authorization to make use of patented inventions . . . include[e] . . . the Department of Health and Human Services, the Department of the Interior, the Department of Defense, the Department of Energy, the Department of State, the National Aeronautical and Space Administration (“NASA”), and the Environmental Protection Agency.” REICHMAN WITH HASENZAH, *LAW AND PRACTICE OF THE UNITED STATES*, above n. 48, ch. V.

⁵⁴ WTO Fourth Ministerial Conference (Doha), Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, (14 Nov. 2001). Paragraph 6 recognized the problem that countries with insufficient or no manufacturing capacity in the pharmaceutical sector have in making effective use of compulsory licensing, and directed the TRIPS Council to recommend an expeditious solution.

⁵⁵ See Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, Quaker United Nations Office, Occasional Paper 9, (Feb. 2002), available at <http://www.quino.org>; Abbott, above n. 41. See also Frederick M. Abbott, Negotiations in the WTO TRIPS Council Pursuant to Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health, World Bank Seminar (3 Feb. 2003), available at <http://worldbank.org> (B-Span archives).

Council of the WTO adopted the Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (“the Decision”).⁵⁶ Adoption of the Decision was preceded by the reading of a Chairperson’s Statement that expressed certain “shared understandings” of the Members regarding the way it would be interpreted and implemented. The Decision establishes a mechanism under which the restriction of Article 31(f) will be waived for an exporting Member when it is requested by an eligible importing Member to supply products under compulsory license issued in the exporting country, and it provides a waiver of Article 31(h) (remuneration) for the importing country when remuneration is paid in the exporting country.⁵⁷

⁵⁶ Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health IP/C/W/405 (30 Aug. 2003) [hereinafter Decision].

⁵⁷ See Frederick M. Abbott, *The Containment of TRIPS to Promote Public Health: A Commentary on the Decision on Implementation of Paragraph 6 of the Doha Declaration* (forthcoming 2004) (manuscript); Carlos Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO 2004 forthcoming) [hereinafter Correa 2004]; Paul Vandoren & Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 J. WORLD INTELL. PROP. 779 (2003).

Paragraph 1 of the Decision defines “pharmaceutical product” broadly, and does not limit application of the solution to specific disease conditions. The definition expressly covers active pharmaceutical ingredients (APIs) and diagnostic “kits.” The definition is sufficiently broad to encompass vaccines. It requires Members other than least developed Members (which are automatically included) to submit a notification of their intention to use the system in whole or in part, which notification may be modified at any time. This notification establishes the Member as an “eligible importing Member”, and several developed Members have opted out of the system in whole or in a limited way.

Paragraph 2 of the Decision establishes conditions for use of the waiver. The importing Member must notify the TRIPS Council of its needs, and (except for Least-Developed Members), must indicate that it has determined that it has insufficient or no manufacturing capacity for the product(s) in question. The latter determination is made in accordance with an Annex to the Decision. When there is a patent in the importing Member, it must indicate that it has issued, or intends to issue, a compulsory license (except for Least-Developed Members that elect not to enforce patents pursuant to Paragraph 7 of the Doha Declaration). The exporting Member must notify the TRIPS Council of the terms of the export license it issues, including the destination, quantities to be supplied and the duration of the license. The products supplied under the license must be identified by special packaging and/or colouring/shaping. Before quantities are shipped, the licensee must post on a publicly accessible website the destination and means it has used to identify the products as supplied under the system.

Paragraph 3 provides for a waiver of the remuneration requirement for the importing country, and Paragraph 4 requires importing Members to implement measures proportionate to their means to prevent diversion of products imported under the system. Paragraph 6 provides an additional waiver of Article 31(f) for regional trading arrangements in Africa (i.e., more than half of which were Least-Developed countries when the Decision was adopted). This waiver allows a Member to export to countries

The obstacles to use of compulsory and government use licensing to redress any imbalance created by patent monopolies should not be minimized. While the threat of compulsory licensing may be easy enough to use as a bargaining lever in negotiations, the realization of production involves reverse engineering of the subject medicine, regulatory review, and achieving production in quantity and under good manufacturing practices. Accomplishing these steps may take one to three years.⁶⁰

ii. Paragraph 7 and least-developed countries

WTO Ministers agreed, in paragraph 7 of the Doha Declaration on TRIPS and Public Health,⁶¹ that Least-Developed Members should not be obligated to implement or apply TRIPS provisions regarding pharmaceutical product patents or regulatory data protection until January 1, 2016. Just as importantly, they also agreed that Least-Developed Members already allowing for such protection did not need to “enforce” such rules until that later date.⁶² The

throughout the region under a single compulsory license, although it does not expressly waive the requirement for licenses to be issued by importing countries of the region. The main benefit of the waiver may be to allow the import of APIs, formulation into finished products, and export throughout the African region.

Paragraph 11 provides that the waiver will remain effective for each Member until an amendment has come into effect to replace it there, and that Members will commence negotiations for an amendment to be based, where appropriate, on the waiver. Although the Decision stated that the negotiations would have a view to completion within six months following the end of 2003, in June 2004 the TRIPS Council extended that tentative completion date until the end of March 2005.

The Chairperson’s Statement indicates, *inter alia*, that Members will act in good faith in using the Decision, providing:

“First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.”

⁶⁰ D.G. Shah, speaking on behalf of the Indian generic manufacturing industry, has suggested that the lead time between initiating a compulsory licensing request in India and making available commercial quantities of the product may be three to four years. D.G. Shah, Presentation at meeting sponsored by Norwegian Ministry of Foreign Affairs and Quaker United Nations Office – Geneva, Utstein Kloster (20–23 July 2002). Eloan Dos Santos Pinhero, Director of the Brazilian public pharmaceutical enterprise, Far Manguinhos, has indicated that an ARV can be taken from the reverse engineering phase through to commercial production in one year. Presentation at The Crisis of Neglected Diseases International Conference (MSF-DNDi) (Mar. 2002).

⁶¹ See Declaration on TRIPS and Public Health, above n. 53, para. 7.

⁶² *Id.*, which provides in relevant part:

We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5

TRIPS Council adopted a decision confirming this flexibility,⁶³ and the WTO General Council added a waiver of Least-Developed Members' obligations regarding so-called "exclusive marketing rights," which might otherwise have been used as a substitute for patent protection to block production, importation and sales of medicines.⁶⁴

The reason the right to "disapply" existing patents is important is that most of the Least-Developed Countries already have legislation authorizing pharmaceutical patent protection, largely as the by-product of the colonial administration of their legal systems. The authority to disapply patents is already being used by public procurement authorities in these countries to import generic versions of medicines that are on-patent in their countries.

iii. Parallel trade and differential pricing

The TRIPS Agreement, as confirmed by paragraph 5(d) of the Doha Declaration,⁶⁵ allows each WTO Member to adopt a rule of international exhaustion of IPRs, and thus to permit parallel importation of medicines. This provision allows each country to seek the lowest priced, lawfully marketed medicine on the world market, which has an obvious benefit in terms of access to lower-priced medicines.

Historically, prices of medicines have varied widely throughout the developed and developing countries, and there have been significant opportunities to exploit pricing benefits through parallel trade.⁶⁶ For a long time, it was not uncommon for the prices of medicines to be higher in Africa than in Europe,⁶⁷

and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

⁶³ Decision of the Council for TRIPS of 27 June 2002, IP/C/25, WTO Doc. No. 02-3664, available at <http://www.wto.org>.

⁶⁴ WTO General Council, Least-Developed Country Members—Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, WTO Doc. WT/L/478 (8 July 2002).

⁶⁵ See TRIPS Agreement, above n. 30, art. 6; Declaration Trips and Public Health, above n. 53, para. 5(d), which provides:

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

⁶⁶ There is little hard data on the extent of parallel trade in medicines, although it is understood to be a common phenomenon in the intra-EU context. While saying that

although wide public attention to this situation may have ameliorated this practice. Although it is tempting to suppose that parallel trade opportunities exist because of price controls and related regulatory measures, evidence for this has been lacking.⁶⁸ Nonetheless, the heavily regulated nature of the pharmaceutical trade places constraints on the extent to which parallel trade opportunities can be readily exploited.⁶⁹

Parallel trade remains an important mechanism for promoting price competition, but it is unlikely to provide the same level of pricing relief as could be obtained by compulsory licensing. In most cases, parallel traded medicines will have been placed on the market by the patent holder, and patent holder prices are likely to be higher than those that would be charged by a compulsory licensee. Still, it is important that this mechanism should be preserved and considered in strategic planning.

An argument can be made that differential pricing favors developing countries because it allows OECD-based Pharma companies to maintain high prices in OECD markets.⁷⁰ In essence, the OECD consumers subsidize advertising costs and R & D for developing country purchasers. Differential pricing and markets open to parallel trade are not mutually exclusive. Pharma companies may contract with purchasers in differentially-priced markets to prevent re-exports. In addition, the OECD countries already for the most part block parallel imports of medicines, which renders concerns over such practices OECD markets illusory.

While differential (or “equity”) pricing may be unavoidable as a near-term solution to the pharmaceutical needs of developing countries, such practices

there have been opportunities to exploit parallel trade, the author does not suggest that there have in fact been significant amounts of world parallel trade in medicines.

⁶⁷ This phenomenon was first called to the author’s attention following a presentation at the Pre-UNCTAD X Seminar on the Role of Competition Policy for Development in Globalizing World Markets, Panel on Competition, IPRs and Transfer of Technology (Geneva, 14–15 June 1999). The author had recalled the pharmaceutical industry assertion that parallel trade would restrict access to inexpensive medicines in Africa. He was advised by several delegates that they waited for their travel to Geneva to buy medicines since they were more expensive in Africa, and was asked where the inexpensive medicines in Africa might be obtained. This anecdotal report was confirmed by several studies. See, e.g., F.M. Scherer & Jayashree Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries*, WHO Commission on Macroeconomics and Health Working Paper No. WG4:1 (June 2001).

⁶⁸ See *id.*

⁶⁹ See also Patricia M. Danzon and Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals* [this volume]

⁷⁰ See, e.g., John H. Barton, *Differentiated Pricing of Patented Products*, July 2001 WHO Commission on Macroeconomics and Health, CMH Working Paper Series, Paper No. WG4:2. See also Keith E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries*, Final Report to the World Intellectual Property Organization (Apr. 2001).

present risks of long-term cartelization of the global medicines market. If the major OECD-based producers can sell at low prices in developing markets, they may be able to prevent the successful emergence of alternative low-cost producers. For this reason, it is important that those responsible for differential pricing arrangements recognize and address the importance of promoting generic competition. This might be accomplished through use of the compulsory licensing mechanism. Among developing countries, more work can be done to develop compulsory licensing arrangements that can be used to promote competition while providing remuneration to originators commensurate with public health and development realities.

iv. Disciplining ancillary IPRs

Trademarks and copyrights play an ancillary role to patents as obstacles to access. The basic function of the trademark is to distinguish the origin of goods, and this function serves a legitimate public purpose. Ancillary uses of trademarks to block parallel imports, to restrict generic substitution and to prevent the functional coloring of equivalent medicines are against the public interest.

Copyright holders have asserted rights to prevent the re-use of information in doctor and patient leaflets accompanying medicines, including information in translations. Since copyright law does not protect facts or data, including scientific content, these claims are an abuse of copyright.

V. Bulk procurement and related mechanisms

Medicines producers may be able to reduce their per-unit costs by producing larger quantities of supply under longer term arrangements. Originator/patent holders on ARVs have argued that their ability and willingness to supply at low prices is dependent on the volume of purchase orders that can be used as the basis to scale up their production.⁷¹ Individual medicines procurers may have difficulty negotiating best prices because of the absence of bargaining power or of transparency in negotiations with private sellers. Acquisition-by-acquisition negotiations on price and terms are time-consuming and a drain on personnel. Sellers and buyers of essential medicines may each benefit from bulk procurement arrangements that combine the purchasing power of governments and/or private medicines procurers with the scaling up of supply capacity.

While bulk procurement arrangements seem likely to reduce the prices of essential medicines, one should not view this option and that of generic production as mutually exclusive. The best way to assure low prices is by stimulating competition among generic producers. Pressure from these producers, largely in India, has effectively brought down prices of ARVs, and make large-scale treatment programs feasible. The World Bank is encouraging

⁷¹ See Garnier, above n. 32.

generic production by adoption of policies that focus on purchases – including bulk purchasing – from the lowest priced lawful producer.⁷²

The heart of the essential medicines problem is determining how to provide low-cost medicines that are safe and effective. Given limited financial resources, the price of medicines operates as a primary constraint on providing access. One feature of any system for providing essential medicines to developing countries is that they must be made available at or near their marginal cost of production in a competitive market. Developing country populations cannot afford to defray the costs of R & D undertaken in the OECD countries, and they certainly can not afford to pay the expenses associated with advertising and marketing.

VI. Local production, transfer of technology, and the public sector

The supply of low-cost essential medicines may be improved by the establishment of production facilities in various regions throughout the world.⁷³ “Local production” provides the infrastructure for enabling countries to make effective use of compulsory licensing. It provides an incentive for governments to procure medicines by channeling public funds to local enterprises, which augments local training and employment opportunities. Once a local pharmaceutical industry becomes established, it is likely to generate positive spin-offs, such as increased attention to local research and development funding for new medicines and related technologies.

Local production efforts should be designed to achieve appropriate efficiencies and economies of scale. In this respect, there is considerable promise for regional arrangements in which facilities and related infrastructure can be allocated in a way that provides benefits to all countries in a region. Meanwhile, countries in immediate need of complex medicines cannot delay their acquisition of imports simply because local production facilities can be built in the future.

Countries with populations requiring long-term large quantity supply of medicines, such as antiretrovirals, should become capable of producing locally. Otherwise, these countries will find themselves in an economically and politically vulnerable position.

In a perfect world, the most efficient and low-cost way to produce medicines for global consumption might be organized around a few very large-scale facilities located in only a few countries. This perfect world does not exist for any product, and there are sound political economy reasons why it does not exist for medicines.

Developing countries are increasingly cooperating with a view toward assisting each other in developing and implementing sustainable production programs. This kind of cooperation is vital.

⁷² See *BATTLING HIV/AIDS: A DECISION MAKER'S GUIDE TO THE PROCUREMENT OF MEDICINES AND RELATED SUPPLIES* (Yolanda Tayler ed., World Bank 2004).

⁷³ See, e.g., work program of Initiative for Pharmaceutical Technology Transfer (IPTT) (on file with author).

Public supply of sophisticated medicines has been accomplished successfully in Brazil and Thailand, and they provide models worthy of study. For the most part, however, the failure of the market to adequately provide essential medicines has not been offset by success in the public sector. There are obstacles here as well. The public sector is potentially burdened by its comparative inability to provide individual incentives, by inefficiency and cronyism.

Public sector supply of essential medicines is a demonstrably viable alternative to the private market. At the very least, the public sector should serve to fill gaps where the market fails. Whether the public sector might serve as the primary source of essential medicines supply is open to debate.

VII. Research and development

The crux of the debate concerning the use of flexibilities in the TRIPS Agreement, such as compulsory and government use licensing, to secure lower priced access to medicines has centered on the implications for R & D in the developed countries. There is no difference of opinion regarding the importance of R & D. The need for new medicines to treat and cure disease is unquestioned. From the standpoint of access to essential medicines, the question becomes “who will pay for the R & D, and how?”

A. *The general R&D problem*

In a study prepared by this author for the British Commission on IPRs, an attempt was made to identify the contribution to Pharma R & D attributable to rents collected from the sale of patented medicines in developing countries. The informal estimates in that report suggested that such contribution was only marginally significant: namely, if developing countries gave no patent protection to pharmaceuticals at all, it would generate an aggregate loss of about one to one and a half billion dollars out of a total of \$35 billion R&D funds spent annually by U.S. PhRMA companies in the United States and abroad (not to mention the billions spent annually by non-U.S.-based Pharma companies outside the United States).⁷⁴ Fully 90 percent of revenues of U.S. PhRMA companies in 2001 came from sales in the United States, Canada, Western Europe and Japan, while 0.3 percent came from sales in Africa.⁷⁵

A recent report by the World Bank indicates that, in 2002, developed countries accounted for more than 95 percent of the \$270 billion of the world's leading twenty country pharmaceutical markets, and that developing countries that might benefit from importing under compulsory licenses for medicines would

⁷⁴ Abbott, above n. 41. Recent data released by U.S. PhRMA indicates that its membership (which includes European and Japanese division spending in the U.S.) had an estimated worldwide R&D expense of \$32.051 billion in 2002. PhRMA, Pharmaceutical Industry Profile, app., tbl. 1 (2003), at <http://phrma.org>.

⁷⁵ PhRMA 2003 Profile, above n. 74, app., tbl. 9.

probably account for less than one or two percent of global pharmaceutical sales.⁷⁶ According to U.S. PhRMA's most recent member company data, in 2001 its members spent 0.1 percent of their worldwide R & D dollars in Africa.⁷⁷

The foregoing figures are approximations, and Pharma has begun assembling data to suggest that its future sales in developing countries (such as China) will account for a greater share of its R & D-supporting revenues.⁷⁸

Yet, even assuming that the developing country contribution to Pharma R & D will grow, everyone can agree at the outset that least-developed countries for the foreseeable future will play no material role in contributing to Pharma R & D. Patent rents from these countries are essentially irrelevant to Pharma and to potential pharmaceutical innovation.

Do the developed countries rely on patent rents from middle and higher income developing countries to fund R&D? It seems unlikely, but more empirical research on this question would be useful. The tentative conclusion against such reliance is strongly reinforced by considering the role of public R & D funding in the United States.

The R & D budget of the National Institutes of Health for 2003 was \$28 billion.⁷⁹ However this figure may be interpreted, this budget clearly swamps contributions from developing countries to U.S. R & D efforts. Moreover, NIH research funding is converted to Pharma patents without any significant royalty payments being returned to the public treasury.⁸⁰

When discussing access to essential medicines, including ARVs, there is little reason to believe that developing countries would so take advantage of Pharma patents as to cause a material impact in the developed world. If so, what explains the aggressiveness with which the right to secure and protect patents in developing countries is defended? One possible explanation is that Pharma worries that developing country exporters will successfully build their

⁷⁶ Carsten Fink, *Implementing the Doha Mandate on TRIPS and Public Health*, World Bank Trade Note 5 (29 May 2003).

⁷⁷ PhRMA 2003 Profile, above n. 74, app., tbl. 4.

⁷⁸ Harvey Bale, PowerPoint Presentation at NYU Law School (Feb. 2003).

⁷⁹ See above n. 5.

⁸⁰ The U.S. Government Accounting Office data regarding the development, and the private versus public returns, on Taxol is astonishing. According to the GAO:

NIH's total Taxol-related spending [is] \$ 484 million through 2002. BMS's sales of Taxol totaled over \$ 9 billion from 1993 through 2002. BMS agreed to pay NIH royalties at a rate equal to 0.5 percent of worldwide sales of Taxol as part of a 1996 agreement to license three NIH Taxol-related inventions developed during the CRADA. Royalty payments to NIH have totaled \$ 35 million." General Accounting Office Reports & Testimony, GAO-03-829, IAC (SM) Newsletter Database (TM) No. 7, vol. 2003, IAC-ACC-NO: 104886946 (LEXIS) (4 June 2003)

businesses on the basis of Pharma R & D and penetrate the higher income developed country markets.

In fact, pharmaceutical producers in India are increasingly penetrating the U.S. market,⁸¹ and Chinese producers will undoubtedly follow. To enter the U.S. market, a Chinese or Indian producer either needs a license for a patented medicine or the capability to supply a medicine that is already off-patent. The presence or absence of patent protection in the Chinese or Indian markets may affect the overall profitability of the Chinese or Indian pharmaceutical industries, but the latter do not appear to lack the capital necessary to build facilities to penetrate the U.S. market. In short, while there may be some correlation between patent protection in the Indian, Chinese and U.S. markets, the one thing seems to have only a modest correlation with the other.

Will Pharma increasingly rely on sales of patented medicines in China (or India) for its own R & D and long-term survival? Perhaps, but imposing higher prices on consumers throughout the developing world due to concerns about access to the Chinese market is a poor way to protect Pharma's interests. These may be better protected directly in a political dialogue between the U.S. and China.

The National Institutes of Health are using public funds to create public goods in the form of R & D on new medicines. An assumption has been made that low-cost private patenting or licensing by Pharma of the relevant research results is the best way to reap the benefits from those public goods. It is worthwhile to consider whether the public good might in fact be increased in the United States and abroad by a broader pattern of licensing that brought multiple producers of medicines into the market and thereby provided low-cost access to medicines in the United States and in developing countries. Similar arrangements might be pursued by the EU, Japan and Switzerland.

B. Drugs for neglected diseases

There is a specific market failure in the case of R & D on diseases of relevance primarily for developing countries, such as sleeping sickness, leishmaniasis, and Chagas disease. The market failure occurs because those afflicted by these diseases do not constitute a profitable private market for new treatments. Private R & D is not therefore directed to developing treatments.

This problem is being addressed in a concrete way by the Drugs for Neglected Diseases Initiative (DNDi),⁸² a collaborative effort formed as an outgrowth of the Drugs for Neglected Diseases Working Group organized by

⁸¹ Author's discussions with D.G. Shah, representing the Indian generic pharmaceutical sector.

⁸² Details available at <http://www.accessmed-msf.org/dndi.asp>.

Doctors Without Borders. Other initiatives are also addressing this problem set.

There are other areas in which the private market, organized around patents, will not provide solutions to critical medicines issues. For example, when the U.S. determined that there was a pressing need for vaccines and treatments to be used to counter bio-terror threats, it immediately announced the availability of government subsidies for such efforts.

William Nordhaus wrote insightfully about the patent-subsidy tradeoff.⁸³ While he concluded that, in the general economic case, patents may be the more efficient means of generating innovation, this did not mean that public subsidies should not also play an important role in innovation. “Prizes” or fixed financial rewards for innovation are another alternative to patents.

When the goal of R & D is well defined, the inefficiencies associated with subsidies may well be minimized. A specific disease requiring a treatment or cure is a known objective. It is well to bear in mind that the United States has provided an enormous level of public subsidy to R & D on medicines.

VIII. The emergence of competitors

China is likely to emerge as a top-flight innovator and low-cost medicines supplier over the course of this decade. It has a strong technology base, the capital to build state of the art production facilities, and a traditional cultural interest in medicines and health. India is already accelerating competitive penetration of the OECD markets.

As China and India begin to challenge Pharma dominance of these markets, allegations of “unfair trade practices” are likely to be heard, and there most likely will be efforts to impose regulatory restrictions designed to protect Pharma.⁸⁴ At the same time, as Chinese and Indian enterprises cross the innovation curve and become net generators of new medicines, these countries may logically develop heightened interest in enforcing patents. They may also become interested in price discrimination, so as to make high margin sales in the OECD, and lower margin sales in the developing world (including their own markets).

Interest in fostering lower-priced access to medicines should not be confused with idealizing or romanticizing the generic producer. With rare exception, pharmaceutical enterprises will seek to maximize their profits. Competitive markets are the best mechanism for encouraging lower prices, and generic production is necessary to achieving that end.

⁸³ WILLIAM D. NORDHAUS, *INVENTION, GROWTH AND WELFARE* (1969).

⁸⁴ An offsetting factor will be the interest of PhRMA in selling into the Chinese and Indian markets.

IX. Conclusions – the hydra without hercules

Facilitating access to essential medicines requires political commitment and a plan of action. At present, most efforts are focused on urgent and immediate problems, such as addressing treatment for HIV/AIDS. This includes promoting additional funding for the procurement of medicines, encouraging generic production, impeding efforts to further cartelize the global pharmaceuticals market, and promoting R & D on drugs for neglected diseases. The press of these urgent needs makes focus on longer term and more comprehensive solutions to essential medicines issues difficult.

The mythical Hydra was a many-headed beast with a remarkable regenerative capacity. The public health situation in developing countries shares these characteristics. The problem is multi-faceted, and addressing one aspect often reveals new challenges. Even Hercules was unable to slay the Hydra single handedly. He required the help of an assistant. Hercules did, however, provide strong leadership and commitment. Political leadership and commitment is likewise needed to address the problem of access to essential medicines, and it is not yet clear from where such leadership and commitment will emerge.