

Finding a Healthy Balance: Evaluating Models for Change to International Intellectual Property Laws Affecting Global Access to Medicine and Realisation of the Human Right to Health¹

Genevieve Wilkinson

Abstract

Human rights have been diffused by waves of globalisation that also swell the economic forces of trade liberalisation so that they include diverse multilateral regimes such as the international intellectual property system (TRIPS). This article considers this system and identifies problems with TRIPS and the way it affects individuals' ability to access medicine and consequently to realise the human right to health. The case studies of India, Thailand and Mozambique demonstrate that the existing TRIPS system is insufficient for progressive realisation of the human right to health and enable us to formulate criteria for a better system. The criteria include an ability to balance providing consumers with essential medicine and innovators, often multinational corporations, with incentives, so that they continue to develop medicine to address health needs. The article proposes a global taxation body that requires States to contribute to a fund which oversees the distribution of essential medicine by streamlining and enhancing existing aid and research and development projects. It creates a multi-stakeholder forum to facilitate this work and encourages States to work with multi-national corporations. If intergovernmental organisations, Civil Society and the media coordinate to overcome obstacles to the adoption and implementation of this model, it can create a feasible balance between competing interests to develop an intellectual property

system which enhances the implementation of the human right to health.

Key words: Health, evaluation, intellectual property, human rights, access to medicine

Resumen

Los derechos humanos han sido difundidos por olas de globalización que también engrosan las fuerzas económicas de la liberalización comercial de manera que incluyen diversos regímenes multilaterales tales como el sistema internacional de la propiedad intelectual (TRIPS). Este artículo considera dicho sistema e identifica problemas con el TRIPS y el modo en cómo afecta la capacidad de los individuos para acceder a la medicina y en consecuencia para darse cuenta del derecho humano a la sanidad. Los casos prácticos de la India, Tailandia y Mozambique demuestran que el sistema de TRIPS existente resulta insuficiente para la comprensión progresiva del derecho humano a la sanidad y nos permiten formular criterios para un sistema mejor. Dichos criterios incluyen una capacidad para el equilibrio ofreciendo a los consumidores medicina esencial y a los innovadores, a menudo compañías multinacionales, incentivos, de manera que continúen desarrollando la medicina con el fin de tratar las necesidades sanitarias. El artículo propone un órgano

¹ This article was adapted from a thesis written at the University of Deusto, Bilbao under the supervision of Professor Felipe Gómez Isa while the author was a candidate for the European Master of Human Rights

and Democratisation at the European Inter-University Centre. Genevieve.wilkinson@gmail.com

global de impuestos que exija a los Gobiernos contribuir a un fondo que supervise la distribución de la medicina esencial racionalizando y mejorando la ayuda existente y los proyectos de investigación y desarrollo. Crea un foro multi-participativo al objeto de facilitar este trabajo y anima a los Gobiernos a trabajar con las compañías multinacionales. Si las organizaciones intergubernamentales, la Sociedad Civil y los medios de comunicación se coordinan con el fin de superar los obstáculos que encuentren en la adopción y ejecución de este modelo, puede crear un equilibrio factible entre intereses participantes para desarrollar un sistema de la propiedad intelectual que mejore la ejecución del derecho humano a la sanidad.

Palabras clave: Sanidad, evaluación, propiedad intelectual, derechos humanos, acceso a la medicina.

Introduction

Every year 18 million people die from curable diseases and hundreds of millions suffer grievously from these same illnesses.² The African child with HIV/AIDS, the Indian child with leukaemia and the elderly Thai man with heart disease all have the human right to health. Without medicine to treat their illness, their ability to realise this right is greatly compromised.

Access to medicine plays a key role in achieving the human right to the highest attainable standard of health. Medical innovation and improving standards of living have enabled us to treat many of the infectious and chronic diseases faced by humans in the last century with increasing effectiveness.³ In recent centuries, intellectual property and, most relevantly, the patent system have developed as an area of law designed to protect the rights of innovators and foster innovation. Rhetorically the system strives to create a balance between the creators of innovation and the users of innovation, although the feasibility of this is doubtful when there are vast economic disparities between users. International intellectual property standards now impact on both the wealthiest and the poorest individuals.

² POGGE, Thomas W., 'Human Rights and Global Health: A Research Program', in BARRY, Christian and POGGE, Thomas W. (eds.), *Global Institutions and Responsibilities: Achieving Global Justice*, Blackwell, Oxford, 2005, p. 190.

The article will initially consider the existing TRIPS system. The basis for this analysis will be three case studies: Thailand, India and Mozambique. The Thailand and India case studies will provide context for an understanding of what could happen if there was widespread implementation of TRIPS flexibilities, which are already approved public health exceptions to the TRIPS regime. Mozambique provides a basis to examine the role of widespread health partnerships augment the existing TRIPS system. This article identifies arguments for change to the existing system to postulate that there is a need to change the TRIPS system so that it meets certain evaluation criteria. An alternative system is assessed according to its ability to deliver minimum core obligations using a rights based approach, balance interests between actors, facilitate sustainable development and respond to globalisation concerns.

The article will then propose an alternative model to the existing system: a taxation based global fund to provide access to drugs in poor countries, which addresses normative and practical dimensions of the access to medicine dilemma in attempting to realising the highest attainable standard of health.

1. Concepts and Actors Relevant to the Access Debate

The debate on essential medicine is situated at the intersection of international intellectual property law, international trade law and human rights law. There is no tribunal which arbitrates in all of these areas. National laws are relevant because the implementation of TRIPS occurs within national legal systems. Consequently understanding the interaction between these laws can be like unravelling a complex web where it is difficult to know which thread of law prevails, as adjudication crosses several distinct jurisdictions.

Creators of pharmaceuticals are entitled to access international intellectual property rights through TRIPS, which is an agreement under the WTO regime. The WTO regime functions independently from the UN regime, although the State membership composition of the organisations is similar.

³ BLUM, John D., 'Law as Development: Reshaping the Global Legal Structures of Public Health', *Michigan State Journal of International Law*, vol. 12, 2003, p. 208.

Intellectual property law developed to protect intangible property which required different regulation than more traditional, tangible forms of property.⁴ As stated, the system of intellectual property strives for a balance between users and creators.⁵

Users are generally consumers or potential consumers of a given invention. Creators are the rights holders who develop the invention. The system grants a limited monopoly to innovators which allows them to commercialise their inventions, often well above production costs, for a limited time period. This provides them with the incentive to innovate new technologies which benefit users. The balance also requires that innovators provide detailed information about these inventions in the public domain so that they can be produced cheaply by other manufacturers when the monopoly expires and also be used by other researchers to develop further technologies which will also benefit users.⁶ The economic objectives of the system are to promote investments in knowledge creation and promote widespread dissemination of new knowledge.⁷

WTO Member States are bound by TRIPS to respect intellectual property rights but generally have coexisting obligations under the UN based International Convention on Economic, Social and Cultural Rights⁸ (ICESCR) to provide the highest attainable standard of health for individuals. The ICESCR codifies Article 25(1) of the Universal Declaration of Human Rights⁹ (UDHR) which provides that: 'Everyone has the right to a standard of

living adequate for the health and well-being of himself and his family.' Although, as a declaration, the UDHR is soft international law¹⁰ it has weight for several reasons.¹¹ The entire UDHR, with the ICESCR and the International Covenant on Civil and Political Rights (ICCPR), has been characterised as a binding interpretation of Article 55 of the UN Charter,¹² which requires the UN to promote universal respect for human rights,¹³ higher standards of living,¹⁴ and solutions for international, economic, social, health and related problems.¹⁵ Importantly Article 56 of the UN Charter, and its counterpart in the UDHR, Article 28, require members to cooperate to achieve the goals articulated in Article 55.

Attaining the health standards established by these instruments often requires States to enable individuals to access pharmaceuticals patented under intellectual property laws which are essential to the treatment of many illnesses. WHO, which is an organisation constituted as the public health component of the UN, identifies Essential Medicines, which are considered necessary for the treatment of various illnesses. There is controversy concerning whether the flexibilities of the TRIPS regime are relevant for all of the Essential Medicines identified by WHO and apply to both those pharmaceuticals which treat infectious disease of global pandemic and those which treat other life-threatening chronic illnesses.

The access to medicine debate is also situated in the realm of international relations.¹⁶ Political will is often the key to the effective implementation of international law and there is a deli-

⁴ LETTERMAN, G. Gregory, *Basics of Intellectual Property Law*, Transnational Publishers, Ardsley NY, 2001, pp. 1-2.

⁵ GUPTA, Amit, 'Patent Rights on Pharmaceuticals and Affordable Drugs: Can TRIPS Provide A Solution?' *Buffalo Intellectual Property Law Journal*, vol. 2, Summer 2004, p. 130. Gupta describes a balance that reflects the tension between the two clauses of Article 27 of the UDHR, which protect both rights to 'share in scientific advancement and its benefits' and rights to the 'protection of the moral and material interest from any scientific...production.'

⁶ LETTERMAN, *op. cit.*, p. 7.

⁷ MASKUS, Keith E., 'Intellectual Property Rights and Economic Development', *Case Western Reserve Journal of International Law*, vol. 32, Summer, 2000, p. 473.

⁸ International Covenant on Economic, Social and Cultural Rights of 16 December 1966, 993 U.N.T.S.; 6 I.L.M. 368 (1967)

⁹ Universal Declaration of Human Rights, General Assembly Resolution 217A (1948), UN Doc. A/810 (1948).

¹⁰ WATERS, Melissa A., 'Creeping Monism: The Judicial Trend Toward Interpretive Incorporation of Human Rights Treaties,' *Columbia Law Review*, vol. 107, April, 2007, p. 667.

¹¹ RASULOV, Akbar, 'Revisiting State Succession to Humanitarian Treaties: Is There A Case for Automaticity?' *European Journal of International Law*, vol. 14, February, 2003, p. 149. It was made unanimously by members of the UN, which satisfies the *opinio juris* element of customary law. This means that if empirical evidence of its practice can be identified it constitutes binding international law.

¹² NEWMAN, F and WEISSBRODT, D, *International Human Rights: Law, Policy and Process*, Anderson, Cincinnati, 1990, p. 582.

¹³ Charter of the United Nations of 26 June 1945, 59 Stat. 1031; T.S. No. 993; 3 Bevans 1153 (1945) (UN Charter) Article 55(c).

¹⁴ *Ibid.*, Article 55(a).

¹⁵ *Ibid.*, Article 55 (b).

¹⁶ SHAFFER, Gregory, 'Who decides? A Comparative Institutional Approach to International Trade Law', *Journal of International Economic Law*, vol. 7, 2004, p. 459.

cate balance between international trade law and international politics.¹⁷ This article aims to provide a legal and political understanding of the issues relevant to access to medicine. Inherent to this is a tension between normative human rights law considerations and practical implementation considerations.

1.1. *What is the International Intellectual Property System?*

TRIPS is the key relevant source for both intellectual property law and international trade law in relation to access to essential medicine.¹⁸ The TRIPS framework protects patents for inventions which involve an 'inventive step' and are 'capable of industrial application,' equally, irrespective of the nationality of the patent holder.¹⁹ As over 40 countries did not provide patent protection for pharmaceuticals prior to TRIPS,²⁰ the implementation structure of this agreement has been staggered for developed, developing and least developed countries.²¹ Least developed countries have until 2016 to implement the provisions although many have already implemented them, prompted by aggressive bilateral trade negotiations external to TRIPS.²² The deadline for full implementation of the agreement for developing countries was 2005.²³ As patents on pharmaceuticals are part of the agreement, the impact of this has been negative changes to the availability and legality of generic pharmaceuticals in the world market, partly because India, one of the largest manufacturers

of generic pharmaceuticals, implemented TRIPS at this time.²⁴ Generic pharmaceuticals are bioequivalent formulations of originator pharmaceuticals which can usually only be legally produced in countries where the TRIPS system operates when the patent for the originator pharmaceutical expires.

TRIPS uses a registration system to protect pharmaceutical patents in a number of ways. It provides patent holders with a bundle of exclusive rights so that they can exploit their invention in the jurisdiction in which a patent has been granted for 20 years.²⁵ As these rights include the right to supply the market with imports of their patented product²⁶ and Member States cannot exclude any field of technology from their patent regime,²⁷ this reduces the likelihood of others manufacturing and selling the invention, or a product which is based on the invention, anywhere in the world, as it is rarely commercially viable. The monopoly that these rights create means that for 20 years the patent holder can usually sell the patented product at very high prices as no-one else is able to sell the same product.²⁸ In exchange for these rights the patent holder publishes a detailed explanation of how the invention works.²⁹ Once a patent expires, the competition usually created by generic sales generally means that the price of a product falls dramatically.³⁰

There are limited exceptions to these exclusive rights of TRIPS.³¹ The enforcement of the agreement's provision is the individual responsibility of Member States.³²

¹⁷ CONDON, Bradley, and SINHA, Tapen, 'Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries', *Northwestern Journal of International Law and Business*, vol. 26, Fall 2005, p. 30.

¹⁸ Patent law has been regulated by international law since the conclusion of the Paris Convention in 1893. Paris Convention for the Protection of Industrial Property, 20 March 1883 as last revised at Stockholm, 14 July 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 (1967). These laws have been interpreted by the Doha Declaration and the 2003 Declaration on Paragraph 6 of the Doha Declaration pursuant to Article 31, Vienna Convention on the Law of Treaties of 23 May 1969, 115 U.N.T.S. 331; 8 I.L.M. 679 (1969) (Vienna Convention).

¹⁹ Article 1, TRIPS.

²⁰ WHO, «WTO and the TRIPS Agreement», available at http://www.who.int/medicines/areas/policy/wto_trips/en/index.html consulted on 13 June 2008.

²¹ Article 65, TRIPS.

²² OVETT, Davinia, 'Making Trade Policies More Accountable and Human Rights-Consistent: A NGO Perspective of Using Human Rights Instruments in the Case of Access to Medicines', in BENEDEK, W., DEFUYER K. and

MARELLA, F. (eds.), *Economic Globalization and Human Rights*, Cambridge: Cambridge University Press, 2007 at pp. 274–275.

²³ *Ibid.*, p. 274.

²⁴ *Ibid.*

²⁵ Articles 27, 28 and 33, TRIPS.

²⁶ Article 28(1), TRIPS.

²⁷ Article 27(1), TRIPS.

²⁸ Article 33, TRIPS.

²⁹ LETTERMAN, *op. cit.*, p. 7.

³⁰ Food and Drug Administration, 'Generic Competition and Drug Prices', April 4, 2006, (consulted on 4 July 2007).

³¹ TRIPS, Articles 8, 28, 30 and 31.

³² FRIEDGEN, Kelly, 'Rethinking The Struggle Between Health & Intellectual Property: A Proposed Framework For Dynamic, Rather Than Absolute, Patent Protection Of Essential Medicines', *Emory International Law Review*, vol. 16, Fall 2002, p. 696. An enforcement regime has been proposed by the EU, but the proposals were largely unpopular. Gerhardsen, TOVE IREN S., 'WTO TRIPS Council Snags on Enforcement, Discusses Biodiversity', p. 3 in *Intellectual Property Watch*, vol. 3, no. 11, November 2006, p. 3.

Serious criticisms of the impact of the implementation of TRIPS by non-developed countries prompted the Doha Declaration of 2001, to interpret how the agreement should operate in practice in relation to public health. The Declaration stated that all countries had the right to enforce TRIPS in a manner consistent with public health and the TRIPS agreement should not prevent Members from taking measures to protect public health.³³

The Doha Declaration reinforces that the TRIPS agreement should be read in light of the object and purpose of the agreement, consistent with customary international law. Importantly, the preamble acknowledges the potentially competing needs of effective enforcement of intellectual property rights and of least developed countries. The Doha Declaration clarifies the right of Member States to implement compulsory licences on public health grounds and decide the grounds for granting these licences. Significantly, Member States have the right to determine what constitutes national emergencies and matters of extreme urgency. A non-exhaustive list of public health crises which would qualify is included, identifying HIV/AIDS, tuberculosis, malaria and other epidemics.³⁴ Practically, the Declaration also permits parallel importing of products to occur, because it enables States to adopt a policy of international exhaustion. This means that a patent holder cannot prevent the on-sale of his product in another country where he holds patents, if it is initially sold under the authority of the patent holder.

³³ Doha Declaration, Paragraph 4.

³⁴ This explicit reference to epidemics can make it more difficult to argue for compulsory licensing of pharmaceuticals for treatment of chronic illnesses like heart disease and diabetes.

³⁵ MALPANI, Rohit and KAMAL-YANNI, Mohga, 'Patients Versus Patients: Five Years After the Doha Declaration', Oxfam Briefing Paper, No. 95, November 2006, available at http://www.oxfam.org/en/files/bp95_patients-vspatients_061114/download (consulted on 27 June 2007), p. 19.

³⁶ As of 14 July 2006, the International Covenant on Economic, Social and Cultural Rights has been ratified by 153 States; the International Covenant on Civil and Political Rights, by 156. See also Article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, 660 U.N.T.S. 195; 5 I.L.M. 352 (1966) (ICERD); in Articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination Against Women of 18 December 1979, 1249 13; 19 I.L.M. 33 (1980) (CEDAW); and in Article 24 of the Convention on the Rights of the Child of 20 November 1989, 1577 U.N.T.S. 3; 28 I.L.M. 1456 (1989) (CRC). The right to health is also recognised in regional hu-

The existing compulsory licensing provisions created a problem for countries without sufficient capacity to manufacture pharmaceuticals under compulsory licence, as States were prevented from exporting products produced under compulsory licence. The problem was referred to the Council of TRIPS for decision. The Council responded in its decision of 30 August 2003 (the August Decision) where it granted countries the right to import generic products from other countries, where the other country also applied to produce these products for the country lacking capacity to do so. Unfortunately, implementing this regime has proved to be cumbersome for prospective producers and recipients.³⁵

1.2. What is the human right to health?

This article will use a legal understanding of the human right to health which can be derived from the UDHR, the ICCPR and the ICESCR.³⁶ The human right to health in Article 25 is transformed into binding international law by Article 12 of the ICESCR which proclaims 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'³⁷ Fundamentally, the right to health is linked both to the right to life, as non-treatment of serious illness is life threatening, and the right to an adequate standard of living.³⁸ However, it is important to recognise that, in practice, the nature of the human right to health is a contested concept, partly because of the way in which economic, social and cultural rights are implemented progressively.³⁹

man rights instruments, such as the European Social Charter of 18 October, 1961, 529 U.N.T.S. 89; Europ. T.S. No. 35 (1961) (art. 11), the African Charter on Human and Peoples' Rights of 27 June 1981, 1520 U.N.T.S. 217, 245; 21 I.L.M. 58, 59 (1982) (art. 16) and Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 17 November 1988, O.A.S. Treaty Series No. 69, 28 I.L.M. 156 (1988) (art. 10).

³⁷ Article 12(1), ICESCR

³⁸ Ovet, *op. cit.*, pp. 281-2. McCLELLAN, Melissa, 'Tools For Success': The TRIPS Agreement And The Human Right To Essential Medicines', *Washington and Lee Journal of Civil Rights and Social Justice*, vol. 12, Fall, 2005, pp. 164-168.

³⁹ 'The amorphous nature of this right – its ambiguity, its elasticity, and the difficulty of translating it into enforceable legal standards has frustrated efforts to give it meaning in international or domestic law. BLOCHE, M. Gregg, and JUNGMAN, Elizabeth R., 'Health Policy And The WTO', *Journal of Law, Medicine and Ethics*, vol. 31, Winter, 2003, p. 530.

The attainment of this right includes realisation of 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases.'⁴⁰ Prevention and treatment is often achieved through the use of pharmaceuticals and the WHO Essential Medicines List reinforces the importance of pharmaceuticals to the treatment of disease.

Comment 14 of the Committee for Economic, Social and Cultural Rights (CESCR) specifically acknowledges that providing access to essential medicine, as defined by the WHO Action Programme on Essential Drugs, is a core obligation.⁴¹ It distinguishes between States which are unable to implement the rights under this Covenant and States which are unwilling to implement the rights, clarifying that unwillingness to implement these rights is a violation of Article 12 of the ICESCR.⁴² Because the ICESCR requires States to achieve the full spectrum of rights in the Covenant progressively, the CESCR has found it necessary to clarify that in the case of the human right to health there are certain minimum core obligations which a State must achieve.⁴³ In order to realise this right it is necessary that medicine be available in sufficient quantity, accessible to everyone without discrimination, acceptable in terms of respectful of medical ethics and customs, scientifically appropriate and of good quality.⁴⁴ Medicine must not only be economically and physically accessible but information about it must also be accessible.⁴⁵

States are required to consider their legal obligations in relation to the right to health when entering into multilateral or bilateral agreements or agreements with international organisations.⁴⁶ Importantly, this requirement is the normative basis for why TRIPS should be interpreted consistently with the human right to health and why the implementation of TRIPS should be analysed using human rights standards. If the TRIPS system is not consistent with the human right to health, the obligations most members of TRIPS have made in the UN Charter and the

ICESCR are not being observed and they are violating international law. These obligations include monitoring the activities of individuals, groups or corporations to prevent violations;⁴⁷ adopting adequate national health policies; sufficient expenditure and appropriate allocation of public resources to health, particularly for the vulnerable or marginalised; and monitoring the right to health at a national level.⁴⁸ The Comment requires that, where possible, States should assist other States to realise the human right to health and provide the necessary aid to facilitate access to essential healthcare where possible and where required.⁴⁹ WHO estimates that of the 40 million deaths in developing countries each year, one quarter of them could be prevented if there were access to inexpensive, effective drugs on the Model List.⁵⁰

1.3. *Who are the actors?*

Despite an increasing awareness of the diverse range of actors operating in the sphere of international law, States predominantly remain the subjects of international law. States are bound by international standards and if these standards are breached, individuals and Civil Society actors publicly identify this but the standards themselves are usually enforced (if they are enforced) by other States or IGOs or tribunals created by States.⁵¹

However, individuals are increasingly able to enforce their human rights with the development of organs, such as the Human Rights Committee, associated with the international treaties creating these rights. This can be a time consuming and expensive process and many of the individuals affected by the access to essential medicine debate may lack the awareness or resources necessary to enforce these rights. In these situations Civil Society and Non-Government Organisations (NGOs) play

⁴⁰ Article 12(2)(c), ICESCR.

⁴¹ CESCR, General Comment No. 14: The right to the highest attainable standard of health, UN Doc. E/C.12/2000/4 (11 August 2000) (General Comment 14). Paragraph 43(d).

⁴² *Ibid.*, Paragraph 47.

⁴³ *Ibid.*

⁴⁴ *Ibid.*, Paragraph 12.

⁴⁵ *Ibid.*

⁴⁶ General Comment 14, Paragraph 50.

⁴⁷ *Ibid.*, Paragraph 51.

⁴⁸ *Ibid.*, Paragraph 52.

⁴⁹ *Ibid.*, Paragraph 39.

⁵⁰ WHO, 'Essential Medicines', 2007c, available at http://www.who.int/medicines/services/essmedicines_def/en/index.html (consulted on 4 July 2007)

⁵¹ CHAFFIN, Sally, 'Challenging The United States Position On A United Nations Convention On Disability', *Temple Political and Civil Rights Law Review*, vol. 15, Fall 2005, p. 136.

a key role as they may be able to raise awareness of individual rights and, through advocacy, lobby States and the international community to enforce human rights standards.⁵²

Although MNCs are significant actors in international relations, they often avoid the direct force of international law.⁵³ There has been substantial debate in the UN about the accountability of MNCs and their standing in international law, particularly once the Draft UN Human Rights Norms for Corporations began progressing through the UN system, but no decisive action has been taken to give MNCs formal status in international law.⁵⁴ Consequently MNCs often avoid regulation because their operations, which potentially breach international law, can occur outside their State of incorporation (Home State) and the States hosting these operations (Host States) are reluctant to enforce international standards and lose potentially lucrative industry.⁵⁵ Pharmaceutical companies are often powerful MNCs who are able to exert significant influence over the negotiations of international regimes, including TRIPS.⁵⁶

2. The current system

Three case studies demonstrate the operation of the existing system and some of the problems that currently limit access to essential medicine consistent with the human rights to help. They form the basis of an argument for change to the existing system and indicate the necessary criteria for a system that is consistent with the human right to health. Thailand and India – have been selected to demonstrate the approach of developing countries to providing their inhabitants with essential medicine and Mozambique demonstrates how the approach of least developed countries in this respect. The case studies can be used as tan-

gible examples of the implementation of the mechanisms to promote public health that have already been approved by the international community.

2.1. Case Study 1 – Cancer drugs in India

India has been one of the most active advocates for a fairer balance between creators and users of essential medicine, lobbying strongly for the Doha Declaration. The US has frequently listed it on its 'Special 301 Priority Watch List.'⁵⁷ Until 2005, India did not allow patents for pharmaceutical products and a thriving generic industry produced competitively priced pharmaceuticals. These generic products were exported to other countries, well below originator prices, increasing consumer access in these countries. Despite this, Chaudhari argues that there were problems with drug quality because of poor drug control administration which meant that certain well-regarded firms could exercise market power and charge higher prices.⁵⁸ Even lower generic prices were not low enough to secure access for India's poor and India's final implementation of TRIPS in 2005 will eventually further restrict access.⁵⁹ India's new Patent Act provides for the patenting of pharmaceutical products, nonetheless it permits the production of all generic drugs which were already being manufactured prior to the implementation of the Patent Act in 2005, unless an application was filed with the Indian Patent Office on or after 1 January 1995. Even if such an application was filed, there are further limitations on patent holder's rights where a generic drug was manufactured and subsequently an Indian patent was filed prior to 2005.⁶⁰ As a result, India can also export these generic drugs to other countries that issue compulsory licences but cannot manufacture them.⁶¹

⁵² Ovet, *op. cit.*, p. 297.

⁵³ DE FEYTER, Koen, *Human Rights: Social Justice in the Age of the Market*, Zed Books, London, 2005, pp. 53-54.

⁵⁴ KINLEY, David and CHAMBERS, Rachel, 'The UN Human Rights Norms for Corporations: The Private Implications Of Public International Law', *Human Rights Law Review*, vol. 6, 2006, p. 447.

⁵⁵ *Ibid.*, p. 455.

⁵⁶ SELL, Susan K., 'Trade Issues and HIV/AIDS', *Emory International Law Review*, vol. 17, Summer 2003, p. 934. SORNARAJAH, M., 'Power and Justice: Third World Resistance in International Law', *Singapore Year Book of International Law*, vol. 10, 2006, p. 37. FORD, Sara M., 'Compulsory Licensing

Provisions Under The Trips Agreement: Balancing Pills And Patents', *American University International Law Review*, vol. 15, 2000, p. 954.

⁵⁷ See generally United States Trade Representative, 2007.

⁵⁸ CHAUDHARI, Sudip, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS and Developing Countries*, Oxford University Press, Oxford, 2005, p. 270.

⁵⁹ *Ibid.*

⁶⁰ MUELLER, Janice M, 'Taking TRIPS to India – Novartis, Patent Law and Access to Medicines', *New England Journal of Medicine*, vol. 356, 8 February 2007, p. 542.

⁶¹ *Ibid.*

India's Patent Act promotes a public health focus.⁶² Section 3(d) 'limits product patents to new chemical entities only, refusing to recognise incremental innovation on a known compound.'⁶³ This prevents the controversial practice of 'evergreening', a method used by pharmaceutical companies to extend the patent life of certain pharmaceuticals by obtaining new patents for the same product where it is used for a different purpose, sometimes as a result of combining them with other pharmaceuticals.⁶⁴ The Indian Government argues that the provision 'is aimed at preventing pharmaceutical companies from obtaining patents on old medicines, [to] prevent trivial patents and new use patents.'⁶⁵ Arguably, preventing evergreening restricts pharmaceutical companies from creating additional monopolies which reduce the ability of consumers to access cheaper generic versions of the pharmaceutical; however this is controversial as there is evidence that this can exclude rights for truly innovative products.⁶⁶

Section 3(d) has been the subject of highly publicised litigation in India by pharmaceutical company Novartis, who has challenged the validity of the decision by the Indian patent body to reject its patent application for Glivec (which has received patents in nearly 40 other countries),⁶⁷ partly because India does not recognise incremental innovation and Glivec is an anti-cancer drug whose active ingredient was deemed to be a modification of an existing compound.⁶⁸ Prior to the Patent Controller's decision to reject its application, Novartis was preliminarily granted exclusive marketing rights over Glivec in In-

dia and brought a law suit against generic producers to prevent them from selling their drugs.⁶⁹ In India, Novartis sells Glivec for US\$26,000 for a year's supply for one user while generic producers offer it at less than ten percent of that price.⁷⁰ Yet Novartis argues that Glivec is free for 99% of Indian patients.⁷¹ Novartis challenged the Patent Controller's decision as contrary to TRIPS and the Indian Constitution and the case was referred to the Indian Constitutional Court. During the litigation many parties urged Novartis to drop the suit because it threatened the operation of the Doha Declaration, setting a precedent for aggressive and costly litigation every time a country attempts to exercise TRIPS flexibilities.⁷² The Indian government urged Novartis to withdraw its suit, warning that although it has not yet issued compulsory licences under the new patent system it can and will do so if necessary.⁷³ The ruling was made against Novartis and considered a triumph for access to medicines although concerns lingered about the ongoing impact this would have on the pharmaceutical industry in India and its willingness to introduce new pharmaceuticals.⁷⁴ The case study exemplifies the challenges faced by countries who seek to integrate public health priorities into intellectual property laws implementing TRIPS.

2.2. Case Study 2 – Heart disease drugs in Thailand

Pharmaceuticals were not patented in Thailand until 1979.⁷⁵ Under the 1979 Patent Law, patented products were only pro-

⁶² GUENNIF, Samira and CHAÏSSE, Julien, 'Present Stakes Around Patent Political Economy: Legal and Economic Lessons from the Pharmaceutical Patent Rights in India', *Asian Journal of WTO & International Health Law and Policy*, vol. 2, March, 2007, p. 91.

⁶³ Patent Act, 3(d); DOREY, Emma, 'Indian Patent Scandal', *Chemistry & Industry*, vol. 7, 9 April 2007, p. 4.

⁶⁴ *Ibid.*

⁶⁵ Indian Ambassador in Belgium, 'Statement at the Exchange of Views on the Novartis Case' made to European Parliament', 11 April 2007, available at <http://www.essentialdrugs.org/edrug/archive/200704/msg00055.php> (consulted 8 July 2007).

⁶⁶ DOREY, *op. cit.*, p. 4.

⁶⁷ *Ibid.*

⁶⁸ ALLEN, Matthew, 'India seeks end to Gleevec patent case,' 11 April 2007, available at http://www.swissinfo.org/eng/front/detail/India_seeks_end_to_Gleevec_patent_case.html?siteSect=105&sid=7704900&cKey=1176293214000 (consulted 8 July 2007).

⁶⁹ KAPCZYNSKI, Amy; CHAIFETZ, Samantha; KATZ, Zachary; and BENKLER, Yochai, 'Addressing Global Health Inequities: An Open Licensing Approach For University Innovations', *Berkeley Technology Law Journal*, vol. 20, Spring 2005, p. 1067.

⁷⁰ MUELLER, *op. cit.*, p. 541.

⁷¹ OLLIER, Peter, 'Novartis Refuse to Back Down in Indian Patent Dispute', *Managing Intellectual Property*, issue 169, May 2007, p. 10.

⁷² BARRACLOUGH, Emma, 'Waxman Urges Novartis to Drop Case', p. 18 in *Managing Intellectual Property*, issue 167, March 2007, p. 18. *Asia Pulse*, 'Novartis Case Reduces Patent Flexibilities: Ex-Swiss President', February 21 2007.

⁷³ OLLIER, *op. cit.*, p. 10.

⁷⁴ BHASKAR, Amit, 'Rethinking section 3(d) in light of the Novartis judgment', 2 June 2008, (available at <http://www.indlawnews.com/display.aspx?3793>) consulted on 15 June 2008.

⁷⁵ RAGAVAN, Srividhya, 'Can't We All Get Along? The Case for A Workable Patent Model', pp. 117–185 in *Arizona State Law Journal*, vol. 35, Spring 2003, p. 174.

tected from generic production if they were locally produced.⁷⁶ The Government maintained a compulsory licensing program. This drew a negative reaction from the US, who placed Thailand on its 301 Priority Watch List.⁷⁷ The Thai Government stopped the program and was removed from the list.⁷⁸ However, HIV/AIDS became the leading cause of death in Thailand so the Thai Government moved decisively to facilitate access to HIV/AIDS treatment for the Thai people as part of its strategy to combat the disease, although only after the US Trade Representative indicated that this was acceptable.⁷⁹

Accordingly, the Thai Government compulsorily licensed two HIV/AIDS drugs in order to provide reduced cost generic versions to HIV/AIDS sufferers. It has also resisted the pressure of the US Government to sign a bilateral trade agreement with restrictive TRIPS plus provisions.⁸⁰ Recently the Thai Government extended its compulsory licensing program to include a drug for the prevention of heart disease, Plavix, and announced its intention to import generic Plavix from India until it was able to produce its own generic version of the medicine.⁸¹ This has created controversy as the Government issued the licences without extensive negotiation with the relevant pharmaceutical companies, as required by Article 31.⁸² The Thai Government claims that it has in fact been negotiating with these drug companies for an extensive period and that the AIDS epidemic in Thailand is an internationally accepted public emergency so there is no need to make a formal declaration of this.⁸³

⁷⁶ *Ibid.*

⁷⁷ *Ibid.*

⁷⁸ *Ibid.*

⁷⁹ RAGAVAN, *op. cit.*, p. 174.

⁸⁰ Oxfam International, 'Public Health at Risk, A US Free Trade Agreement could threaten access to medicines in Thailand', Oxfam Briefing Paper, No. 86, April 2006, available at http://www.oxfam.org/en/files/bp86_thailand_publichealth/download (consulted on 27 June 2007), p. 3.

⁸¹ GERHARDSEN, Tove Iren S., 'Thai compulsory licenses stir policy debate', p. 3 in *Intellectual Property Watch*, Vol. 4, No 2, February 2007a, p. 3.

⁸² *Ibid.*

⁸³ Thai White Paper, The Ministry of Public Health and The National Health Security Office Thailand, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent*, February 2007, Sangsue Co., Ltd., Thailand, available at <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> (consulted on 27 June 2007), p. 8.

Abbott, the owner of the antiretroviral drug Kaletra which Thailand licensed, retaliated by announcing it would not register seven other HIV/AIDS product patents, which would make them unavailable in Thailand.⁸⁴ Negative international reaction to this threat has resulted in Abbott reopening negotiations with the Government, which is also renegotiating with the two other patent owners with mixed success.⁸⁵ Abbott offered the Government a more sophisticated version of Kaletra at a reduced price but the Thai Government was wary of the company's conditions that no generic version of the drug can be sold in Thailand for a fixed period. The generic prices remain substantially cheaper⁸⁶ and the Government has stated that it will not issue compulsory licences where originators offer drugs cheaper than generic producers.⁸⁷ However it has pledged to licence vital drugs, including cancer drugs, not meeting these criteria.⁸⁸ The adequacy of the dialogue between the Thai Government and the pharmaceutical companies is controversial⁸⁹ because it is unresolved whether countries should use compulsory licensing systematically or as a last resort when pharmaceutical companies will not negotiate accessible prices.⁹⁰

This is one of the first attempts by a developing country to interpret the Doha Declaration flexibilities to permit compulsory licences for a pharmaceutical designed to treat a non-infectious disease, although it has been acknowledged that in some countries these non-infectious diseases threaten more lives than the more globally publicised pandemics.⁹¹ The owner of the Plavix

⁸⁴ VAUGHAN, Martin and GERHARDSEN, Tove Iren S., 'Thailand Supported, Criticised in Effort to Use TRIPS flexibilities', *Intellectual Property Watch*, vol. 4, no. 4, 2007, p. 1.

⁸⁵ TREERUTKUARKUL, Apiradee, 'Government considers revoking compulsory licence for Efavirenz', in *Bangkok Post*, 25 May 2007.

⁸⁶ Kaisernetwork.org, 'Abbott Offers To Sell Antiretroviral Aluvia At Reduced Price In Thailand, Health Official Says', April 2007a, (consulted on 27 June 2007).

⁸⁷ Kaisernetwork.org, 'Thailand Will Not Issue Compulsory Licenses For Patented Drugs If Pharmaceutical Companies Match Generic Prices, Health Minister Says', May 16 2007b, (consulted on 27 June 2007).

⁸⁸ The Nation, 2007.

⁸⁹ Vaughan and Gerhardsen, *op. cit.*, p. 1.

⁹⁰ Condon and Sinha, *op. cit.*, p. 5.

⁹¹ LANJOUW, Jean O. 2001. «A Proposal to Use Patent Law to Lower Drug Prices in Developing Countries.» Commission on Macroeconomics and Health Working Paper Series, Work Group 2, Paper 11., pp. 4-5.

patent indicated the matter was of 'serious concern',⁹² and it was surprised a compulsory license was issued as the drug was for individual use, not for a 'public emergency' and it conducted no negotiations with the Thai Government.⁹³ Negotiations subsequently occurred but the Thai government indicated that Sanofti-Aventis' price reduction proposals were not sufficient and it planned to import a generic version of Plavix from India.⁹⁴

In May 2008, a Thai official announced that distribution of these compulsorily licensed drugs has occurred and is resulting in greater access for the Thai people to these pharmaceuticals.⁹⁵

The Thai Government has released a paper which explains the rationale for its actions, including a quite neutral written response to the actions from the US Trade Department, indicating that the US had no major objections.⁹⁶ Despite this apparent neutrality, Thailand was placed on the US 301 Priority Watch List in April 2007, partly because of these licences.⁹⁷ The public health system in Thailand reaches 78% of the Thai population, and the Thai Government has been increasing its spending on health by 4% every year.⁹⁸ One of the aims of the program is to provide Thai citizens with access to all medicine on the WHO Essential Medicines list.⁹⁹ The Thai Government argues that the high cost of patented medicine on this list has meant that it is unable to achieve this goal and talks with pharmaceutical companies to improve the situation have been unsuccessful.¹⁰⁰ As a consequence it has issued compulsory licences and consequently facilitated access to these drugs for a greatly increased number of Thai people.

The Thai case study is not a perfect embodiment of the theoretical model for fully exercising the flexibilities of TRIPS

because of the confusion as to whether the Government correctly implemented Article 31 without explicitly declaring a public health emergency or whether past negotiations were sufficient to fulfil the Article 31 requirements. The situation demonstrates potential ambiguities in the Doha Declaration and the potential resultant controversy and uncertainty. The outcome of ongoing negotiations may demonstrate the way that compulsory licensing prompts pharmaceutical companies to negotiate voluntary licences with royalties low enough to satisfy governments' stated health goals. It foretells unresolved tensions between governments and pharmaceutical companies, as increasing numbers of developing countries, like Brazil, announce their intention to pursue compulsory licences.¹⁰¹

2.3. Case Study 3 – Mozambique

This case study will look at the potential role of both inter-governmental and private-public partnerships. It will focus on access to HIV/AIDS antiretrovirals, an imperative which has been the most visible in the access to medicine debate, attracting a global response of manpower and money. Nonetheless antiretrovirals presently remain inaccessible for millions suffering with the disease and will need to be priced lower if their provision is to become financially sustainable for donors and eventually for governments themselves.¹⁰² Mozambique is a least developed country with an interesting history of partnership with many donors, predominantly European countries and the World Bank, who contributed to rebuilding the health system in Mozambique following the end of the civil war which had decimated it in the

⁹² ZAHISKA, Nicholas, 'Thai Move to Trim Drug Cost Highlights Growing Patent Rift', *The Wall Street Journal*, 30 January 2007, p. A8.

⁹³ GERHARDSEN, Tove Iren S., 'Thai Drug Licences Rile Industry: Talks Underway', *Intellectual Property Watch*, Vol. 4, No. 3, March 2007b, p. 5.

⁹⁴ TREERUTKUARKUL, A., 'Govt to Import Generic Version of Heart Drug; Health Minister Sticks to Guns over Prices', p. 2 in *Bangkok Post*, 27 June 2007, p. 2.

⁹⁵ SILVERMAN, Ed, 'Thai Official: Compulsory Licensing is Working' 9 May 2008, available at <http://www.pharmalot.com/2008/05/thai-official-compulsory-licensing-is-working/> (consulted on 15 June 2008).

⁹⁶ Thai White Paper, *op. cit.*, p. 56.

⁹⁷ GHOSH, Nirmal, 'Battle rages over Thai Actions on AIDS Drugs', *Strait Times*, Singapore Press Holdings, 28 May 2007, 2007.

⁹⁸ Thai White Paper, *op. cit.* pp. 1-2.

⁹⁹ *Ibid.*, p. 2.

¹⁰⁰ *Ibid.*, pp. 5-6.

¹⁰¹ JACK, Andrew, and LAPPER, Richard, 'Brazil spurns patent on HIV drug', *Financial Times UK*, 5 May 2007, p. 9.

¹⁰² VASAN, Ashwin; HOOS, David; MUKHERJEE, Joia S.; FARMER, Paul E.; ROSENFELD, Allan G.; PERRIENS, Joseph H., and TURMERN, Tomris, 'The pricing and procurement of antiretroviral drugs: an observational study of data from the Global Fund', *World Health Organisation Bulletin*, vol. 84, no. 5, May 2006, p. 393.

1990s.¹⁰³ This included donor funding for pharmaceuticals. Unfortunately a great deal of the infrastructure that was built was destroyed by devastating floods in 2000.¹⁰⁴ Mozambique is currently committed to developing a sector wide approach to healthcare¹⁰⁵ and as part of its Poverty Reduction Strategy Plan (PRSP) is developing and implementing strategies to deal with the HIV epidemic.¹⁰⁶

Mozambique is a member of the WTO and unlikely to access the benefits of the liberalised trading system and rise out of poverty, unless it achieves rapid growth over a long period of time, an uncertain outcome predicted to take decades.¹⁰⁷ However, its economic forecast has improved with recent debt cancellations.¹⁰⁸ In the 1980s International Monetary Fund structural adjustment programs significantly reduced Government spending on health. This has had long term impacts on the quality of the Mozambican health system¹⁰⁹ and transformed the practice of providing essential medicine to Mozambicans for nothing¹¹⁰ to charging fixed fees for pharmaceuticals. The impact of this has diminished because Mozambique has not systematically increased these fees consistent with inflation.¹¹¹

Mozambique's disease burden arises mainly from infectious and parasitic diseases, particularly malaria, pneumonia, measles,

tetanus, tuberculosis, gastrointestinal diseases and HIV/AIDS.¹¹² Easily treatable diseases such as malaria, diarrhoea and respiratory infections contribute to a heavy burden of disease.¹¹³ The HIV/AIDS epidemic in Mozambique is widespread but delivering HIV treatment is complicated because there are problems with providing treatment for even basic ailments. The National AIDS Council spearheads the Mozambique Government's strategy for addressing HIV.¹¹⁴ In 2004 the Government compulsorily licensed a HIV retroviral drug in an attempt to address the problem.¹¹⁵ Pfizer has donated Diflucan to provide treatment for the symptoms of HIV/AIDS. Despite this, WHO estimates that 16% of the population have HIV/AIDS and life expectancy has dropped from approximately 50 years to 45 years for females and 46 years for males.¹¹⁶ In a progress report to UNAIDS in January 2008 it was estimated that there are 1.6 million Mozambicans infected with HIV,¹¹⁷ of these it was estimated that about 300,000 required antiretroviral treatment for the disease.¹¹⁸ The government estimates that antiretroviral treatment is currently provided to 88,211 people a significant increase from 2006,¹¹⁹ and this number was estimated to be over 100,000 people in April 2008.¹²⁰ These figures are substantially higher than most treatment estimates for sub-Saharan Africa, although representatives of NGOs dispute the accuracy of government figures and

¹⁰³ COLLINS, Carole L. J., 'Mozambique's HIV/AIDS Pandemic: Grappling with Apartheid's Legacy', Social Policy and Development Programme Paper No. 24, Geneva: United Nations Research Institute for Social Development, February 2006, p. 17. BROWN, Adrienne, 'Current Issues in Sector-Wide Approaches for Health Development: Mozambique Case Study', World Health Organisation, Geneva, WHO/GPE/00.4, 2000., p. v.

¹⁰⁴ BROWN, *op. cit.* p. 1.

¹⁰⁵ *Ibid.*, p. 9.

¹⁰⁶ *Ibid.*, p. 13.

¹⁰⁷ ARNDT, Channing, 'The Doha Trade Round and Mozambique', World Bank Policy Research Working Paper No. 3717, Washington D.C.: The World Bank Development Research Group Trade Team, September 2005, p. 22.

¹⁰⁸ IOL website, 'Mozambique's Debt gets Cancelled,' (consulted 28 June 2007).

¹⁰⁹ CLIFF, Julie, 'Reconstructing Health in Post War Mozambique', *Association of Concerned African Scholars Bulletin*, no. 50-51, 1998, p. 3. Collins, *op. cit.*, p. 17.

¹¹⁰ BATLEY, Richard, Bjornstad, Liv and CUMBI, Amelia, 'Evaluation of General Budget Support – Mozambique Country Report', May 2006, (available at <http://www.oecd.org/dataoecd/41/57/36685764.pdf>) consulted on 8 July 2007, p. 110.

¹¹¹ LINDELOW, Magnus, *Utilization of Health Services in Mozambique*, Unpublished Phd Thesis, University of Oxford, Oxford, 2004, p. 70.

¹¹² *Ibid.*, p. 18.

¹¹³ *Ibid.*, p. 25.

¹¹⁴ Republic of Mozambique National Aids Council, 'Universal Declaration of Commitment on HIV and AIDS', January 2008, (available at http://data.unaids.org/pub/Report/2008/mozambique_2008_country_progress_report_en.pdf), consulted on 15 June 2008, p. 83

¹¹⁵ LOVE, James Packard, 'Recent examples of the use of compulsory licenses on patents', KEI Research Note 2, 2007, (available at http://www.keionline.org/index.php?option=com_content&task=view&id=41) consulted on 27 June 2007, p. 16.

¹¹⁶ WHO, 'Mozambique', 2007, available at <http://www.who.int/countries/moz/en/> (consulted on 26 June 2007), using 2005 WHO.

¹¹⁷ Republic of Mozambique National Aids Council, *op. cit.*, p. 22.

¹¹⁸ Agencia de Informacao de Mocambique, 'Mozambique: Report on HIV/Aids at Assembly', 10 May 2007a, available at <http://allafrica.com/stories/200705100726.html> (consulted on 28 June 2007).

¹¹⁹ Republic of Mozambique National Aids Council, *op. cit.*, p. 55. The figure for 2007 was 44,100.

¹²⁰ 'HIV Mozambicans Faring Better', 12 June 2008, available at <http://en.afrik.com/article13811.html> (consulted on 15 June 2008)

argue that, despite the progress made in Mozambique, access to antiretroviral drugs needs to increase.¹²¹

Many intergovernmental health partnerships have worked on health development projects within Mozambique for over a decade.¹²² The Mozambican health budget has been consistently underfunded.¹²³ More than 80% of HIV/AIDS expenditure in 2001 was from external donors.¹²⁴ However there is a problematic and fragmented historical relationship between donors and the Government, and within the donor community itself. This has led to inefficiency, instability, problems with accountability and transparency and complaints from the Mozambican Ministry of Health that it lacks control over health decisions because they are often donor driven.¹²⁵ Donors resent the influence of donor coordinators, previously the Swiss Development Corporation but now the World Bank.¹²⁶ The tension has been only partially eased by pooled funding systems, partly because these do not cover all of the available funds for the pharmaceutical sector.¹²⁷

One of the projects funded by Switzerland, the Netherlands, Norway, Denmark and Canada has been to provide pharmaceuticals. Initially the system was 'subject to unpredictable funding, erratic purchasing cycles, difficulties with long term planning and tied donations which resulted in frequent stock outs on one side and expiring drugs on the other side' because types and qualities of medicines were chosen only after donors allocated funding.¹²⁸ Since 1998-9 a common pool for pharmaceuticals,

Fundo Comum Medicamentos, operates with several donors making multi-year commitments to and delivering through this program.¹²⁹ Now some donors are redirecting these funds into a global budgeting system and drug funding will eventually become an earmarked part of budget support.¹³⁰ NGOs, which have been frequently employed by donors in healthcare projects as part of a neo-liberal emphasis on privatisation, have also been criticised for creating parallel health structures, undermining local control of health programs and contributing to local social inequality.¹³¹

Public-private partnerships addressing HIV/AIDS are identifiable in Mozambique. MSF has worked to provide comprehensive healthcare to HIV/AIDS sufferers since 2001, including voluntary counselling and HIV testing, prevention of mother-to-child transmission of the virus and treatment with antiretroviral medicine.¹³² This included directly providing antiretrovirals to 5,600 patients per month in Spring 2006 and working with the Ministry of Health to make healthcare available beyond main hospitals and at the primary healthcare level.¹³³ The number is growing but MSF's efforts cannot reach all of the 16% of Mozambicans infected with HIV. MSF trains healthcare workers as part of the program but is currently campaigning to raise awareness of the devastating impact of an acute healthcare worker shortage in Southern Africa.¹³⁴

A pharmaceutical project between Mozambique and Pfizer has resulted in donations of Diflucan for treatment of HIV/AIDS

¹²¹ Kaisernetwork.org, 'Mozambique Should Increase Number of People With Antiretroviral Access To Boost Fight Against Disease, Advocate Says', 2007c, (consulted on 28 June 2007).

¹²² African Program for Onchocerciasis Control; Concept Foundation; Diflucan Partnership Program; Global Alliance for Vaccines and Immunization; Global Fund to Fight AIDS, TB and Malaria; HIV/AIDS Treatment Consortium; Clinton Foundation AIDS Initiative; International Partnership Against AIDS in Africa; Maternal to Child Transmission; NetMark -Plus (insecticide treated net social marketing programme); Stop TB; Viramune Donation Program.

¹²³ BROWN, *op. cit.*, p. 11.

¹²⁴ MARTIN, H Gayle, *A Comparative Analysis of the Financing of HIV/AIDS Programmes In Botswana, Lesotho, Mozambique, South Africa, Swaziland and Zimbabwe*, HSRC Publishers, Cape Town, October, 2003, p. 25.

¹²⁵ BROWN, *op. cit.*, p. 21 and p. 24. COLLINS, *op. cit.*, p. 17.

¹²⁶ BROWN, *op. cit.*, p. 22.

¹²⁷ *Ibid.*, p. 18.

¹²⁸ ENEMARK, Ulrika, ALBAN, Anita, and VAZQUEZ, Enrique C.S., 'Purchasing Pharmaceuticals', HNP Discussion Paper, September 2004, available at

<http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/Chap14Final.pdf> (consulted on 28 June 2007), p. 28.

¹²⁹ *Ibid.*, pp. 28-29.

¹³⁰ BATLEY et al., *op. cit.*, p. 70, p. 48.

¹³¹ PFEIFFER, James, 'International NGOs and primary health care in Mozambique: the need for a new model of collaboration', pp. 725-738 in *Social Science & Medicine*, vol. 56, 2003, p. 727.

¹³² MSF, 'Mozambique Activity Report', 2006, available at http://www.msf.org/msfinternational/invoke.cfm?objectid=95A16BFA-5056-AA77-6CDF21E0F6EEA9B9&component=toolkit.article&method=full_html (consulted on 28 June 2007).

¹³³ *Ibid.*

¹³⁴ MSF, 'Help Wanted: Confronting the Health Care Worker Crisis to Expand Access to HIV/AIDS Treatment: MSF Experience in Southern Africa', May 2007, available at http://www.msf.org/source/countries/africa/southafrica/2007/Help_wanted.pdf (consulted on 27 June 2007), pp. 2-3.

patients with life-threatening opportunistic infections.¹³⁵ This program includes training of health and professionals, patient education and ongoing monitoring and support. It has no time or cost limits. A similar program exists with Boehringer Engel and Abbott, who provide Viramune, to reduce mother-to-child transmission of the HIV/AIDS virus, upon government request from eligible countries.¹³⁶

Another partnership example is the VillageReach partnership between the Mozambican Foundation for Community Development and the Government of Mozambique. Supported by the Gates Foundation and the World Bank, the program addresses the broader health needs of Mozambicans living in remote northern areas. Seventy percent of Mozambicans live in rural areas. The focus of the project is to create an access platform to provide access to essential services by providing vaccine delivery, energy communications and waste management services to 173 health clinics in northern Mozambique which service 3.5 million Mozambicans.¹³⁷ This means that when pharmaceutical treatment is available it can be provided and supervised in rural areas. It is an important example of the way in which health partnerships operate, directly and indirectly promote access to medicine. Part of the project involves building businesses in the area so that locals can jointly fund the project and its success has prompted over US\$7 million in additional grant funding to allow VillageReach to extend the total number of people served to over five million.¹³⁸

Although Mozambique's increasing provision of antiretroviral medicine to its citizens should not be discounted, the reality is that the existing HIV/AIDS treatment system is 80% funded by external aid,¹³⁹ yet a significant number of Mozambicans who need antiretrovirals still cannot access them. Projects like VillageReach attempt to build healthcare that is accessible and locally sustainable but the majority of aid directed towards Mozambique is less focused on these outcomes. The disease bur-

den and economic problems faced by a country like Mozambique reduce the likelihood that even projects like VillageReach result in minimum core obligations being fully realised, although projects of these sorts should be promoted. This prognosis is negative because, although access to treatment is increasing, rates of infection are also increasing,¹⁴⁰ so the long term economic prospects for Mozambique, and consequently their ability to eventually achieve minimum core obligations regarding health and access to essential medicine, are not strong. The partnership model does have a number of strengths, although it needs to be more coordinated, but the economic cost of the system to donors for a statistically low return is such that it is difficult to see how this approach can be consistent with the human right to health in the medium term. It is possible that with an exponential increase in aid and resources the partnership model will work, but the increased funding necessary, and required changes to the governance dimension of that funding, suggest that there may be a more economically feasible approach to address the needs of least developed countries.

2.4. *What problems limit access to essential medicine consistent with the human right to health?*

The case studies do not demonstrate an implementation of the existing system that enables access to essential medicine consistent with the human right to health. There are some critical problems apparent with each case study.

The case studies of Thailand and India demonstrate that developing countries need to continue to lobby developed countries to support public health flexibilities and work with MNCs based in their territories. Only then can they make the extensive compulsory licensing necessary for essential medicine workable so that the system can achieve a balance which avoids the twin

¹³⁵ Diflucan, 'Priority Countries for the Diflucan Partnership', January 25, 2005, available at <http://www.diflucanpartnership.org/en/program/countries.aspx> (consulted on 28 June 2007)

¹³⁶ HALE, Victoria G.; WOO, Katherine; LEVENS LIPTON, Helen, 'Oxymoron No More: The Potential Of Nonprofit Drug Companies To Deliver On The Promise Of Medicines For The Developing World', pp. 1057-1063 in *Health Affairs*, vol. 24, issue 4, Jul/Aug 2005, p. 1059.

¹³⁷ World Bank, 'Mozambique: VillageReach - Health Care for Remote Communities', available at <http://web.worldbank.org/WBSITE/EXTERNAL/>

OPPORTUNITIES/GRANTS/DEVMARKETPLACE/0,,contentMDK:21049634~pagePK:180759~piPK:180708~theSitePK:205098,00.html (consulted on 28 June 2007).

¹³⁸ *Ibid.*

¹³⁹ MARTIN, *op. cit.*, p. 25.

¹⁴⁰ DFID, 'Mozambique: HIV/AIDS Fact Sheet', 2006 (consulted on 28 June 2007).

market failures of insufficient access to medicine and insufficient incentive to innovate. Developing countries can work to create a transparent system of licensing to encourage generic pharmaceutical production and provide certainty to innovator pharmaceutical companies. However the gains for the right to health have clearly been driven by the governments of India and Thailand. Although the governments have strong support from NGOs, the current TRIPS regime does not create specific rights for individuals. There is no single, accountable, transparent system for ensuring that rights to health are being achieved. This is clearly not a rights based approach and it remains difficult to see how the current system can transform itself so it adopts a rights based approach, unless worldwide coordination with UN human rights bodies occurs and all countries domestically observe their existing human rights obligations to provide a human right to health and pursue this in implementing TRIPS.

The reaction of pharmaceutical companies to very limited implementation of the Doha Declaration indicates that, even if these recommendations are implemented to the existing system, it is unlikely to achieve a strong system. Countries should pursue the spirit of the public health exemptions but attempt to do so within the letter of WTO law to avoid the criticism Thailand attracted for not meticulously following the procedures prescribed by the Doha Declaration. The balance between users and creators remains precarious, as increasing numbers of developing countries attempt to negotiate increasing numbers of compulsory licences. TRIPS plus implementation may change this but this will merely restrict affected countries from any possibility of fulfilling minimum core obligations for the human right to health under the TRIPS system.

The Mozambique case study shows that the key elements to partnership programs in their current state remain funding and good governance. Least developed countries rely on donor aid, which must be dramatically increased for Mozambique, and

many other developing countries, to achieve minimum core obligations regarding access to medicine. This funding would also need to operate in a way that is more systematic and inclusive of all stakeholders, adopting stringent governance standards which are not currently identifiable in many African Aid programs.¹⁴¹ Ultimately this aid must be transformed from intrusive donor aid programs and voluntary drug donations into a system supporting grassroots localised projects with long term sustainability goals, like the VillageReach project. Potentially, in the context of a broader sustainable development focus, these countries could improve their economic capacities so that it is feasible for them to exercise the flexibilities in TRIPS.

3. Criticisms of the existing system

The case studies provide a context for understanding the criticisms of the existing system, which include problems with implementation and operation of TRIPS and broader critiques of the underpinnings of the entire system.

3.1. *Imbalance between creators and users in a global environment*

A recurring argument is that the patent system as it relates to pharmaceuticals creates expensive access to medicine in the developing world resulting in a statistically small number of people being able to access essential medicine.¹⁴² The fundamental premise of national intellectual property systems, balance, may not translate successfully to TRIPS as, in this context, it applies extremely economically disparate users.¹⁴³ This is apparent both between developed and developing countries and again between developing countries like India and Thailand and least developed countries like Mozambique. This makes it complex to address the apparent need for mechanisms to shift the balance

¹⁴¹ See generally VAN DIESEN, Arthur, 'The Quality of Aid: Towards an Agenda for More Effective International Development Co-operation', April 2000, available at <http://www.christian-aid.org.uk/indepth/0004qual/quality1.htm> (consulted on 28 June 2007).

¹⁴² *Ibid.*, p. 525. CSETE, Joanne, 'Several For The Price Of One: Right To Aids Treatment As Link To Other Human Rights', *Connecticut Journal of International Law*, vol. 17, Spring, 2002, p. 265.

¹⁴³ CROOK, Jamie, 'Balancing Intellectual Property Protection with the Human Right to Health', pp 524-550 in *Berkley Journal of International Law*, vol. 23, 2005, p. 545. The fundamental premise of a national intellectual property system is that it provides a balance between users and creators which gives creators a continuing incentive to innovate but gives users access to the invention, while publication enables other creators to improve the invention, which may further benefit users.

to favour developing and least-developed countries when they are the users in question.¹⁴⁴

Creators operating within the system must balance the risk and rewards associated with research, costs of product development and obligations to investors.¹⁴⁵ Because they are fundamental to increasing standards of healthcare, the strength of creators' rights must be recognised in any debate about balance. The aggressive approach of Novartis in its Glivec litigation against India demonstrates the importance of these rights to patent owners. This indicates that originator pharmaceutical companies do not see an extensive compulsory licensing system as compatible with expectations of profitability and control. It is not practical to disregard creators' rights; it is preferable to incorporate these rights in any new model proposed, the difficulty is how.

Multi-national corporations who are likely to be affected by an alternative system argue that it is more important to address other issues in order to achieve desired health outcomes,¹⁴⁶ including:

- Lack of adequately resourced healthcare systems to provide the proper dispensing of essential medicine;
- Dearth of personnel to teach patients about taking this medicine and to monitor their status and compliance with drug regimes; and
- Issues of quality such as counterfeit and substandard pharmaceuticals.¹⁴⁷

However the approach of Pfizer, Boehringer Engel and Abbott to supplying certain pharmaceuticals to HIV/AIDS patients in Mozambique, demonstrates that it is possible for MNCs to work effectively within the system, although the certainty and sustainability of such programs remains open to question.

3.2. Circumvention of TRIPS

The balance of rights that TRIPS aims to create is further distorted by bilateral trade agreements which include intellec-

tual property provisions in excess of the minimum protection of TRIPS.¹⁴⁸ Developed countries seeking to enforce higher intellectual property standards on developing countries are increasingly proposing TRIPS plus rules as part of trade agreements and intellectual property technical assistance packages which greatly increase patent protection by:

- Extending the term of the patent (for unreasonable delays);
- Extending the scope of patent protection to new uses of medicine, which allows for patent protection to be extended (known as evergreening);
- Restricting the ability of countries to issue compulsory licenses by offering alternative voluntary licenses with higher royalties;
- Limiting parallel importation of cheaper patented medicine;¹⁴⁹ and
- Applying new data protection restrictions which grant exclusivity on pharmaceutical test data, which will delay the introduction of generic pharmaceuticals as producers will be unable to use the data to obtain marketing authorisation.¹⁵⁰

There may be no direct legal inconsistencies with these agreements, yet the TRIPS plus requirements undermine the commitment to public health in the Doha Declaration commitment to public health. The Thai case study demonstrates that the American Special 301 Priority Watch list, enforcing intellectual property rights as prioritised by the US not by TRIPS, can strongly influence any implementation of the flexibilities of TRIPS. In this case the Thai government ultimately decide that better access to essential medicines was more important, but it would be surprising to see a more heavily aid dependant country like Mozambique eschew TRIPS plus obligations.

3.3. Administrative burdens

The practical operation of the TRIPS agreement has been difficult for countries seeking to implement the August Decision,

¹⁴⁴ Condon and Sinha, *op. cit.*, p. 14.

¹⁴⁵ *Ibid.*

¹⁴⁶ ABBOTT, Frederick M., 'The TRIPS - Legality Of Measures Taken To Address Public Health Crises: A Synopsis', *Widener Law Symposium Journal*, vol. 7, Spring, 2001, p. 72.

¹⁴⁷ FRIEDGEN, *op. cit.*, p. 705.

¹⁴⁸ OVETT, *op. cit.*, pp. 278-280.

¹⁴⁹ *Ibid.*

¹⁵⁰ *Ibid.*, p. 278.

which allows them to import goods under a compulsory licence in circumstance where product manufacture is not possible.¹⁵¹ Although the system is more flexible for least developed countries, for others both the importing and exporting State must pass legislation and make detailed undertakings about the proposed import and their manufacturing capacities,¹⁵² which has hindered the efforts of countries such as Canada to export generics, despite passing legislation to do so.¹⁵³ Correa comments that the costs in distinguishing generic products from originator products, including creating different shaped and coloured pharmaceuticals, distinctive from the originals, mean that generic producers will need a reasonable profit expectation to justify this investment,¹⁵⁴ which may not be justified by economies of scale even in a country with a thriving generics market like India.¹⁵⁵

3.4. Insufficient infrastructure

An argument used by pharmaceutical companies to counter criticisms of the high cost of patented pharmaceuticals in the developing world is that the real problem for access is the lack of infrastructure to manufacture, distribute and administer essential medicine.¹⁵⁶ Where that infrastructure exists there are concern that it is not sufficient to produce medicines of an acceptable quality, as was demonstrated in a recent study by Africa Fighting Malaria which found that 35% of anti-malarial drugs in 6 African cities were substandard.¹⁵⁷ For some countries there is insufficient infrastructure for in-country production however the potential exists to import medicine at low costs using compulsory licensing. There are still limits to the economic feasibility of extensive drug supply in many countries, even in a country like India with a thriving generics industry, and international aid may need to continue to fill this gap. Even in Mozam-

bique where use of public-private partnerships has positive outcomes, particularly in building health infrastructure, the funding it currently provides is not sufficient to enable the Government to provide sufficient essential medicine to meet the minimum core obligations for the human right to health and there is a shortage of healthcare workers to administer them.

3.5. Which medicines are essential to access?

Although infectious diseases are the usual focus of the access to medicine debate, chronic, non-communicable illnesses also comprise a significant part of the disease burden in developing countries, who bear the majority of the global disease burden in this field.¹⁵⁸ Treatment of these illnesses is often dependant on patented medicine¹⁵⁹ and the problems described in this chapter in relation to access to these medicines generally apply to these non-communicable chronic illnesses. Consequently Thailand and India have attempted to address these illnesses as part of their compulsory licensing schemes. This has met with strong resistance from pharmaceutical companies and raised questions as to what health exceptions are envisaged by the deliberately vague Doha Declaration.

3.6. Existing solutions are ad hoc

There are also concerns that many of the existing approaches to addressing access to essential medicine in the third world are based on voluntary actions which States and MNCs are not bound to maintain.¹⁶⁰ Consequently there is uncertainty as to whether States like Mozambique can plan with an expectation that these existing commitments to support health programmes and provide discounted drugs are met and further commitments will be made.¹⁶¹

¹⁵¹ MALPANI and KAMAL-YANNI, *op. cit.*, p. 19. McClellan, *op. cit.*, p. 173.

¹⁵² CONDON and SINHA, *op. cit.*, pp. 12-13.

¹⁵³ MASKUS, *op. cit.*, p. 173. Lanjouw, *op. cit.*, p. 24.

¹⁵⁴ CORREA, Carlos M., 'TRIPS and Access To Drugs: Toward A Solution For Developing Countries Without Manufacturing Capacity?' *Emory International Law Review*, vol. 17, Summer 2003, p. 403.

¹⁵⁵ *Ibid.*, p. 404.

¹⁵⁶ FRIEDGEN, *op. cit.*, p. 692. Friedgen notes that any approach to solving the access to medicine problem should also include adequate health infrastructure, trained medical personnel, prevention and follow-up programs and renewed research efforts regarding tropical or world diseases.

¹⁵⁷ BATE, Roger, COTICELLIL, Philip, TRENL, Richard and ATTARAN, Amir, 'Antimalarial Drug Quality in the Most Severely Malarious Parts of Africa – A Six Country Study' 7 May 2008, (available at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0002132>) consulted on 15 June 2008.

¹⁵⁸ KAPCZYNSKI *op. Cit.*, 2005, p. 1097.

¹⁵⁹ Treatments for non-communicable chronic illnesses are found on WHO's Essential Medicines list, which is mandated by the CESCR as consistent with the realisation of the human right to health.

¹⁶⁰ McCLELLAN, *op. cit.*, p. 171.

¹⁶¹ *Ibid.*

Mozambique is very reliant on others in relation to health-care development. This makes it difficult for the Government to plan with autonomy. DFID argues that in increasing access to essential medicine in developing countries, differential pricing is preferable to donations which 'will not provide a solution to the general, long-term needs for essential medicines in developing countries' particularly for chronic conditions 'where consistency of supply is vital.'¹⁶² Donations are uncertain and may carry hidden costs, distort national healthcare priorities, involve unwanted or unsuitable products and undermine the development of local markets by locking out competition.¹⁶³ Donor aid also makes it difficult for the Government to take responsibility for the provision of essential medicine. There is also evidence of past conflicts within donor groups which diminishes the effectiveness and credibility of health projects.¹⁶⁴ Sector-wide approaches to healthcare could help solve this problem and build sustainability if donors support them and involve local NGOs in the approach.¹⁶⁵

The philosophy underpinning the Thai Government's justification for its recent compulsory licenses is consistent with the WTO goal of sustainable development¹⁶⁶ yet this has not averted the negative reactions of pharmaceutical companies. This indicates that the exception system may need to be calibrated differently so that its implementation is more harmonious, effective and, accordingly, sustainable. This might be achieved if there were a more regulated environment for the types of discussions currently occurring in Thailand yet any form of regulation may take, such as arbitration, would be subject to great scrutiny as potential destabilisers of the existing compromise.

The August Decision is recognition that there is presently insufficient infrastructure in some countries to implement the flex-

ibilities of TRIPS but the existing system does not adequately address the development of this infrastructure to facilitate the production, distribution and supervision of essential medicine. Projects are being carried out by NGOs, WHO and the World Bank but there needs to be inter-linkages between the systems. The TRIPS system, while it potentially facilitates profits for pharmaceutical MNCs and revenue for the States in which they pay taxes, does not economically contribute to donor funded infrastructure projects. Despite this, poorer countries pay a 'poverty penalty' as a result of fulfilling international obligations that require prioritising trade interests to the detriment of welfare.¹⁶⁷ Because there is no funding arrangement linked to TRIPS, there is less certainty regarding funding for these infrastructure projects. Morgan suggests that practical solutions like fast-tracking approval of WHO pre-qualified products can diminish the impact of infrastructure limitations,¹⁶⁸ however treatment delivery and the absence of qualified practitioners remains problematic.¹⁶⁹ In practice the reluctance of developing countries to implement TRIPS flexibilities indicates that the system is still weak, as economic and social development would require systematic implementation of TRIPS flexibilities to achieve the human right to health.

3.7. Neglected diseases

There is statistical evidence that only 10% of the world health research and development budget is spent on 90% of the global disease burden.¹⁷⁰ Condon and Sinha argue that neglected diseases are an indication that the balance created by TRIPS has not created adequate research incentives for neglected diseases and consequently the global patent system does not drive innovation effectively.¹⁷¹ Even where drugs are

¹⁶² DFID, 'Increasing Peoples' Access to Essential Medicines in Developing Countries: A Framework for Good Practice', March 2005, available at <http://www.dfid.gov.uk/pubs/files/pharm-framework.pdf> (consulted on 27 June 2007), p. 2.

¹⁶³ *Ibid.* McCLELLAN, *op. cit.*, p. 171.

¹⁶⁴ BROWN, *op. cit.*, p. 18.

¹⁶⁵ See generally VAN DIESEN, Arthur 'Aid to Mozambique: an End to Dependence? An Assessment of the Quality of Aid to Mozambique, with Special Reference to British and EC Aid for Health and Education,' July 1999, available at <http://www.christian-aid.org.uk/indepth/9907moza/mozamb1.htm> (consulted on 28 June 2007).

¹⁶⁶ Thai White paper, *op. cit.*, pp. 1-2.

¹⁶⁷ RAGAVAN, *op. cit.*, p. 779.

¹⁶⁸ MORGAN, Maxwell R., 'Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment', pp. 45-111 in *University of Toronto Faculty of Law Review*, vol. 64, Winter, 2006, p. 83.

¹⁶⁹ MSF, *op. cit.*, pp. 2-3.

¹⁷⁰ KAPCZYNSKI et. al, *op. cit.*, p. 1037. CURRAT, Louise J.; DE FRANCISCO, Andres; AL-TUWAHRI, Sameera; GHAFAR, Abdul; JUPP, Susan; *10/90 Report on Health Research: 2003-2004*, Switzerland: Global Forum for Health Research, 2004, p. xv. Neglected diseases include tuberculosis and tropical diseases.

¹⁷¹ CONDON and SINHA, *op. cit.*, p. 26.

developed for these illnesses there may only be limited quantities available because production is considered unprofitable.¹⁷² The current relationship between pharmaceutical companies and countries like India and Thailand may not encourage the private sector to invest more in the development of new medicine, particularly for neglected diseases, which may have a long term impact on health. The system may need to develop alternative incentives for neglected disease research.

3.8. What are the arguments for change to the existing system?

The existing system is inconsistent with the realisation of the human right to health and participants in the existing system knowingly violate rights to health and to life.¹⁷³ It is necessary to use a rights based approach to address this. States must observe their international responsibilities to build and economic, social and cultural order in which human rights can be realised as fully as possible.¹⁷⁴

The TRIPS system neglects the ideals of sustainable development as it is over-reliant on utility maximisation at the expense of distributional consequences. It is not sufficient to simply give aid to countries without developing strategies to facilitate this economic and social development.¹⁷⁵

The system must be responsive to globalisation: diseases can spread quickly;¹⁷⁶ health should be prioritised as a global public good;¹⁷⁷ global governance is increasingly important with its inherent concepts of accountability and transparency of global actors.¹⁷⁸

¹⁷² FRIEDGEN, *op. cit.*, pp. 704-5. Jamie CROOK, *op. cit.*, p. 545. HUNT, HUNT, Paul, 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health - Mission to Mozambique', E/CN.4/2005/51/Add.2, 4 January 2005, available at <http://daccessdds.un.org/doc/UNDOC/GEN/G05/101/64/PDF/G0510164.pdf?OpenElement> (consulted on 28 June 2007), Paragraph 79.

¹⁷³ POGGE, *op. cit.*, p. 203. Shaffer, *op. cit.*, p. 463. Csete, *op. cit.*, p. 271.

¹⁷⁴ Article 28, UDHR. Pogge, *op. cit.*, pp. 202-203.

¹⁷⁵ 'Sustainable development programs entail a partnership among the public and private sectors, and civil society. Participation, empowerment, strengthened institutions, environmental protection and conservation, and focus on the rural poor are all foundations for sustained and inclusive economic growth.' NELSEN, Patricia, 'An African Dimension to the Clean Development Mechanism: Finding a Path to Sustainable Development in the Energy Sector',

4. What criteria will I use to evaluate potential models that change the existing system?

To address the problems identified with the existing system and the arguments for change to the existing system, this thesis will use four criteria for evaluation of the proposed models for change.

4.1. Delivers minimum core obligations using a rights based approach

It is necessary that the system guarantees basic healthcare for all human beings with respect to access to essential medicine which includes pharmaceuticals that are necessary to treat infectious and chronic diseases which are life threatening or create a serious reduction in economic productivity.¹⁷⁹

Essential medicine must be:

- available in sufficient quantity;
- accessible to everyone without discrimination;
- acceptable in the sense of respectful of medical ethics and customs; and
- of good quality and scientifically appropriate.¹⁸⁰

A desirable component of a new system would be the ability to accommodate increasing standards of health (in the pursuit of the highest attainable standard of health) so that the model can function when countries have or develop the capacity to fulfil the human right to health beyond realisation of minimum core obligations. A rights based approach should

Denver Journal of International Law and Policy, vol 32, Fall 2004, p. 623, quoting the World Bank Environmentally and Socially Sustainable Network.

¹⁷⁶ JOST, Timothy Stoltzfus, 'Comparative and International Health Law', pp. 141-147 in *Health Matrix: Journal of Law-Medicine*, vol. 14, Winter, 2004, p. 146. In these situations, compulsory licensing of pharmaceuticals has been used by both developing and developed countries to address the consequences of the potential ease of infection diffusion. See generally Love, *op. cit.*

¹⁷⁷ SHAFFER, *op. cit.*, p. 459.

¹⁷⁸ BENEDEK, 2006, p. 1. AGINAM, 2004, p. 310.

¹⁷⁹ FIDLER, 2004, p. 79.

¹⁸⁰ YAMIN, Alicia, 'Not Just a Tragedy: Access to Medication as a Right under International Law' *Boston University International Law Journal*, vol. 21, Fall 2003, p. 337.

acknowledge the relationship between access to medicine and human rights and that the associated rights are held by individuals.¹⁸¹

4.2. *Balancing of interests between actors*

Evaluation will focus on how the models proposed provide safe, effective and realistic treatment for ill populations and realisation of legitimate expectations of profitability and control for creators and owners of patents. The system should create certainty for users that their access to essential medicine is secure¹⁸² and certainty for creators so that they can make development and manufacturing investments with a level of financial security.¹⁸³

4.3. *Sustainability*

It is necessary to determine whether or not the proposed model is an incentive to achieve economic and social development by encouraging partnerships and empowered participation by stakeholders, including sufficient flexibility so that it will promote the development of a standard of health beyond that required by minimum core obligations so that as the country develops and is able to increase the level of health it provides the model can adapt and whether or not the access to medicine model is consistent with the development of infrastructure to facilitate the production, distribution and supervision of those medicines.

4.4. *Addresses globalisation concerns*

Evaluation will consider whether or not the system: responds to threats of global pandemics; acknowledges the importance of global public goods; and is consistent with theories of global governance.

¹⁸¹ It should be possible to identify duty holders who must respect, protect and fulfil those rights. The duty holders should be accountable under the system. The actions of the duty holders and the system itself should be transparent. The processes operating within the system should be human rights consistent. The success of the system should be measured against established standards.

5. **Model Four – Global taxation based fund**

Using the formulated criteria, this article proposes a global taxation based fund as an alternative to the existing system. A key component of the sustainability of any model for change is its economic feasibility, as indicated by the Mozambique case study. This feasibility can be improved by creating a global fund to finance the diverse number of healthcare initiatives that would be necessary to provide global access to essential medicine.¹⁸⁴

However several issues emerge. Should States, or MNCs, or both, be taxed? Under what umbrella would agreement be reached – the UN, or the WTO, or a separate multilateral institution? Would such a system create another expensive and ineffective layer of bureaucracy? This model builds on the value of partnership, identified in the analysis of Mozambique, in addressing global health problems in order to create an equitable global system that redresses current imbalances between stakeholders. It is based on another model based in the environment sector, the Global Environment Fund (GEF), which is a mechanism for funding the multilateral agreements in relation to protecting the ozone layer.¹⁸⁵ The new system would be a mechanism for funding agreed global public health priorities, which can be agreed by key stakeholder using human rights mechanisms, WTO agreements and WHO instruments.

The Global Health Fund would be administered by a Board comprising five developed countries and five developing countries, which would set a budget, using rights based criteria, that would support:

- Purchasing (including advance purchasing) or subsidising of essential medicine for countries that would otherwise be unable to provide them to their population;
- Research and development projects for essential medicine, including chronic and infectious diseases, particularly neglected diseases, noting the economic desirability

¹⁸² POGGE, *op. cit.*, p. 202.

¹⁸³ FRIEDGEN, *op. cit.*, pp. 709-10.

¹⁸⁴ MORGAN, 2006, p. 50. Opderbeck, 2005, p. 530.

¹⁸⁵ MARSHALL, Dena, 'An Organization For The World Environment: Three Models And Analysis' *Georgetown International Environmental Law Review*, vol. 15, Fall, 2002, p. 83.

of preventative vaccines.¹⁸⁶ These funds will be provided on the understanding that if the outputs are commercially successful, the grant will be repaid with a percentage of the profits reflective of the original contribution;

- Licensing arbitration, so that equitable voluntary licenses, which reflect the global public goods of health, knowledge and open trade, can be negotiated; and
- Providing technical assistance for all countries where appropriate; and
- Building infrastructure projects to increase healthcare access in poor countries.

Like the GEF, the Global Health Fund would be outside the UN but inclusive of representatives of the UN structures and the World Trade Organisation. It would consist of all members of the UN. It would be annually funded by these members, using a sliding scale for contributions based on Gross National Product, but also taking into account taxation gathered by Home countries on profits made by pharmaceutical companies. Part of the payment could be made in kind: countries would be credited with a proportion of the value of pharmaceutical company donations made to poor countries which measurably reduce the global disease burden and countries can also receive credit for the health development projects that they participate in, where these projects are consistent with a series of sustainability and governance criteria which will be decided on by the Board. To increase the standard of healthcare aid, representatives of these projects will be invited to participate in a collaborative dialogue to attempt to coordinate activities and build relationships so that knowledge and experience can be shared. The Board will also pursue streamlining and efficiency goals to attempt to ensure that existing projects do not duplicate each other. To facilitate accountability, all countries will be required to contribute and countries will be taxed more heavily if they attempt to reduce their existing healthcare budgets in order to 'free ride' on the new system.

Although there are arguments that MNCs should fund such a global drug purchasing fund,¹⁸⁷ this proposal takes a conservative approach, reflective of the existing realities of international law, in which MNCs are not yet full subjects of international laws but States are responsible for their regulation.¹⁸⁸ Potentially this system could apply an equitable fee scale to MNCs for accessing certain services, such as licensing arbitration for voluntary licences. Where appropriate, MNCs would also be encouraged to continue donations and voluntary licensing programs, as these can be considered part of a country's annual payment. In this way, governments are encouraged to work with MNCs to create sufficient taxing incentives to encourage them to donate or subsidise pharmaceuticals for poor countries. However, a goal of the Fund will be to achieve balance between stakeholders. All stakeholders, including MNCs and NGOs, will be encouraged to participate in dialogues.

The advantages of the model are that it will enable TRIPS to continue to operate, although an amendment must be made to the agreement to recognise the competence of the Global Health Fund in relation to public health matters. This model would not change the position of MNCs in international law but it would encourage them to continue to donate pharmaceuticals, where appropriate, and provide a rights-based mechanism in which MNCs can negotiate fair voluntary licenses with third world countries. It should enable a consistent culture of partnerships to develop, as it provides countries that fund them with an incentive to ensure that they comply with global governance norms.

However the main problem remains that of political will. There will be substantial set up costs to build this fund and this will be prohibitive.¹⁸⁹ Mercurio identifies a role for IGOs and the media to educate governments and voters on the extent of the global health deficit.¹⁹⁰ He gives the massive international economic response to the 2004 Boxing Day Tsunami disaster as an example of the power of worldwide broadcasting to move people to action.¹⁹¹ NGOs committed to access to

¹⁸⁶ KREMER, Michael, and GLENNISTER, Rachel, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases*, Princeton University Press, Princeton, N.J., 2004, p. 69.

¹⁸⁷ BLUM, *op. cit.*, p. 226. BERGER, Jonathan Michael, 'Tripping Over Patents: Aids, Access To Treatment And The Manufacturing Of Scarcity', *Connecticut Journal of International Law*, vol. 17, Spring, 2002, , pp. 175-176.

¹⁸⁸ KINLEY and CHAMBERS, *op. cit.*, pp. 495-497.

¹⁸⁹ MERCURIO, Bryan, 'Resolving The Public Health Crisis In The Developing World: Problems And Barriers Of Access To Essential Medicines', pp. 1-80 in *Northwestern University Journal of International Human Rights*, vol. 5, Fall 2006, p. 31.

¹⁹⁰ *Ibid.*, p. 32.

¹⁹¹ *Ibid.*

medicine campaigns, like MSF and Oxfam, need to continue to work with the media to enhance the public's understanding of the disastrous dimensions of the global health deficit. Images can be powerful and campaigns can gain momentum and legitimacy with the support of international organisations, as was the case in the aftermath of the Tsunami disaster. Pharmaceutical companies also have strong lobby interests in the US¹⁹² and the Thai and Indian cases studies indicate that they may be dissatisfied with compulsory licensing provisions as they currently exist and may be more willing to change if a favourable system is presented to them.

The WTO and relevant UN agencies would play a direct role in Model Four, yet the decision-making Board would be composed of developed and developing countries, not IGO representatives. Situating the institution outside of the WTO could defuse concerns that WTO bodies are an inappropriate forum to adjudicate human rights issues.¹⁹³

5.1. *Delivers minimum core obligations using a rights based approach*

It will be problematic to determine what level of health obligations should be met. This tension may be eased by a separate multilateral institution, as this can more objectively balance the competing demands of trade and human rights goals in realising health priorities. This model adopts a holistic approach to providing access to medicine, addressing both chronic and neglected diseases. It deals with infrastructure and research and development goals. This makes it more feasible that medicine can be developed and then, when it is distributed, treatment can be provided by skilled professionals. It recognises the rights of individuals to access essential medicine and establishes that the duty to achieve this rests primarily with States, IGOs and the international community. It does not exclude stakeholders such as NGOs and MNCs and provides a mechanism to encourage them to participate productively in the system. Part of the work of the fund would be to create a series of human rights con-

sistent standards to assess the operations of countries and development projects. The overall goals of the fund can be used as a standard to measure the success of the system it creates. If all these elements are successfully implemented, delivery of health will be one of the strengths of the model.

5.2. *Balancing of interests between actors*

This proposal attempts to redress the balance between users and creators by not significantly impairing creators' legitimate expectations of profitability and control. It also creates economic funding for the safe, effective and realistic treatment of ill populations. One of the problems with this model may be convincing wealthy countries, who do not have large pharmaceutical industries but are likely to be heavily taxed, that this will be advantageous to them. Many of them currently provide health related aid so the proposed recognition of their existing commitments should be persuasive. The use of pharmaceutical company profits to determine the level of contribution required may also respond to these reservations. Additionally, persuasive moral arguments can be made to support the adoption of this model. This model should also increase efficiency by streamlining existing projects. The value of disease eradication in our increasingly globalised world enhances the desirability of the proposed coordinated approach to research and development projects.

5.3. *Sustainability*

Including a wide range of stakeholders in this system will benefit the WTO's understanding of the sustainable development impacts of trade liberalisation.¹⁹⁴ This model promotes economic and social development because funding relies on accountability and developing countries will be expected to take responsibility for prioritising healthcare in their countries and their budgets, including adopting an essential medicine strat-

¹⁹² LINARELLI, John D., 'What Do We Owe Each Other in the Global Economic Order: Constructivist and Contractualist Accounts', *Journal of Transnational Law and Policy*, vol. 15, Spring, 2006, p. 182.

¹⁹³ PETERSMANN, Ernst-Ulrich, 'Challenges To The Legitimacy And Efficiency Of The World Trading System: Democratic Governance And Com-

petition Culture In The WTO', *Journal of International Economic Law*, vol. 7, September 2004, p. 589.

¹⁹⁴ WTO Secretariat, 'What WTO for the xxist century?' Switzerland: WTO Secretariat, 2007 available at http://www.wto.org/english/res_e/booksp_e/public_forum06_e.pdf (consulted on 4 July 2007), p. 196.

egy which commits to provide medicine for their population.¹⁹⁵ Consequently all countries will be required to make contributions and remove taxes, tariffs and duties on essential medicine, which can sometime double their prices.¹⁹⁶ Where countries do not meet their goals, technical assistance will be provided to address the reasons for this, but a failure to be accountable will result in increased contribution levies or reduced assistance. Technical assistance will be available to train the poorest countries to participate effectively within the system, building on existing multilateral WTO training projects.¹⁹⁷

The associated construction of infrastructure and proposed streamlining of existing projects should also increase systematic accountability and enable the standard of healthcare to improve beyond minimum core obligations. All these characteristics are strengths. The primary weakness is that it will be an expensive system to maintain and require increased contributions from States. Although the impact of this should be diminished by creating an equitable taxation structure, there remains a problem of harnessing sufficient political will for governments to agree to direct more funds towards health. There is also the problem of States' withholding funds to show their disappointment with the system, as they have done in the UN in recent decades.¹⁹⁸ For this reason the institution must be situated outside of the UN bureaucracy and efficiency and enforceability must be a focus. The technical and organisational expertise of the WTO is likely to contribute to this efficiency.

5.4. Addresses globalisation concerns

The proposed system creates a strong response to globalisation concerns. The technical assistance component can improve global responses to global pandemics but the research and development component provides a longer term strategy for addressing this problem. Kremer and Glennester argue that focusing advance purchasing funding on developing vaccines for these diseases is economically beneficial and this model can

accommodate this approach.¹⁹⁹ The system balances and promotes the protection of the global public goods of health and knowledge. Although it modifies the open trade system, the way in which it enables pharmaceutical corporations to maintain intellectual property rights and operate with certainty in markets where a lucrative monopoly is not appropriate should override concerns about the modifications it makes to the non-discrimination principles of TRIPS. Most importantly, it promotes global governance and gives countries incentives to participate in stream-lined projects consistent with global governance priorities.

5.5. Overall analysis

The separation of this institution from both the WTO and the WHO should make it easier to negotiate a standard for achieving minimum core obligations of health. This model also accommodates improving standards of health. The separation should be advantageous for creating a rights based approach. TRIPS will need to be amended to reflect this. This model has great potential to maintain a balance that is acceptable to pharmaceutical corporations, placing direct responsibility on States to encourage MNCs to participate in the system as good corporate citizens. For this reason the balance feature is a strength of this model, dependent on States also behaving as good citizens and respecting the proposed taxing system. There are valid arguments that this model does not make MNCs accountable enough but the proposed approach is consistent with the existing realities of international law and international trade.

The restrictive approach of the model lamentably ignores broader issues of poverty and sustainable development which are relevant to many of the stakeholders and should also be addressed in a multi-stakeholder forum. Yet, the model is restrictive because it attempts to present achievable goals, without precluding broader cooperation in wider fields. If it is effective it might be the basis for more ambitious projects. In keeping this

¹⁹⁵ MERCURIO, *op. cit.*, p. 36, p. 41.

¹⁹⁶ *Ibid.*, p. 45.

¹⁹⁷ WTO, 'Workshop helps trade officials use health patent flexibilities', 2006 (consulted on 8 July 2007).

¹⁹⁸ SCHNOOR, Britta A., 'International Law, The Power of the Purse, And Speaking With One Voice: The Legal Cacophony Created by Withholding

U.S. Dues From the United Nations', *Iowa Law Review*, vol. 92, March, 2007, p. 1156.

¹⁹⁹ KREMER and GLENNESTER, *op. cit.*, p. 69.

restrictive focus it seems more feasible that political will can develop to drive the massive funding commitment that would be necessary for this model. Political will remains the greatest obstacle for its adoption and it is the role of interested stakeholders to develop and drive the desire of other stakeholders to efficiently address the dilemma of access to medicine.

Conclusion

Legal, moral, economic and political issues drive the current debate on access to medicine. Any proposals or recommendations must address these issues if they are to be meaningful. It is not sufficient to merely take the legal and moral human rights arguments to suggest a path for change. Without a consideration of the political and economic issues there will be insufficient international political will to implement these changes. This is the reality of a globalised world in which the institutions of economic globalisation compete with the universalist discourse of human rights. Consequently while this analysis has considered worthy legal and moral criteria such as achieving minimum core obligations, developing a rights based approach and sustainable development, it has also considered whether the balance between creators and users, as well as between developed and developing countries, is adequately addressed. As a result, the proposed Global Health Fund is consistent with existing normative standards which it uses to create a system which is also innovative in the way it responds to MNC sensitivities while indirectly encouraging them to cooperate as good global citizens.

The need for change to the current TRIPS system has been clearly established in the case studies from India, Thailand and Mozambique, which demonstrate the failures of the TRIPS system to adequately realise human rights goals or achieve a satisfactory balance between individuals needing treatment and pharmaceutical companies. Theoretically, it is possible that the current systems could address the existing human rights obligations of the international community but there is insufficient evidence from the case studies that this could occur in practice. The TRIPS system as it stands does not provide a rights based approach or focus on sustainability, which would entrench a commitment to human rights, so as to provide certainty about access to medicine to individuals and governments of developing countries, who currently bear many of the burdens but realise few of the benefits of globalisation. Additionally, the

measures being realised in the Indian and Thai case studies do not address the sensitivities of pharmaceutical companies, so attempts to use these measures are frequently subject to obstruction by these companies, as demonstrated by the Novartis court case concerning the registration of Glivec in India and the retaliatory response, announced by Abbott, of refusing to register new drugs in Thailand in response to a compulsory licence issued by the Thai Government for Kaletra. Although the partnerships analysed in Mozambique are responsive to these sensitivities, they need to be transformed so that they more consistently foster sustainable development at a grass roots level. When this occurs they can be a strong auxiliary feature of any model where they are developed to address infrastructure and treatment needs.

The case studies indicate clear global governance gaps in the TRIPS system which would improve with enhanced cooperation between the WTO and WHO. The apparent reluctance of the WTO to work with UN bodies reduces the feasibility of this recommendation. However the Global Health Fund relies on enhanced coordination between IGOs and participation of other key stakeholders to achieve adequate access for all. The proposal translates a successful collaboration projects from the environmental sphere into the public health sphere.

The Global Health Fund responds to pharmaceutical industry sensitivities and addresses the historical separation of the WTO from the UN by facilitating cooperation through a separate institution. This institution functions both as a forum for stakeholders to coordinate public health initiatives with respect to access to medicine, and a decision making board, comprising representatives from developed and developing countries, which oversees funding, organisation and accountability for these initiatives. In this way, the many initiatives which already exist to address problems concerning access to medicine can be streamlined to promote transparency and efficiency. The Fund would be financed by taxing WTO members, using a formula which assesses States' Gross National Profit, tax profits obtained from pharmaceutical MNCs and existing contributions to public health. Importantly, this responds to the obligations of the international community to provide an economic and social order in which human rights can be realised. Although it requires a substantial financial commitment, the success of the GEF provides a successful precedent, although its funding requirements are more modest.

The proposed system is an excellent vehicle for adopting the principles of global governance – openness, participation and transparency – and ensuring that these values are infused into the projects it administers. Similarly a focus on sustainable development could be diffused through all institutional activities. All of the arguments for change outlined in this article can be harnessed by agents for change, such as Civil Society and the media, to urge WTO Member States that it is legally and morally important to adopt this model, as well as practically and politically advantageous. The proposal is ambitious, however the case studies indicate that an ambitious model, which addresses the inevitable funding requirements of providing access to essential medicine in a world that is still vastly unequal, must be adopted if the human right to health is to be effectively and sustainably integrated into all parts of the world. The Global Health Fund indicates far-reaching improvement in achieving human rights without significantly diminishing MNC profits and should receive MNC support accordingly. The proposed system is strong in the way that it encourages States to work with MNCs to make pharmaceuticals more accessible where necessary.

The model proposes a balance between users and creators which is essential to the premise of the intellectual property system. It empowers States, IGOs, MNCs and Civil Society to improve the existing TRIPS system. This article has infused this concept of balance into an analysis of the human rights dimensions of the access to medicine debate and proposals for change to the existing intellectual property system. Although the role of MNCs as important actors in the international system is apparent, the most effective existing way to implement obligations on these actors remains actions by Home and Host States as proposed by the Global Health Fund. This model creates strong incentives for States to work with MNCs so that access to medicine and human rights goals can be achieved collaboratively. The emphasis placed on States reflects their existing international obligations to create an economic and social environment in which human rights for all can be achieved, while the involvement of many stakeholders in the implementation of the proposed system also reflects a changing international environment in which the responsibility for implementing human rights is shared.

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