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Achieving social justice in the human rights/intellectual property debate: Realising the goal of access to medicines

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Summary

What happens when the assertion of intellectual property rights by their holders impacts on the human rights of consumers, in particular, their right to access health care and health products such as medicines? Proponents of access to medicines as a human right reference the soft law of human rights and the broad ethical frameworks within which human rights understandings are situated but, paradoxically, the pharmaceutical companies that hold proprietary interests in medicines also claim human rights to their medical discoveries. They argue that the ecology of research and development on medicines is inextricably linked to the possession of exclusive rights in the form of patent and data protections. The proprietary interests of pharmaceutical companies are stringently pursued and enforced by global powers via their trade policy and otherwise. Thus, this article argues that human rights must trump those proprietary rights, for a number of reasons, and seeks to introduce a social justice perspective on the human rights/intellectual property debate. It begins by reviewing the competing paradigms of the right to health versus proprietary intellectual property rights, showing how the human rights regime has achieved superiority in theory, but inferiority in practice. It proceeds to delineate the context in which essential medicines have increasingly

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become endangered global public goods. This is primarily because of strong intellectual property protections afforded to pharmaceutical companies with the advent of the TRIPS Agreement, TRIPS-plus bilateral and regional trade agreements between the USA and the European Union and developing countries, and other measures designed to broaden, strengthen and lengthen intellectual property protections worldwide. The article then explores the potential for lobbying, advocacy, law reform measures and activism in achieving the objective of 'access to medicines for all', and demonstrates the extent to which human rights advocacy programmes can contribute to doing so through the delivery of rights-based education and training to targeted audiences.

1 Introduction

While efforts at promoting the human right to health at the grassroots level are often directed at public education, street law programmes or as an adjunct to the delivery of health services, other efforts are aimed at influencing human rights outcomes through policy formulation and advocacy and campaigning for better laws, policies and practices. Central to efforts of conscientising and campaigning in the health context is an understanding of the role of intellectual property rights in making life-saving and life-enhancing medicines unaffordable in low- and middle-income countries. Proponents of access to medicines as a human right reference the soft law of human rights and the broad ethical frameworks within which human rights understandings are situated, but paradoxically the pharmaceutical companies which hold proprietary interests in medicines also claim human rights to their medical discoveries and argue, further, that the ecology of research and development on medicines is inextricably linked to the possession of exclusive rights in the form of patent and data protections. The proprietary interests of pharmaceutical companies are stringently pursued and enforced by global powers via their trade policy and otherwise.

This article begins by reviewing the competing paradigms of the right to health versus proprietary intellectual property rights, showing how the human rights regime has achieved superiority in theory, but inferiority in practice. The article proceeds to delineate the context in which essential medicines have increasingly become endangered global public goods, primarily because of strong intellectual property protections afforded to pharmaceutical companies with the advent of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),[1] TRIPS-plus bilateral and regional trade agreements between the United States of America (USA) and the European Union (EU) and developing countries, and other measures designed to broaden, strengthen and lengthen

1 Art 8(1) Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C (1994) 33 *International Legal Materials* 81.

intellectual property protections worldwide. The article then explores the potential for lobbying, advocacy, law reform measures and activism in achieving the objective of 'access to medicines for all'. It further demonstrates the extent to which human rights advocacy programmes can contribute to doing so through the delivery of rights-based education and training to targeted audiences.

In the Sufi tradition there is a saying that 'when you hear hoofbeats, think of a zebra'.[2] In the context of intellectual property, a similar saying might be: 'When you encounter patent and data rights, think of monopolies and denial of care.' Thus, this contribution explores different ways of understanding and responding to the dominant intellectual property narrative about the private prerogatives of ownership, enclosure and profit maximisation, versus the resurgent counter-narrative of fighting to harness the engines of science and innovation to address the global burden of disease and to ensure equitable and affordable access to life-saving technologies for all.

2 Paradigm of health and human rights

This section appraises the paradigm which informs the twin concepts of health and human rights.[3] It reviews the right to health under international law, the relationship between health and human rights, the general nature of right-to-health obligations, and the role of non-state actors. Within this context, it explores the notion of access to medicines and whether intellectual property rights may be regarded as human rights.

2.1 The origins of the right to health under international law

It is instructive to explore how the notion of the right to health has evolved under international law. The first articulation of the right to health, offered by the Constitution of the World Health Organisation (WHO), is as follows:

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.[4]

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2 S Friedlander *When you hear hoofbeats think of a zebra* (1992): A tract on Sufism – the Islamic mystic philosophy which promotes the idea of narrative as providing new ways of seeing things, of thinking about them, and of responding to them.

3 This section draws substantially from YA Vawda 'Access to life-saving medication in South Africa: The case for legislative reform' unpublished LLD thesis, University of KwaZulu-Natal, 2011; B Baker 'Placing access to essential medicines on the human rights agenda' in JC Cohen *et al* (eds) *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing* (2006).

4 WHO Constitution, adopted by the International Health Conference, New York, 19 June-22 July 1946, and opened for signature in July 1946. This followed the Charter of the United Nations, adopted on 26 June 1945, and which, while not making specific reference to the right to health, imposes by treaty a legal

Thereafter, the Universal Declaration of Human Rights (Universal Declaration)[5] gave greater content to this right, by proclaiming it as a right to 'health and well-being' within the framework of a standard of living which includes food, clothing, housing, medical care and social services and security, therefore, the major determinants of health. The non-binding Declaration of Alma-Ata on Primary Health Care (Alma-Ata Declaration)[6] expands the definition of health to include 'complete physical, mental and social well-being, and not merely the absence of disease or infirmity', and posits that the achievement of this fundamental human right was 'a most important world-wide social goal'.

The most comprehensive articulation of the right to health in a legally-binding international treaty is contained in the International Covenant on Economic, Social and Cultural Rights (ICESCR),[7] which elaborates on the general rights found in the Universal Declaration.[8] Article 12 states:

> The State Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

Each state is required to achieve this through taking 'steps … to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant …'[9] Such steps shall include economic, technical and, in particular, legislative measures.[10] Article 12 further identifies the steps that states must take in the pursuit of right-to-health objectives, including the reduction of still-births and infant mortality; the promotion of the healthy development of the child; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; and the creation of conditions to assure medical services and attention to all in the event of ill health.[11]

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obligation on member states to take action to achieve universal respect for human rights; http://www.who.org (accessed 31 January 2006).

5 Adopted by UN General Assembly Resolution 217 A (III) 10 December 1948. UN GAOR, 3rd session, Supp 13, UN Document A/810 (1948).

6 Adopted at a joint WHO/UNICEF conference held in the Soviet Union in 1978, and which defines health as 'a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity', and affirms that 'the attainment of the highest possible level of health is a most important world-wide social goal'.

7 Adopted by UN General Assembly Resolution 2200 A (XXI) 16 December 1966. Interestingly, although South Africa draws heavily on this document in its Bill of Rights, and signed the Covenant in 1994, it has not as yet ratified it.

8 R Elliot *TRIPS and rights: International human rights law, access to medicines, and the interpretation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (2001) http://www.aidlaw.ca (accessed 31 January 2006) (Canadian HIV/AIDS Network 2001).

9 Art 2 ICESCR.

10 Art 12, read with art 2 ICESCR.

11 Arts 12(2)(a) to (d) ICESCR.

To further these objectives, the United Nations (UN) established the Committee on Economic, Social and Cultural Rights (ESCR Committee) to administer the Covenant and to monitor its implementation by states, primarily through the submission of reports. Regrettably, there is no effective enforcement mechanism if states do not submit reports or fall short of their obligations under the Covenant.[12] However, defaulting states might suffer embarrassment in international fora if they fail to meet their obligations. In the discharge of its mandate, the ESCR Committee issues General Comments, which provide guidance on the interpretation and implementation of its provisions. Among the most noteworthy of such General Comments are those that clarify states' obligations in terms of socio-economic rights.[13] Most relevant to this discussion is General Comment 14, discussed further below, which contains a comprehensive interpretation of the concept 'the highest attainable standard of health'.[14]

2.2 Relationship between human rights and public health

It can be said that public health and human rights are natural bedfellows. Together with the drive for human development, 'each reflects shared individual and collective aspirations for a better life … grounded … in values revolving around fundamental concepts of dignity, justice, well-being and progress'.[15] There is evidence of the state's role in public health measures since ancient times, such as early Roman attempts to improve public sanitation, and later the protection of public health under eighteenth century European monarchs. However, it was not until after World War II, with the establishment of the WHO, that the discourse of an enforceable human right to health developed, encompassing both public and individual health perspectives.[16]

While the relationship between public health and human rights may seem obvious, these disciplines have not always been linked explicitly. This may be because they originate from quite different philosophical positions, have distinct language and terminology, and have been perceived to play different societal roles. Yet 'health and human rights are both powerful, modern approaches to defining and

12 J Dugard *International law: A South African perspective* (2005) 321.

13 ESCR Committee General Comment 3, The nature of state parties' obligations (1990) UN Doc E/1991/23 http://www1.umn.edu/humanrts/gencomm/epcomm3.htm (accessed 31 August 2009) (General Comment 3).

14 ESCR Committee General Comment 14, The right to the highest attainable standard of health (2000) UN Doc E/C.12/200/4 http://www1.umn.edu/humanrts/gencomm/escgencom14.htm (accessed 31 August 2009) (General Comment 14).

15 D Tarantola *et al* 'Human rights, health and development' (2008) *University of New South Wales Faculty of Law Research Series* Working Paper 47.

16 See H Hestermeyer *Human rights and the WTO: The case of patents and access to medicines* (2007) 83-84 for a discussion on the genesis of this concept.

advancing human well-being'.[17] The past few decades have witnessed a burgeoning debate on the intersection between public health and human rights, primarily because of the violation of the rights of people living with HIV/AIDS, as well as the increasing focus on women's health issues and the violations of human rights in conflict-ridden areas.[18] The resulting convergent paradigm is increasingly influencing responses to health issues by international organisations, legal and health professionals, governments and civil society.[19]

Reduced to its essentials, the convergence paradigm on public health and human rights posits a synergistic intersection between the four imperatives of public health (disease and impact reduction; the promotion of healthy lifestyles; the strengthening of health systems; and the development of health-sensitive policies) and the three human rights obligations to respect, protect and fulfil the right to health.[20] In other words, the main strategies of public health policy may be rendered meaningless unless they are accompanied by a firm commitment to the promotion of human rights, including both prohibitions against discrimination and the avoidance of health harms and the promotion of accessible, affordable and high-quality preventative and curative health services. A good example of the convergence paradigm is the policy of HIV testing, comprehensive prevention, and access to anti-retroviral therapy as it has been adopted and rolled out in South Africa and other countries. This policy is premised on the notion of (i) expanded voluntary testing in health facilities and in communities, that respects patient autonomy and protects them through proper health information and counselling protocols; and (ii) providing treatment literacy and adherence support, prevention advice, services and technologies, and access to highly-active anti-retroviral therapy, psycho-social support and palliative care.

Furthermore, there is another reason why the convergence paradigm is important:[21]

> Anchoring public health strategies in human rights can enrich the concepts and methods used to attain health objectives, by drawing attention to the legal and policy context within which health interventions occur, as well as bringing rights principles such as non-discrimination and the participation of affected communities in the design, implementation, monitoring and evaluation of health programs and interventions.

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17 JM Mann *et al* 'Health and human rights' in JM Mann *et al* (eds) *Health and human rights: A reader* (1999) 7. This is a seminal work which explores, *inter alia,* the 'inextricable linkage' between health and human rights.

18 S Gruskin & D Tarantola 'Health and human rights' in R Detels & R Beaglehole (eds) *The Oxford textbook of public health* (2001) 311.

19 S Gruskin *et al* 'History, principles, and practice of health and human rights' (2007) 370 *The Lancet* 449-455.

20 D Tarantola *Building on the synergy between health and human rights: A global perspective* (2000) http://www.popline.org/node/258322 (accessed 10 May 2013).

21 Gruskin *et al* (n 19 above).

Adopting this perspective has increased attention to equitable access for vulnerable populations, including rural populations, sex workers, injecting drug users, men-who-have-sex-with-men, migrants, prisoners, people with disabilities, and others.

2.3 Right to health obligations of states

The human rights paradigm provides an appropriate framework for analysing the right to health and serves as a useful guide to advocacy and action on health issues. As stated previously, early human rights discourse was limited to advocacy with regard to civil liberties and state action.[22] The historical resistance to the justiciability of economic, social and cultural rights held sway because they were considered to be different in nature from civil and political rights. Fortunately, the narrow focus on civil and political rights came under withering criticism, and international law evolved to recognise all human rights as interdependent, individual and mutually supporting.[23] This shift has also been signified by the adoption of rights-based constitutions in many countries, including African ones, which recognise socio-economic rights as judicially enforceable.[24]

The rights set out in ICESCR have been further elaborated by the ESCR Committee,[25] notably in two General Comments focusing on the nature of state obligations and the content of the right to health. On the nature of states' obligations, the Committee's General Comment 3 confirms the widely-accepted position that the UN Charter, customary international law and ICESCR constitute binding legal obligations in order to realise human rights.[26] Regarding the content of the right to health, General Comment 14 clarifies that 'health is a fundamental human right indispensable for the exercise of other human rights' and must be understood as 'a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realisation of the highest attainable standard of health'.[27] While not legally binding on states, these Comments are an

22 See International Covenant on Civil and Political Rights, adopted by General Assembly Resolution 2200 A (XXI) on 16 December 1966.

23 See eg S Liebenberg 'Socio-economic rights' in M Chaskalson *et al* (eds) *Constitutional law of South Africa* (1999); P de Vos 'Pious wishes or directly enforceable human rights? Social and economic rights in South Africa's 1996 Constitution' (1997) 13 *South African Journal on Human Rights* 67.

24 For discussion of these aspects of socio-economic rights, see DM Chirwa 'The right to health in international law: Its implications for the obligations of state and non-state actors in ensuring access to essential medicine' (2003) 19 *South African Journal on Human Rights* 541.

25 An expert body established in 1985 by the UN Economic and Social Council, with the objective of formulating General Comments which help define 'the normative content of the rights recognised in the Covenant'.

26 General Comment 3 para 1.

27 General Comment 14 para 1.

authoritative source of expert analysis and interpretation of legally-binding rights.

Furthermore, the Committee notes that the right to health, as with all human rights, imposes three types of obligations on state parties for the benefit of their citizens and residents, namely, to respect, protect and fulfil such rights – the last of which includes obligations to facilitate, provide and promote health services and the determinants of health.[28] Both negative and positive obligations are envisaged. Not only are states required to refrain from directly or indirectly interfering with the enjoyment of the right to health, but they are also required to take measures preventing third parties from so doing.[29] The fulfilment of these obligations requires states to take the appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realisation of the right to health.[30] In addition, foreign state parties also have obligations to protect human rights and the right to health in other countries and to prevent third parties over whom they exercise control from violating those rights.[31] In particular, foreign states have obligations to help ensure access to essential health commodities elsewhere, to provide health aid via international assistance to developing countries, and to ensure that international agreements do not undermine or adversely affect the right to health of others.

In terms of enforceability, international law is generally understood to be based on a combination of customary law and consent (the law of treaties). Human rights law, however, has largely defied these narrow categories by suggesting an additional foundation – human dignity – which makes claims on all actors, regardless of custom or consent. Thus, key international instruments (the Universal Declaration, ICESCR and the International Covenant on Civil and Political Rights (ICCPR)) recognise that not only are rights derived from custom or consent, but they also acknowledge those rights derived 'from the inherent dignity of the human person'.[32]

2.4 Right to health obligations of non-state actors

The preoccupation with state action, as is evident in the foregoing discussion, has raised the question whether human rights obligations

28 General Comment 14 paras 33-37.

29 General Comment 14 para 35.

30 General Comment 14 para 33. See also revised Guideline 6: 'Access to prevention, treatment, care and support', jointly issued by UN High Commissioner for Human Rights and UNAIDS *HIV/AIDS and human rights: International guidelines: Third international consultation on HIV/AIDS and human rights* (2002), which requires the state to, *inter alia*, legislate for safe and affordable medicines; to ensure equitable access to goods, services and information for HIV/AIDS treatment, including ARVs, diagnostics and other technologies for preventative, curative and palliative care.

31 General Comment 14 para 39.

32 C Jochnick 'The human rights challenge to global poverty' (1999) 4 *Centre for Economic and Social Rights* http://www.cesr.org/text%20files/actors.PDF (accessed 31 August 2004).

bind persons and institutions other than states. One consequence of a state-centric only approach is that it fails to address the roots of poverty-related violations, in particular with regard to economic, social and cultural rights that lie beyond national borders.[33] The singular emphasis on the role of the state is increasingly being challenged, particularly as it has often allowed non-state actors to escape sanctions for human rights violations, especially in the context of increasing privatisation of health services and the influential role of national and multinational corporations in determining formal and informal health policy.[34] In the real world, transnational corporate power is more ascendant than state power, especially where both developed and developing states have become captive to business interests. In an era of corporate hegemony, it makes sense to shine the spotlight on the true seats of power, and not just on increasingly constrained government bureaucracies.

Moving the conception of human rights beyond the state-centric paradigm could serve two purposes. Firstly, it confronts the dominant neo-liberal view which tends to marginalise issues of development and poverty, and provides a vision for the notion that 'entrenched poverty is neither inevitable nor acceptable'.[35] Secondly, it provides a legal framework within which to begin holding the most influential non-state actors accountable for their roles in creating and sustaining poverty.[36] This approach seeks to contextualise socio-economic rights, and to relocate them in the realm of advocacy and positive action. Furthermore, it enables rights advocates to challenge and hold accountable such significant players as multinational drug manufacturers, multilateral fora such as the World Trade Organisation (WTO) which are responsible for formulating trade rules impacting on health, as well as the World Bank and International Monetary Fund whose policies and loan conditions can have far-reaching implications for health and development.

Although ICESCR primarily addresses the human rights obligations of sovereign states, according to General Comment 14 the Convention also emphasises that other social actors, including specifically the private business sector, 'have responsibilities regarding the realisation of the right to health'.[37] A violation of the right to health, in this context, can occur through the direct action of private

33 Jochnick (n 32 above) 1.

34 These comprise not only institutions such as the World Bank and International Monetary Fund, which influence government policy through aid packages and conditions, but also pharmaceutical companies and other corporations supplying the health sector, and whose pricing structures impact on the availability and accessibility of health goods and services. See also S Narula 'International financial institutions, transnational corporations and duties of states' (2011) *New York University Public Law and Legal Theory Research Paper Series* Working Paper 11-59.

35 Jochnick (n 32 above) 1.

36 As above.

37 General Comment 14 para 42.

entities insufficiently regulated by a state.[38] Accordingly, the failure of a state 'to regulate corporations so as to prevent them from violating the right to health of others; and the failure to protect consumers … from practices detrimental to health, for example, by … manufacturers of medicines' is a breach of the obligation to protect the right to health.[39] Foreign states are also obligated to prevent third parties, including private sector multinational corporations, from violating the right to health in other countries, and by ensuring that their own international agreements do not adversely impact on the right to health.[40]

Efforts to put real juridical teeth into the corporate human rights arena have been fraught with disappointment.[41] The most recent effort resulted in a mandate[42] to Professor Ruggie from Harvard University, who proposed a new Framework for Business and Human Rights in 2008, and Guiding Principles to implement the Framework in 2011.[43] Ruggie's efforts unfortunately merely recapitulate the legal *status quo*, which contains aspirational frameworks, but no hard substantive rules or remedial procedures.[44] His 2007 Mapping Report[45] explicitly repudiated earlier claims at the UN that human rights norms applied directly to corporations.[46] He conceded,

38 General Comment 14 para 48.

39 General Comment 14 para 51.

40 General Comment 14 para 39. See also L Ferreira 'Access to affordable HIV/AIDS drugs: The human rights obligations of multinational pharmaceutical corporations' (2002) 71 *Fordham Law Review* 1133.

41 P Feeney 'Business and human rights: The struggle for accountability in the UN and the future direction of the advocacy agenda' (2010) 6 *Sur International Journal of Human Rights* 161.

42 See Human Rights Commission Resolution 2005/69 para 1(a).

43 Special Representative of the Secretary-General, Protect, respect and remedy: A framework for business and human rights UN Doc A/HRC/8/5 para 9 (2008); Special Representative of the Secretary-General, Guiding principles on business and human rights: Implementing the United Nations 'protect, respect and remedy' framework, UN Doc A/HRC/17/31 (2011).

44 For discussion of the 2008 Framework Report, see D Bilchitz 'The Ruggie framework: An adequate rubric for corporate human rights obligations' (2010) 12 *Sur International Journal of Human Rights* 199-229; RJ Anderson 'Reimagining human rights law: Toward global regulation of transnational corporations' (2010) 88 *Denver University Law Review* 183-236. For a discussion of both the 2008 Framework Report and the Guiding Principles, see JH Knox 'The Ruggie rules: Applying human rights law to corporations' (2011) http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1916664; SA Aaronson & I Higham '"Re-righting business": John Ruggie and the struggle to develop international human rights standards for transnational firms' (2011) http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1922224 (accessed 31 August 2012).

45 Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises 'John Ruggie: Business and human rights: Mapping international standards of responsibility and accountability for corporate acts' para 44, UN Doc A/HRC/4/35 (19 February 2007).

46 See Sub-Commission on the Promotion and Protection of Human Rights, Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights, UN Doc E/CN.4/Sub.2/2003/12/Rev 2 (2003). For the Sub-Commission's commentary on the Norms, see Commentary on the

however, that there were indirect effects mediated through the human rights duties of states to regulate private actors, and that there were soft law norms pushing corporations to respect human rights and to provide voluntary remedies for violations. His Guiding Principles were adopted by the Human Rights Council in June 2011.[47]

2.5 Access to medicines as a human right

Although General Comment 14 refuses to specify the exact health facilities, goods and services that must be delivered by states, partially because of differing health needs among populations and partially because of differing levels of development, there is a basic 'core' obligation to guarantee access to essential medicines.[48] Pursuant to General Comment 14, the right of equal and timely access to health facilities, goods and services includes the provision of a basic health service; appropriate treatment of prevalent disease; and the affordable supply of essential drugs.[49] Delivering universal access to essential medicines, as defined by the WHO, is a core, non-derogable duty of all member states, as is providing progressively improving health services and other measures to prevent, treat and control epidemic and endemic diseases.[50]

At the most basic level, access to medicines refers to the ability of all persons to receive the medicines necessary for the treatment of any condition afflicting them, and that these medicines are available, accessible, acceptable, and of good quality. *Availability* requires that there must be sufficient quantities of the medicine and that shortages are avoided. *Accessibility* entails physical, informational and economic access. To ensure universal access to medicines, they have to be accessible to everyone, without discrimination, especially for the most vulnerable and marginalised sections of the population. However, they must be affordable as well, so that poorer households are not disproportionately burdened by health expenses.[51] These obligations of accessibility and affordability might require states to be health-cognisant 'when entering into bilateral or multilateral agreements with other states, international organisations and other entities, such as multilateral corporations'.[52] *Acceptability* refers to a need for the observance of medical ethics and sensitivity to the cultural norms of

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Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, UN Doc E/CN.4/Sub.2/2003/38/Rev 2 (2003). For a description by one of the principal drafters of the Norms, see D Weissbrodt & M Kruger 'Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights' (2003) 97 *American Journal of International Law* 901.

47 Human Rights Council Resolution 17/4 paras 1 & 6(a), UN Doc A/HRC/RES/17/4 (6 July 2011).

48 General Comment 14 para 12(a).

49 General Comment 14 para 17.

50 General Comment 14 paras 43(d) & 44(c).

51 General Comment 14 para 12(b).

52 General Comment 14 para 50.

individuals. Finally, medicines must be scientifically and medically appropriate and of good quality; the obligations on producers must be enhanced by rigorous drug registration standards; and there should be enforcement of good manufacturing practices and pharmaco-vigilance.[53]

The interpretive impetus provided by General Comment 14 has generated even more attention within the UN system, further clarifying the right to treatment and to medicines. There have been increased commitments internationally, particularly with respect to HIV/AIDS, including explicit treatment goals set within the Declaration of Commitment on HIV/AIDS[54] and the Millennium Development Goals.[55] Similarly, in Resolution 2001/33 of April 2001, the UN Commission on Human Rights (UNCHR) recognised that 'access to medication in the context of HIV/AIDS is one fundamental element for achieving progressively the full realisation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[56] According to this resolution, the entire international community has an obligation to 'facilitate, wherever possible access in other countries to … pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS' and to 'ensure … that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable … pharmaceuticals and medical technologies'. In 2002, the UNCHR adopted Resolution 2002/32, which, like Resolution 2001/33, called on states to[57]

> pursue policies … which would promote (a) the availability in sufficient quantities of pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS … (b) the accessibility to all … of such pharmaceuticals or medical technologies and their affordability for all …

Further crystallising the right to treatment in the HIV/AIDS context, UNAIDS and the UN High Commissioner for Human Rights held a consultation on HIV/AIDS and Human Rights in 2002, and issued a revised Guideline 6: Access to prevention, treatment, care and support.[58] The Commentary on the revised Guideline declares:

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53 General Comment 14 paras 12(a) to (d).

54 United Nations General Assembly Declaration of Commitment on HIV/AIDS ('Global Crisis-Global Action'), Resolution A/RES/S-26/2 (27 June 2001).

55 United Nations Millennium Declaration, Resolution A/RES/55/2 (8 September 2001).

56 Access to medication in the context of pandemics such as HIV/AIDS, Human Rights Commission Resolution 2001/33 (2001).

57 Access to medication in the context of pandemics such as HIV/AIDS, Human Rights Commission Resolution 2002/32 para 2 (2002).

58 Office of the United Nations High Commissioner for Human Rights and Joint United Nations Programme on HIV/AIDS, HIV/AIDS and human rights: International guidelines: Third international consultation on HIV/AIDS and human rights, UNAIDS/02.49E (2002) (revised reprint March 2003).The World Health Assembly has added its voice to that of the UNCHR, declaring that member states should act to increase access to treatment and prevention of HIV-related illnesses

> States should enact legislation to provide for … safe and effective medication at an affordable price. States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV/AIDS … treatment …, including anti-retroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV/AIDS and related opportunistic infections and conditions.

In their Recommendations for Implementation of Guideline 6, UNAIDS and the UNCHR recommended that states should implement and support policies allowing the purchase of cheaper generic medicines, diagnostics and related technologies,[59] specifically by amending domestic legislation to incorporate to the fullest extent possible any safeguards and TRIPS-compliant flexibilities for promoting and ensuring access to medicines.[60] Other states, particularly developed countries, should avoid taking measures that would undermine access to HIV/AIDS treatment, including medicines, and that they should ensure that bilateral, regional and international agreements involving intellectual property issues do not impede access to treatment, including anti-retroviral and other medicines.[61]

2.6 Is intellectual property a human right?

Proponents of strong intellectual property protection argue that certain provisions in international instruments secure intellectual property protection as a human right. Most often cited is the recognition of the right to the 'protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author'.[62] However, this view is not without opposition, mostly because this one clause is counterbalanced by article 15(1)(b) of ICESCR, which recognises everyone's right 'to enjoy the benefits of scientific progress and its applications'. Opponents argue that such protection is incompatible with the need to balance the interests of consumers and rights holders in circumstances where human rights and consumer interests clearly deserve priority, such as when it

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through measures, including those that ensure the provision and affordability of drugs. 'HIV/AIDS: Confronting the epidemic' Resolution WHA 53:14 (2000); 'Scaling up treatment and care with a co-ordinated and comprehensive response to HIV/AIDS' Resolution WHA 57.14 (2004); 'Contribution of WHO to follow-up of the United Nations General Assembly special session on HIV/AIDS' Resolution WHA 55.12 (2002); 'Ensuring accessibility of essential medicines' Resolution WHA 55.14 (2002); 'Intellectual property rights, innovation and public health' WHA Resolution 56.27 (2003).

59 Revised Guideline 6 para s.

60 Revised Guideline 6 para z.

61 Revised Guideline 6 para paras y & z. See 'The impact of the agreement of trade-related aspects of intellectual property rights on human rights' Report of the High Commissioner, E/CN 4/Sub 2/2001/13 (2001).

62 Art 27(2) Universal Declaration and art 15(1)(c) ICESCR.

concerns access to essential medicines.[63] Citing Schermers,[64] who holds that property rights cannot generally be included in the category of fundamental human rights, Drahos[65] suggests that intellectual property rights are distinguishable from fundamental human rights, in that 'human rights are of such importance that their international protection includes the right, perhaps even the obligation, of international enforcement', a claim which cannot be made for intellectual property rights. This latter view is supported by the ESCR Committee, which takes the view that 'intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments', and thus fall outside the ambit of human rights protection.[66] Accordingly, article 15(1)(b) should always be interpreted to prioritise human rights over property rights.[67] Even within the WTO, member states have unanimously agreed that the TRIPS Agreement should be interpreted 'in a manner supportive of WTO members' right to protect public health and, in particular, to promote *access to medicines for all*'.[68]

Some commentators,[69] departing from the view that intellectual property rights are human rights, argue instead that these rights necessarily result in a more limited role in international law for human rights norms, in particular the right of access to medicines. In the light of the potential conflict between this human rights regime and the intellectual property/trade regime as exemplified by the TRIPS Agreement, and in view of the lack of a clear normative hierarchy, they contend that dispute settlement in the trade arena must default to dictates of intellectual property rights enshrined in international economic rules, and that human rights arguments can serve merely

63 See PK Yu 'Reconceptualising intellectual property interest in a human rights framework' (2007) 40 *University of California Davis Law Review* 1039; D Matthews 'Intellectual property rights, human rights and the right to health' (2009) Queen Mary University of London Legal Studies Research Paper 24/2009; S Narula 'The rights-based approach to intellectual property and access to medicines: Parameters and pitfalls' (2011) New York University Public Law and Legal Theory Research Paper Series, Working Paper 11-60; SP Marks 'Access to essential medicines as a component of the right to health' in A Clapham & M Robinson (eds) *Swiss human rights book: Realising the right to health* (2009) 80.

64 HG Schermers 'The international protection of the right of property' in F Matscher & H Petzold (eds) *Protecting human rights: The European dimension* (1988) 565-580.

65 P Drahos 'The universality of intellectual property rights: Origins and development' in WIPO (ed) *Intellectual property and human rights. A panel discussion to commemorate the 50th anniversary of the Universal Declaration of Human Rights* http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf (1998) 15 (accessed 31 January 2012).

66 ESCR Committee General Comment 17 (2006) follow-up discussion.

67 See P Cullet 'Patents and medicines: The relationship between TRIPS and the human right to health' (2003) 79 *Journal of International Affairs* 139 159.

68 Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 para 4 (November 2001) (our emphasis).

69 See, eg, discussion in Hestermeyer (n 16 above).

for the interpretation of the TRIPS Agreement, and not as a defence to an infringement of its provisions.[70]

However, a significant weight of opinion stands in favour of a more proactive role for international human rights law, as enunciated on several occasions by the ESCR Committee.[71] This is evident in the experiences of both established and nascent democracies. Thus, it has been observed,[72] both India and South Africa have demonstrated the efficacy of human rights instruments and litigation in delivering public health benefits. These successes are attributable to several factors: a strong civil society; an independent and competent judiciary; respect on the part of the state for the rule of law; and the use of empirical medical evidence to support legal submissions.[73]

The most celebrated decision in South African jurisprudence in this regard is the *Treatment Action Campaign* case,[74] in which the Court considered both domestic constitutional provisions as well as the state's obligations under international law in interpreting the right of access to health care.[75] In the Indian context, although health-related rights are dealt with under non-enforceable directives of policy and are not an entrenched right in the Constitution, public interest litigation has focused on the right to life provision.[76] Successive decisions of the Indian courts have interpreted the right to life to include the right to a life with dignity, which encompasses access to health care.[77]

On the question of the conflict between the two regimes, the ESCR Committee's approach is that states cannot in good faith enter into other treaties which have the effect of undermining their prior obligations to human rights. Provisions in trade agreements, such as the TRIPS Agreement, which negatively impact on the right to health, are untenable as 'there is a strong presumption that retrogressive measures taken in relation to the right to health are not

70 Hestermeyer (n 16 above) 207. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was adopted by the World Trade Organisation in 1994, and seeks to 'harmonise' intellectual property rights protection globally.

71 See, eg, discussion in Canadian HIV/AIDS Network (2001) http://www.scielosp.org/pdf/ bwho/v80n12/8012a10.pdf (accessed 31 January 2006).

72 JA Singh *et al* 'Do human rights matter to health?' (2007) 370 *The Lancet* 521.

73 Singh *et al* (n 72 above) 526.

74 *Minister of Health & Others v Treatment Action Campaign & Others* (No 2) 2002 5 SA 721.

75 In this instance, the Court held that the policy of government, which restricted the use of the anti-retroviral drug Nevirapine for the prevention of transmission of HIV from mother to child to only 18 pilot sites, was unreasonable on several counts, notably that it failed to address the needs of mothers and unborn babies who had no access to these sites, and that it denied the rollout of the drug at locations where the capacity existed to do so.

76 Art 21 Constitution of India http://india.gov.in/govt/constitutions_india_bak.php #eng (accessed 11 March 2013).

77 See eg *Francis Coralie Mullin v The Administrator, Union Territory of Delhi* (1981) 2 SCR 516; *Bandhua Mukti Morcha v Union of India* 3 SCC 161, 1984; *Consumer Education and Research Centre v Union of India* 3 SCC 42, 1995; *Consumer Education and Research Centre v Union of India* 3 SCC 42, 1995.

permissible'.[78] Thus, the ESCR Committee made the following call to the WTO in 1999:[79]

> The end which trade liberalisation should serve is the objective of human well-being to which the international human rights instruments give expression. In this regard, the Committee wishes to remind WTO members of the central and fundamental nature of human rights obligations.

These obligations extend also to bilateral, plurilateral and multilateral agreements entered into by states, as well as to their participation in various international fora, which may result in similar adverse effects on human rights.[80] The Maastricht Guidelines, formulated by an independent group of internationally-recognised experts on economic, social and cultural rights, asserts:[81]

> It is particularly important for states to use their influence to ensure that violations do not result from the programmes and policies of the organisations of which they are members. It is crucial for the elimination of violations of economic, social and cultural rights for international organisations … to correct their policies and practices so that they do not result in deprivation of economic, social and cultural rights.

3 Economic justifications of intellectual property supremacy

An oft-cited defence of intellectual property supremacy rests on an economic analysis of innovation incentives, whereby intellectual property rights are allegedly needed as pragmatic incentives for the large and risky investments that pharmaceutical companies make in the arduous process of inventing new medicines and improving them over time.[82] The economic justification for patents on medicines is utilitarian in nature – its focus is benefits arising from a temporary period of exclusive rights and from public disclosure of the invention in the patent application. This must be contrasted with the costs arising from supra-competitive pricing that typically excludes poor countries and poor patients from access to the newest medical technologies.[83]

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78 Para 32 General Comment 14.

79 Paras 5 & 6 Statement of the ESCR Committee to the Third Ministerial Conference of the WTO, Seattle E/C 12/1999/9 (26 November 1999).

80 PK Yu 'Intellectual property and human rights in the non-multilateral era' Drake University Legal Studies Research Paper Series, Research Paper 11-04 (2011).

81 ESCR Committee Maastricht Guidelines on Violations of Economic, Social and Cultural Rights (22-26 January 1997) para 19.

82 International Federation of Pharmaceutical Manufacturers and Associations 'The pharmaceutical innovation platform: Meeting essential global health needs' (2008) http://www.ifpma.org/Documents/NR9565/IFPMA-PharmaInnovPlatform-Final-Nov2007.pdf (accessed 13 March 2012).

83 A Pouris & A Pouris 'Patents and economic development in South Africa: Managing intellectual property rights' (2010) IEEE Conference on Management of Innovation and Technology http://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=05492924 (accessed 13 March 2012); S Flynn *et al* 'An economic justification for

According to the economic theory, ordinary market forces do not result in optimal levels of innovation and product or process research and development, if competitors can routinely copy and market new technologies without bearing any of the investment costs associated with the original invention. The inventor necessarily needs to recoup its sunk costs, but cannot do so in competition with copiers who market at or near the marginal cost of production. The rational response to this risk of unfettered copying and competitive failure is either not to invest in research and development at all, or to keep inventions secret, which in turn decreases the dissemination of knowledge that supports future inventive activity.

In support of its claim that pharmaceutical innovators need exclusive rights in order to recoup the costs of successful and unsuccessful research and development activities, the industry cites studies by DiMasi and others. These studies estimated that average out-of-pocket costs as of the year 2000 for a selected subset of new medicines was $403 million pre-tax, taking into account the R&D costs of compounds abandoned during product development, and that average capital opportunity costs at an 11 per cent discount rate added $399 million per approved drug, to give a grand total of $803 million per successful drug.[84] Industry estimates expanded that estimate to $1,3 billion as of 2005,[85] and *Forbes Magazine* came out with an astronomical estimate of $4 to $11 billion per drug as of 2012.[86] Countering these inflated claims, independent researchers Light and Warburton found after tax median research costs to be much lower – $56 million plus unknown company costs of discovery – based on publicly-released information from drug companies.[87] These researchers do not include highly-inflated and hypothetical opportunity costs of earning potentially foregone, had the money simply been invested in index funds.

A second economic justification of the patent regime is that the adoption of intellectual property rights spurs foreign direct investment and thus economic development and industrialisation in low- and middle-income countries. The literature on this proposition is inconclusive at best, with Maskus, a leading researcher, concluding

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83 open access to essential medicine patents in developing countries' (2009) *Journal of Law, Medicine and Ethics* 184-208 http://www.wcl.american.edu/pijip/go/fhp2009 (accessed 12 March 2012).

84 JA DiMasi *et al* 'The price of innovation: New estimates of drug development costs' (2003) 22 *Journal of Health Economics* 151-185.

85 PhRMA 'Drug development costs have increased' (2005) http://www.phrma.org/drug-development-costs-have-increased (accessed 13 March 2012).

86 M Herper 'The truly staggering cost of developing a new drug' *Forbes Magazine* 19 February 2012 http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/ (accessed 13 March 2012).

87 DW Light & R Warburton 'Demythologizing the high costs of pharmaceutical research' (2011) 6 *BioSocieties* 1-17 http://www.pharmamyths.net/files/Biosocieties_ 2011_Myths_of_High_Drug_ Research_Costs.pdf (accessed 13 March 2012).

that FDI decisions are not based on intellectual property rights considerations, but rather on infrastructure, human capital, and regulatory issues.[88] Yet, another justification is that heightened intellectual property rights will spur domestic innovation but, here again, evidence to date suggests that strengthened patent rights increased foreign filings, but do not appreciably increase domestic filings.[89]

However, a more fundamental critique of the economic justifications of intellectual property rights is that they ignore the distortion caused by the pursuit of innovation-based monopolies, particularly with respect to pharmaceuticals. For example, the pursuit of so-called blockbuster drugs with sales in excess of $1 billion per year distorts research in two ways. Firstly, right holders seek to game the patent system with minor variations to existing blockbusters in order to strengthen and lengthen their monopolies and, secondly, competitors seek to invent around granted patent claims in order to develop me-too versions of existing successful therapies and to expand their share of the blockbuster pie, often with little or no improvement in therapeutic performance.[90] Companies are motivated to rush products to the market; exaggerate safety, efficacy, and use claims; and promote them strongly before long-term health effects are well understood. In addition, to secure marketing advantages, pharmaceutical companies spend disproportionately on what are best called 'marketing studies' – highly-selective research that will enable them to make successful sales pitches to medical prescribers and/or directly to patients.[91] In some cases, pharmaceutical companies will invent and deceptively promote a new disease – a tactic that the literature calls disease mongering.[92]

In a trenchant examination of the therapeutic efficiency of existing pharmaceutical research, Donald Light finds that pharmaceutical

88 EK Maskus 'Intellectual property rights in the global economy' Institute for International Economics, Washington DC (2000). See also L Brantetter *et al* 'Intellectual property rights, imitation, and foreign direct investment: Theory and evidence' NBER Working Paper Series 13033 (April 2007) http://www.nber.org/papers/w13033.pdf?new_window=1 (accessed 13 March 2012).

89 J Lerner '150 years of patent protection' (2002) 92 *American Economic Review* 221-225. A recent study in middle-income developing countries, which included South Africa, also concluded that patent laws are unlikely to promote local innovation in pharmaceuticals, and that governments should look elsewhere to encourage innovation. See also CM Correa 'Pharmaceutical innovation, incremental patenting and compulsory licensing' South Centre (September 2011) http://www.thaidrugwatch.org/download/rp_41_pharm_complice_ccorrea.pdf (accessed 24 March 2012).

90 A Hollis 'Me-too drugs: Is there a problem?' (2004) http://www.who.int/intellectualproperty/topics/ip/Me-tooDrugs_Hollis1.pdf (accessed 13 March 2012).

91 H Brody & DW Light 'Efforts to undermine public health – The inverse benefits law: How drug marketing undermines patient safety and public health' (2011) 101 *American Journal of Public Health* 399-404.

92 'Disease mongering collection' (2006) *PLoS Medicine* http://www.ploscollections.org/article/browseIssue.action?issue=info:doi/10.1371/issue.pcol.v07.i02 (accessed 13 March 2012).

investments by private companies contribute minimally to basic research, and that only a small portion of expenditure produces significant therapeutic gains (11 to 23 per cent).[93] More to the point, at least for low- and middle-income countries, the search for market rewards distorts research towards therapies and treatments for chronic and life-style diseases that mainly affect rich people in rich countries.[94] Since innovators earn little or no money on diseases primarily affecting poor people in poor countries – so-called neglected disease or WHO Class III conditions – there is insufficient research in these vital areas.[95] There is comparable underinvestment in antibiotics,[96] vaccines and other prevention technologies that patients do not take for long periods of time.

However, one of the most telling critiques of the economic justification for intellectual property rights on medicines is that the patent system and the secret, siloed research efforts that accompany it can actually interfere not only with access to needed commodities, but also with the very process of efficient and effective research and development itself.[97] There is growing evidence that so-called patent thickets, patents on up-stream, research platforms, and secrecy about interstitial advances and failures, interfere with an innovation ecology. This ecology would thrive with more open source and collaborative research where rewards for innovation could be divided based on therapeutic gain and advances in knowledge, instead of who gets to the patent office first and lays down the thickest and broadest carpet of patent claims. These telling critiques have prompted the exploration of non-patent-based systems for rewarding incremental and break-through innovation, including a research and development treaty, prize rewards, and other novel approaches.[98]

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93 DW Light 'Basic research funds to discover important new drugs: Who contributes how much?' in MA Burke & A de Francisco *Monitoring financial flows for health research 2005: Behind the global numbers* (2006) 29-43.

94 ER Dorsey *et al* 'Financing of US biomedical research and new drug approvals across therapeutic areas' *PLoS One* 4(9):e7015 (2009). http://www.plosone.org/article/info:doi%2F10.1371%2Fjournal.pone.0007015 (accessed 13 March 2012).

95 N Ford 'The enduring crisis in neglected diseases' in Cohen *et al* (n 3 above) 109-15; M Moran *et al* 'Neglected disease research and development: Is innovation under threat?' *G-Finder* (2011) http://policycures.org/downloads/g-finder_2011.pdf (accessed 13 March 2012); J Lexchin 'One step forward, one step sideways? Expanding research capacity for neglected diseases' (2010) 10 *BMC Journal of International Health and Human Rights* 1-10 http://www.biomedcentral.com/content/pdf/1472-698X-10-20.pdf (accessed 13 March 2012).

96 K Outterson 'The vanishing public domain: Antibiotic resistance, pharmaceutical innovation and global public health' (2005) 67 *University of Pittsburgh Law Review* 67.

97 B Hirschler 'Drug companies learning how to share' *Reuters* 28 September 2011 http://www.reuters.com/article/2011/09/28/us-pharmaceuticals-research-idUSTRE78R3RP20110928 (accessed 13 March 2012).

98 J Love 'Measures to enhance access to medical technologies, and new methods of stimulating R&D' (2007) 40 *University of California Davis Law Review* 679; J Love & T Hubbard 'The big idea: Prizes to stimulate R&D for new medicines' (2007) 82 *Chicago-Kent Law Review* 1519-54.

Taken all together, the litany of concerns about the merits of pragmatic economic justifications for prioritising intellectual property rights over human rights cannot hold sway.

4 Concluding comment on a human rights framework

International law unequivocally establishes a fundamental right to health (or, more appropriately, a right to access health care) and access to medicines is clearly a key component of that right. Some would argue that access to essential medicines comprises a minimum core of non-derogable rights available to citizens, and that the state cannot justify its inability to provide them by resorting to the argument of resource constraints. It is increasingly being argued that these rights also extend to a variety of non-state actors, given their influence in both the determination of policy, as well as health care delivery and implementation. This has led to activists demanding that binding human rights norms apply to business entities.[99] Because multinational corporations operate at a transnational level, they often have the freedom to apply inferior human rights and safety standards in different countries. One contribution argues that countries would not readily relax their human rights and safety standards merely to attract investment, if corporations could be held to universal standards of conduct.[100] Thus, individuals and communities are expected to increasingly make demands on all these actors, in order to realise their fundamental right to health.

This has put proponents of the rights-based access movement on a collision course with defenders of the proprietary rights of intellectual property rights holders and their developed country government backers. Activists in developing countries have adopted and extended the discourse of human rights to mount successful campaigns against government intransigence and corporate greed. According to Baker:[101]

> Although they have relied on a rhetoric of a human right to health, access to medicines, and indeed to life itself, they have implemented that rhetoric with sophisticated campaigns aimed at removing structural impediments and leveraging resources to actually increase access to medicines on the ground.

99 See Chirwa (n 24 above) 562.

100 S Deva 'Human rights standards and multinational corporations: Dilemma between "home" and "Rome"' (2003) 7 *Mediterranean Journal of Human Rights* 69-97 SSRN http://ssrn.com/abstract=637666 (accessed 31 August 2009). The author uses the Bhopal disaster as a case study to show that a 'no standards standard' in business practice fails to protect even basic human rights.

101 BK Baker 'Placing access to essential medicines on the human rights agenda' in Cohen *et al* (n 3 above) 239.

5 Context of medicines as essential public goods

5.1 Why are medicines unaffordable?

Several factors have been identified as contributing to the lack of access to essential drugs and vaccines in developing countries. According to *Medicins Sans Frontières*, these include the poor quality of drugs; a lack of availability due to fluctuating production; prohibitive costs of some drugs and vaccines; and the impact of the TRIPS Agreement. This Agreement seeks to harmonise intellectual property rights and, in particular, imposes a uniform baseline of patent rules globally. By virtue of its membership of the WTO, South Africa is obliged to comply with the provisions of the TRIPS Agreement.

There is a direct relationship between the price of a medicine and its patent status. A patent is a legal title granted by the government, allowing a temporary monopoly for a specified number of years, for the production and sale of a new invention.[102] This entitles the patent holder to exercise exclusive rights over the manufacture, sale and distribution of the patented article, thus enabling it to set a price which, in the absence of competition, may have no bearing on the actual costs of producing the item, even when adding in the cost of research and development for it and dry hole[103] prospects.[104]

While it is true that the intervention of philanthropic institutions such as the Clinton Foundation[105] and the Global Fund have helped create demand by working with both drug manufacturers and government treatment plans, and thus have succeeded in lowering prices of anti-retrovirals, many other drugs remain unaffordable to developing country governments.

5.2 Essential public goods?

The increasing privatisation of knowledge and the products of knowledge have been a significant feature of the capitalist system from its earliest phases. It was typified by the 'enclosure movement',[106] the design to fence off public spaces and bring them

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102 International Council of AID Service Organisations (ICASO) *Compulsory licensing and parallel importing* (1998). See also sec 25(2)(a) of the Patents Act 57 of 1978.

103 Borrowed from the oil-prospecting industry, the term 'dry hole' refers to an unsuccessful venture, such as a drug development project which does not yield a viable product. See *The free dictionary* http://www.thefreedictionary.com/dry+hole (accessed 20 February 2011).

104 The advisability of patenting inventions in the field of public health has been extensively debated in the literature. See, eg, FM Abbott 'The enduring enigma of TRIPS: A challenge for the world economic system' (1998) 1 *Journal of International Economic Law* 497.

105 Clinton Foundation http://fex.ennonline.net/35/agencyprofile.aspx (accessed 30 November 2009).

106 J Boyle 'Fencing off ideas: Enclosure and the disappearance of the public domain' in A Agostino & G Ashton (eds) *A patented world? Privatisation of life and*

under private ownership and control. This culminated in according proprietary status to the products of the intellect – the recognition of intellectual property rights. In more recent times, the harmonisation and integration of intellectual property rights, through institutions such as the WIPO and WTO, signify a new wave of the enclosure movement, with intellectual property right protection now having a global reach. Protagonists of this approach have argued that the new property regime has given rise to 'unparalleled expansion of productive possibilities'.[107] But for whose benefit? Life-saving medicines and medical devices, critical to the health and well-being of individuals and societies alike, have not escaped appropriation as private assets.

Medicines are thus often viewed as private commodities because of various factors, including, amongst others:

- Reigning bioethical models with their focus on patient autonomy have emphasised individual aspects of health care, reinforced by the fact that medicines are privately consumed.[108]
- The market pre-selects consumers of highly-priced medicines, by excluding those individuals who cannot afford them.

But medicines are – at least partially – public goods in the sense that they have significant implications for public health, are also global in their development and impact, and are prone to regulation in their development, manufacture, allocation and use.[109] The public dimensions of medicines are well known, directly from their role in public health vaccination measures, as well as in the treatment of epidemic and endemic diseases. The public dimension also entails the public consequences emanating from choices made in research and development of new medicines, and the profiteering surrounding lifestyle drugs which draws resources away from research into so-called 'neglected' diseases.

In contrast to private goods, 'public goods' are goods that are essentially social in character, even though (like medicines) they may be intended for private consumption.[110] Public goods also often have positive externalities, meaning that their broad accessibility and use benefit the public at large, not just those who use them. This public benefit is most obvious in the instance of vaccination, where herd immunity develops because of wide diffusion. However, the same dynamic can be seen with respect to the prevention and treatment of infectious diseases. Indeed, because healthier populations have increased capacity in the economic, cultural, political and self-

knowledge (2006) 19.

107 Boyle (n 106 above) 20.

108 WE Parmet 'Pharmaceuticals, public health, and the law: A public health perspective' in Cohen *et al* (n 3 above) 78.

109 As above.

110 Knowledge Ecology International *KEI Proposal: A WTO agreement on the supply of knowledge as a global public good* (June 2008).

actualising sphere, there are positive externalities for treating chronic and even temporary disease conditions. Medicines, therefore, cannot merely be regarded as private goods.

Drug development itself has assumed a global character. It may be true that most innovation in this area emanates from laboratories in developed countries. However, developing countries make a significant contribution to the development of medicines in several ways, including sharing knowledge of indigenous plants and their properties, and controversially, being involved as research participants in clinical trials for medicines, from which they sometimes may not themselves benefit.[111]

A major change in the recent discourse on global health concerns the 'framing, norms, and policy approaches to addressing the problem of globally inequitable access to drugs, diagnostics, vaccines and other health technologies'.[112] This development is due, in no small part, to the global political and social mobilisation on the issue of access to affordable anti-retrovirals, which has fomented a re-think of the traditional approaches to understanding medicines as private goods, has focused attention on the global demand for access to health technologies for all (as opposed to merely 'neglected' diseases), and has highlighted the need for new, more inclusive governance mechanisms to manage pharmaceutical and related innovation.[113]

Thus, both the human rights framework and the characterisation of medicines as public goods contribute to our analysis of the intellectual property regime governing pharmaceuticals. This analysis reinforces the argument that, firstly, obligations of governments in respect of trade treaties cannot supercede their obligations to fulfil their human rights obligations – in this instance the right to access health care and essential medicines. Secondly, the 'public goods' character of medicines makes a strong argument for removing them from the realm of private commodities entitled to unfettered intellectual property rights protection.

6 Discussion on the potential for teaching and advocacy at the intersection of human rights and intellectual property

Historically, training in intellectual property was offered by institutions operating within the UN system, such as the World Intellectual Property Organisation (WIPO), or patents offices in developed

111 Parmet (n 108 above) 84.

112 S Moon 'Medicines as global public goods: The governance of technological innovation in the new era of global health' (2008/2009) II *Global Health Governance* 2.

113 Moon (n 112 above) 13.

countries. Such training has not been ideologically neutral, and has been criticised because developing country examiners of patents and other forms of intellectual property tend to adopt the biases and priorities of their developed country trainers.[114] More recently, a much more balanced approach to the training is being undertaken with, for example, the United Nations Development Programme (UNDP) dedicating resources and personnel to this task, in collaboration with international non-governmental organisations (NGOs) such as the South Centre.[115]

In the African context, intellectual property was (and to a large extent still is) taught and researched as a speciality area, focused predominantly on the corporate perspective, as opposed to a 'developmental' perspective. The latter approach seeks to situate the effects of intellectual property laws and policies in the developing country context, with specific attention to their public health and public interest dimensions. South African intellectual property practice is singularly focused on the private law aspects – the protection and enforcement of the rights of intellectual property rights holders.[116] Some university courses are beginning to address this deficiency, most notably at Master's level.[117] However, these courses are generally aimed at post-graduate students or public sector employees. No course previously catered for the training, participation or perspectives of activists and advocacy specialists in the area of intellectual property rights and their impact on the accessibility of medicines.

In an effort to increase knowledge about intellectual property and human rights framework and to capacitate participants to engage in country and regional campaigns to overcome intellectual property barriers and to promote access to medicines, the authors of this article developed an intensive two-week short course that was supported by the Open Society Institute and delivered at the University of KwaZulu-Natal in Durban, South Africa.[118] In addition to focusing on economic, legal and regulatory issues affecting access to medicines,

114 See CD Bierbeck & S Roca *An external review of WIPO technical assistance in the area of co-operation for development* (August 2011) http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_1-annex1.pdf (accessed 13 March 2012); P Drahos 'Trust me: Patent offices in developing countries' (November 2007) Centre for Governance of Knowledge and Development Working Paper http://www.cgkd.anu.edu.au (accessed 13 March 2008).

115 UNDP/South Centre 'Intellectual property enforcement and access to essential medicines' Regional Consultation, 22-23 June 2011, Pretoria, South Africa, Final Report (on file with authors).

116 See YA Vawda 'Intellectual property: Putting the "public" back into "private" law' (January-February 2008) *De Rebus* 75.

117 The University of Pretoria's Centre for Human Rights, eg, offers a one-week short course on 'Human rights and access to medicines' http://www.chr.up.ac.za/index .../human-rights-a-access-to-medicines.html (accessed 24 March 2012).

118 Since 2008, the UKZN School of Law has offered a short course on Intellectual Property and Access to Medicines, training a cross-section of groups: academics, community activists, government decision makers, and advocates for social justice. Details may be sourced at http://ipatm.ukzn.ac.za/Homepage.aspx.

the course also devoted a full third of its curriculum to the development of strategic access to medicines campaigns by its participants.

The UKZN Intellectual Property and Access to Medicines short course has, in its five years of existence, trained over 65 participants drawn initially from most regions of Africa, but has more recently focused on Eastern and Southern Africa. These countries are clearly diverse with respect to climatic, economic, linguistic, cultural, religious and social differences, and with respect to their legal systems. However, they all have significant commonalities – widespread poverty, under-development, poor health, high mortality and poor development indices, scarcity of skills, fragile health and other infrastructure, and unaffordably high prices for essential medicines. In addition, many of these countries have legal and regulatory regimes which provide strong intellectual property protection for medicines and other related products. The impact of intellectual property rights on access to medicines was palpable, and could grow worse in the future if countries were to accede to efforts by the pharmaceutical industry and their rich country surrogates to seek wider, stronger and longer intellectual property protections and enhanced intellectual property enforcement measures. Thus, the potential for advocacy in this area is enormous, and the challenges no less daunting. Campaigners for access are often viewed as threats to state security, and are met with repression, including apparently culturally and legally-sanctioned homophobia.[119]

The potential for successful advocacy using the perspectives, skills and knowledge gained in training courses such as the UKZN one, coheres around four specific areas:

1 *Impact on policy and law making through community-based actions and campaigns*. The best example of this is the strategy of the Treatment Action Campaign of South Africa (TAC), in moving government to roll out HIV/AIDS anti-retroviral treatment, first to expectant mothers and their babies, and then to the general population of the HIV-infected from 2004 onwards. Graduates of the UKZN course have been involved in grassroots campaigns relating to stock-outs of medicines, demands for faster roll-out of the HIV treatment programme, the adoption of safer medicines, and earlier initiation of treatment.

2 *Law reform measures through participation in the judicial and public policy process*. Examples abound, but notably the victory of persons living with HIV/AIDS in Kenya who succeeded in moving the High Court to suspend certain provisions of anti-counterfeiting legislation, as it threatened their access to generic medicines. Earlier, the TAC had used the South African Competition Commission to challenge high drug prices for anti-retroviral

119 See L Duff 'Is Africa homophobic?' *SANGONeT Pulse* 19 March 2012 http://www.ngopulse.org/article/africa-homophobic (accessed 24 March 2012).

medicines, resulting in multiple licences to generic companies. In November 2011, drawing on the expertise of UKZN course graduates, the TAC and Doctors without Borders launched a campaign to reform South Africa's patent legislation, to utilise the 'flexibilities' available in the TRIPS Agreement and the Doha Declaration[120] to make the law more access-friendly. Course graduates have also been involved in similar campaigns to reform patent legislation in Uganda to maximise the availability of TRIPS-compliant flexibilities.

3 *Development of national, regional and international solidarity through co-ordinated action, support and campaigns*. Here the current international campaign to extend the time period within which least developed countries must become TRIPS compliant is noteworthy, and that campaign has involved multiple graduates of the UKZN course.

4 *Capacitating academics to understand intellectual property law through 'developmental' lenses, as much of law school teaching is based on traditional, corporate-biased theory and practice*. The course enables participants to challenge conventional notions of the benefits and limitations of intellectual property protection. Thus far, academics from the Universities of KwaZulu-Natal and Zululand (South Africa), Makerere University (Uganda), the University of Malawi and the National University of Lesotho have benefited from the course.

One significant outcome generated by this course is the emergence of a pan-African solidarity among the participants, which persists beyond the duration of the course. The intensive interaction over two weeks yields a strong camaraderie, and participants develop a deeper understanding of their respective realities, challenges and prospects for change. They continue to offer one another guidance and support in their work, albeit on an informal basis.

Advocacy efforts such as those spawned by the UKZN Intellectual Property and Access to Medicines course speak directly to issues of social justice, by capacitating individuals and organisations to effectively analyse, understand and engage with complex issues affecting the daily lives of people across Africa and much of the developing world. It seeks to do so by focusing on the human right to health and access to essential medicines. In so doing, such courses are making a significant contribution to developing capacity and expertise on the African continent, while consolidating collaboration with northern partners.

120 WTO *Declaration on the TRIPS Agreement and public health* (14 November 2001) http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 20 February 2013).

7 Conclusion

The interests of achieving social justice require that a counter-narrative be presented to the dominant narrative which promotes intellectual property rights protection at all costs – even at the expense of the right to access essential medicines.

The human rights paradigm enables the articulation of such a counter-narrative. It is only when human rights are respected in word and deed, when the value of medicines as public goods is acknowledged, and when the erosion of the 'commons' is arrested, that social justice will prevail.