BALANCING PATENTS AND ACCESS TO MEDICINE

The controversy arising from the HIV/AIDS pandemic and global health crisis has triggered and spurred the call for better access to medicines and medical treatments. Some developing countries have expressed concerns that patents on medicines and treatments may impede access to affordable healthcare. This article builds on the works of eminent scholars in relation to patents and public health. It seeks to highlight the need to persevere with the quest to achieve an appropriate trade-off between protection of ideas to encourage innovation and investment thereof and ensuring that protection itself does not stifle further innovation and access to medicine for public health. This is particularly so in the development of new technologies and medicines which entail considerable investment in research and development that is fraught with significant risks and uncertainties. It will also provide some observations on selected avenues of reform.

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I. Introduction

1 The controversy arising from the HIV/AIDS pandemic and global health crisis has triggered and spurred the call for better access to medicines and medical treatments. Major concerns have been expressed by some developing countries that the implementation of strong intellectual property regimes may "affect their efforts to improve public health"[1] and that patents on medicines and treatments "may be hampering governments' attempts to deal with urgent policy issues" by "unacceptably imped[ing] access to affordable healthcare, thus frustrating public health programs".[2] This has also be reiterated by the Coalition for Intellectual Property Rights ("CIPR") which regards the "cost of pharmaceutical products as an important concern in developing countries" since most poor people in these countries "pay for their own drugs and state provision is normally selective and resource-constrained. This is generally not the case in the developed world where costs are mainly met by the state or through insurance schemes".[3]

2 Since one of the key objectives of the patent system is to reward innovation by allowing innovators to charge "higher prices" for protected products, it has been argued that a fully functional patent system would result in an inverse relationship between the cost of such products and affordability of access.[4] This has led some to suggest that the global intellectual property system may be facing a crisis of public legitimacy as questions are being raised, for example, on how patents

1 Commission on Intellectual Property Rights ("CIPR"), *Integrating Intellectual Property Rights and Development Policy* (2002) at p 29 at <http://www.ipr commission.org/> (accessed 5 February 2009). For the UK response, see <http://www.iprcommission.org/papers/pdfs/govt_response/govt_response.pdf> (accessed 8 July 2009).

2 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 28. See, for example, the recent outcry by a consortium of non-governmental organisations in Kenya over the high cost of Aids drugs. This has called for a consideration of the following: "How does a mercilessly globalizing world balance the 3Ps – Pharmaceuticals, Patents and Profits – with the right of patients to access essential drugs?" See Odour Ong'wen, "Crocodile Tears: How 'Trips' Serves West's Monopoly" The East African (2001).

3 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 30 at <http://www.iprcommission.org/> (accessed 5 February 2009).

4 See Lall & Albaladejo, "Indicators of the Relative Importance of IPRs in Developing Countries" (Working Paper No 85, Queen Elizabeth House Working Paper Series QEHWPS85, 2002) at pp 2–3. See also CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 30 at <http://www.iprcommission.org/> (accessed 5 February 2009).

may be blocking the access of ordinary people to medicines[5] and their "right to health".[6]

3 This can be contrasted with the views expressed by those in the pharmaceutical industry that it is "more strongly dependent on the patent system than most other industrial sectors to recoup its past R&D [research and development] costs, to generate profits, and to fund R&D for future products".[7] Indeed, the CIPR noted that:[8]

> [S]urveys have shown that the pharmaceutical companies, more than any other sector, think patent protection to be very important in maintaining their R&D expenditures and technological innovation. The industry understandably takes a close interest in the global application of IPRs [intellectual property rights], and generally resists the contention that they constitute a major barrier to access or a deterrent to development in developing countries.

4 Whilst it may be easy to give in to the temptation for enhanced protection as a means of "promoting the public good", some critics have cautioned against shifting "control and ownership over technology from the public to the private, serving to commodify vital technological information that they argue should remain in the public domain".[9] Its impact, particularly in relation to access to medicine in developing countries, needs to be carefully assessed, since if prices are raised this will "fall especially hard upon poor people, particularly in the absence of

5 See, for example, Khor, *Patents System Facing Legitimacy Crisis, Earth Trends* (2001) at <http://www.twnside.org.sg/title/et0110.htm> (accessed 23 November 2008).

6 See Anand Grover, *Promotion and protection of all human rights, civil, Political, economic, social and cultural rights* (Report of the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, including the right to development) (A/HRC/11/12, 31 March 2009) stating that (at p 5): "The right to health was first addressed in the 1948 Universal Declaration of Human Rights. It is established under article 12 of the International Covenant on Economic, Social and Cultural Rights and is also well recognized in the Convention on the Elimination of All Forms of Discrimination against Women and the Convention on the Rights of the Child." In addition (at p 6): "States have an obligation under the right to health to ensure that medicines are available, financially affordable, and physically accessible on a basis of non-discrimination to everyone within their jurisdiction. Developed States also have a responsibility to take steps towards the full realization of the right to health through international assistance and cooperation."

7 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 29 at <http://www.iprcommission.org/> (accessed 5 February 2009).

8 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 29 at <http://www.iprcommission.org/> (accessed 5 February 2009).

9 *WIPO Patent Agenda: Options for Development of the International Patent System*, WIPO Doc A/37/6 (2002) Annex I, 3 (Memorandum of the Director General).

widespread provision for public health as exists in most developed countries".[10]

5 This paper will build on the works of eminent scholars in relation to patents and public health issues. It will seek to highlight the need to persevere with the quest to achieve an appropriate trade-off between protection of ideas to encourage innovation and investment thereof and ensuring that protection itself does not stifle further innovation and access to medicine for public health. This is particularly so in the development of new technologies and medicines which entail considerable investment in research and development that is fraught with significant risks and uncertainties. It will also provide some observations on selected avenues of reform.

II. Public interests: access to medicine and treatment

6 In 2001 alone, HIV/AIDS, malaria and tuberculosis have together claimed 5.7 million lives and "caused debilitating illness in many millions more".[11] By 2020, AIDS will have "caused more deaths than any other disease epidemic in history".[12] With the tremendous progress that has been made in scientific and technological development, "these diseases should have been brought under control. Yet, in developing countries today they continue to kill at an alarming rate. And at times – as in recent outbreaks of influenza – they also kill at an alarming rate in the industrialized countries".[13] The table below reveals further information on the health crisis:

10 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 30 at <http://www.iprcommission.org/> (accessed 5 February 2009).

11 See WHO Infectious Disease Report 2002 at <http://www.who.int/infectious-disease-report/2002/pdfversion/Ch0Introduction.pdf> (accessed 9 June 2009).

12 See WHO Infectious Disease Report 2002 at <http://www.who.int/infectious-disease-report/2002/pdfversion/Ch0Introduction.pdf> (accessed 9 June 2009).

13 See WHO Report on Infectious Diseases 1999 at <http://www.who.int/infectious-disease-report/index-rpt99.html> (accessed 9 June 2009).

HIV/AIDS, tuberculosis and malaria – the basic facts, 2000[14]			
Disease	**Deaths per year**	**New cases per year**	**Percentage in developing countries**
HIV/AIDS	3 million	5.3 million	92%
Tuberculosis	1.9 million	8.8 million	84%
Malaria	More than 1 million	300 million	Nearly 100%

7 The need to alleviate suffering arising from the global health crisis, particularly those in developing and least-developed countries that are facing a critical need for urgent access to medicines to treat these and other diseases,[15] merits serious attention. This has prompted some to argue that:[16]

> [H]ealthcare considerations must be the main objective in determining what IP regime should apply to healthcare products. IP rights are not conferred to deliver profits to industry except so that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare.

8 In this context, the CIPR has also succinctly noted the dilemma facing healthcare in developing countries as follows:[17]

> How can the resources necessary to develop new drugs and vaccines for diseases that predominantly affect developing, rather than developed, countries be generated when the ability to pay for them is so limited? Even when there is a developed country market from which these resources can be recovered through high prices, how can the affordability of these drugs in developing countries be secured?

14 World Health Organization Infectious Disease Report 2002.

15 For a discussion on access and benefit sharing in relation to infectious diseases and the emergence of a new international federalism, see Hocking, "Access and Benefit Sharing under CBD, WIPO and WHO: Evidence for a new International Federalism?" (Conference paper delivered at the CIPL Symposium, Canberra, 26 May 2008). See also Fisher and Syed, *Drugs, Laws & the Health Crisis in the Developing World* (Stanford University Press, forthcoming 2010).

16 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 30 at <http://www.iprcommission.org/> (accessed 5 February 2009).

17 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 31 at <http://www.iprcommission.org/> (accessed 5 February 2009).

> How can conflicts between the two objectives – covering R&D costs and minimizing consumer costs – be resolved?"

9 Apart from the IP issues, access to affordable medicine also involves a complex web of intricate "non-patent related" obstacles such as poverty; corruption; civil strife, economic and societal problems, poor healthcare infrastructure, diagnostics and medical workforce; poor supply, distribution and delivery systems particularly to rural areas; substandard medicines; financial and administrative mismanagements, taxes and custom duties, complexity of medical therapy, *etc.* These have been succinctly discussed elsewhere[18] and are beyond the scope of this article.

III. Some observations on selected avenues of reform[19]

10 Article 8 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides that:

> Members may ... adopt measures necessary to protect public health ... and to promote the public interest in sectors of vital importance to their socio-economic and technological development.

11 This has been affirmed by the World Trade Organization ("WTO") Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration"):[20]

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18 See, for example, WHO Commission on Macroeconomics and Health (2001); Gelder & Cudjoe, "Patent-busting: Punishing the Poor" *The Straits Times* (2 May 2008) at p 23; Wilder, "Market Segmentation: Techniques, actors and incentives – the use of intellectual property rights" (Paper presented at the Workshop on differential pricing and financing of essential drugs, WHO and WTO Secretariats, Norway, 8–11 April 2001); Mercurio, "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines" 5 Northwestern University Journal of International Human Rights 1; CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at <http://www.iprcommission.org/> (accessed 5 February 2009). Note also comments made in March 2002 by Sir Richard Sykes (former Chairman of GSK) that "IP protection is not the cause of the present lack of access to medicines in developing countries" quoted in the CIPR Report, at p 30.

19 Some of these proposals have been discussed in the author's earlier work, see Ng S K, "The Impact of the International Patent System on Developing Countries" (WIPO Doc A/39/13 Add.3, 2003) (Report commissioned by the Director-General of the WIPO and submitted by the WIPO Secretariat to the WIPO 39th General Assembly of Member States of WIPO).

20 See para 4 of the DOHA Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2) at <http://www.worldtradelaw.net/doha/tripshealth.pdf> (accessed 23 July 2008). Note also Arts 8 and 73 of the TRIPS Agreement relating to the protection of public health and essential security interests. Indeed, it has been argued that the flexibility and safeguards allowed under the TRIPS Agreement, particularly that relating to the protection of public health, should be preserved. See Carlos Correa & Sisule Musungu, "The WIPO Patent Agenda: The

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> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

12 The ultimate goal in this discussion is to ensure that medicines can fulfil their central role in improving their access for some and health for all. In this regard, it is important to note that adequate safeguard to ensure the safety of drug supply is imperative. Similarly, the recommendations proceed solely on the basis of improving access to and affordability of medicines. It does not purport to analyse other "non-patent related" factors contributing to problems relating to medical access and affordability which have been mentioned above.

13 Numerous options proposed include the call to incorporate a general exception into the draft Substantive Patent Law Treaty ("SPLT") that deals with the protection of public health and environment.[21] Other policy avenues include compulsory licensing, parallel imports, limiting patentability, price control and differential pricing, patent pools, centralised drug purchase facility,[22] competition law, charity (drug donation), provision of aid, voluntary licensing and appealing for greater corporate responsibility to society. In conjunction with the other published studies on the laws and other related issues,[23] some observations on a few of the selected proposed options will be discussed.

Risks for Developing Countries" (Working Paper No 12, Trade-Related Agenda, Development and Equity, South Centre (T.R.A.D.E) 2002) ("South Centre Report") at p 27. See also the Royal Society, *Keeping Science Open: the effects of intellectual property policy on the conduct of science* (2003) at p 15, where the Royal Society endorsed the importance of ensuring an adequate supply of medicines to developing countries at low prices.

21 See Carlos Correa & Sisule Musungu, "The WIPO Patent Agenda: The Risks for Developing Countries" (Working Paper No 12, Trade-Related Agenda, Development and Equity, South Centre (T.R.A.D.E) 2002) at p 20. See also Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913 at 916, on how many of today's developed countries also excluded pharmaceutical products from patent protection until quite recently.

22 For example, UNITAID Drug Purchase Facility applying its market dynamics toolkit comprising of pool procurement, volume price negotiation, *etc.*

23 See, for example, CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at <http://www.iprcommission.org/> (accessed 5 February 2009); see WIPO Patent Agenda (A/36/14); WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6); Carlos Correa & Sisule Musungu, "The WIPO Patent Agenda: The Risks for Developing Countries" (Working Paper No 12, Trade-Related Agenda, Development and Equity, South Centre (T.R.A.D.E) 2002) at p 20; Scherer & Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Countries' (2002) 5 Journal of International Economic Law 913; Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition*

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A. Off-patent drugs

14 It has been noted that the vast majority of pharmaceutical products are off-patents and are therefore available for use in the public domain. A recent survey suggests that only about 20% of anti-retroviral drugs for treating HIV/AIDS remain patented.[24]

15 Developing countries have been urged to create a "vigorously competitive supply" of these generics[25] and to ensure that "trade in generic drugs is not restricted and that vigorously competitive world markets emerge".[26] However, it has been noted that many developing countries "have hurt themselves by not taking full advantage of the opportunities for encouraging generic substitution".[27] This has led to the argument that perhaps the impact of patents on public health may be "moot for many in the developing countries where inadequate

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and Prices in Developing Countries (Report presented to the WIPO under terms of Special Service Agreement, 2001); International Intellectual Property Institute ("IIPI"), *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000) at <http://www.iipi.org> (accessed 5 February 2009); Faunce, "Innovation and Insufficient Evidence: The Case for a *WTO Agreement on Health Technology Safety and Cost-Effectiveness Evaluation*" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010). See also Cornish, *Intellectual Property: Omnipresent, Distracting, Irrelevant?* (Oxford University Press, 2002).

24 See Kirk, "Competing demands on public policy" (Paper presented at the WIPO Conference on the International Patent System, Geneva, 25 to 27 March 2002) quoting a recent study on 53 African countries published in the Journal of the American Medical Association that only three of 15 anti-retroviral drugs for treating HIV/AIDS remain patented.

25 See, for example, Kanavos, "Generic policies: rhetoric vs reality" (2008) Euro Observer (Vol 10, No 2) 1, Vandoros, "Generic policies and the 'Generic Paradox'" (2008) Euro Observer (Vol 10, No 2) 7, Seeley, "Maximising the benefits from generic competition" (2008) Euro Observer (Vol 10, No 2) 9 at <http://www.euro.who.int/Document/Obs/EuroObserver_Summer_2008.pdf> (accessed 24 April 2009).

26 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913 at p 916. See also a recent survey by Frost & Sullivan Asia Pacific noting that the East Asian market is driven by generic pharmaceutical companies whose current strength lies in their dominance of local markets. A recent survey on the generic pharmaceutical markets in Malaysia, Philippines, Singapore and Taiwan shows the following: The total generic pharmaceutical market in the four countries was estimated at more than $500m in 2001 and is expected to reach over $1bn by 2007: see Frost & Sullivan Asia Pacific, "The Asian Generic Pharmaceutical Market" (2002) at <http://pharmalicensing.com> (accessed 5 February 2009). See also Frost & Sullivan Asia Pacific, "The Generic Invasion – An Inside Scoop to the Pot of Gold" (2003) at <http://pharmalicensing.com> (accessed 5 February 2009).

27 Scherer & Watal, 'Post-TRIPS Options for Access to Patented Medicines in Developing Countries' (2002) 5 Journal of International Economic Law 913.

healthcare and health infrastructure poses a much more immediate and significant problems".[28]

16 The table below reveals further interesting information:

Medicines	*Patents and related information*
Anti-tuberculosis Anti-Malarial	Some 95% of the pharmaceutical products on the World Health Organization's Essential Drugs List are now "off patent".[29] The 2007 WHO model list of essential medicines includes 10 anti-tuberculosis drugs and 14 anti-malarial drugs.[30]
Anti-retroviral	Most anti-retroviral drugs are not protected by patents in the majority of developing countries.[31] The WHO's Essential Drugs List – includes some drugs used for the treatment and prevention of HIV/AIDS – which are now "off patent".[32] The 2007 WHO model list of essential medicines includes 20 anti-retroviral medicines.[33]

17 Notwithstanding this, issues concerning the affordability of patented drugs will continue to hog the agenda. Indeed, the African, Caribbean and Pacific Group of States ("ACP") have noted that in view of the outbreak of new diseases, such as SARS, a solution that is straightforward, easy to implement and effectively workable, needs to be found now as a matter of urgency.[34] A further evaluation of some possible solutions is therefore timely.

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28 See Mercurio, "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines" 5 Northwestern University Journal of International Human Rights 1.

29 WIPO, *Striking a Balance: Patents and Access to Drugs and Health Care* at <http://www.wipo.int/export/sites/www/freepublications/en/patents/491/wipo_pub_491.pdf> (accessed 5 February 2009).

30 See *WHO Model List of Essential Medicines* (15th list, March 2007) at <http://www.who.int/medicines/publications/08_ENGLISH_indexFINAL_EML15.pdf> (accessed 29 April 2009).

31 IIPI, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000) at <http://www.iipi.org> (accessed 5 February 2009).

32 WIPO, *Striking a Balance: Patents and Access to Drugs and Health Care* at <http://www.wipo.int/export/sites/www/freepublications/en/patents/491/wipo_pub_491.pdf> (accessed 5 February 2009).

33 *WHO Model List of Essential Medicines* (15th list, March 2007) at <http://www.who.int/medicines/publications/08_ENGLISH_indexFINAL_EML15.pdf> (accessed 29 April 2009).

34 See Communication from the African, Caribbean and Pacific Group of States ("ACP") on para 6 of the DOHA Declaration on the TRIPS Agreement and Public Health (28 May 2003) at <http://www.wto.org>.

B. Patented drugs

18 The call by some developing countries for better access to affordable medicine is an important and pertinent issue in relation to some patented drugs. While the price demanded by the owner of the patent is undoubtedly a major component, it may well be misleading to conclude that some drugs are exorbitant by virtue only of the fact that they are patented. It should be borne in mind that it is difficult to establish meaningful criteria to determine absolute or objective affordability. It is often relative and varies directly with the degree of poverty. The final price of a patented drug payable by the consumer is a function of many variables that incorporate the selling price of the manufacturer, availability of substitutes or alternative treatment, distribution costs and profit mark-ups, economies of scale, regulatory and structural impediments, subsidies, taxes and other custom tariffs.

19 Moreover, the argument that "nations cannot simply free-ride on the research and development efforts of multinational pharmaceutical enterprises"[35] may be difficult to ignore. It is submitted that the options highlighted below may yield some relief to the tensions between these competing interests.

(1) Competition from generics

20 It has been noted that "pharmaceutical product prices fall sharply when generic entry occurs following the expiration of the patents".[36] Take, for example, the prices for anti-retroviral drugs (in 2001) where the "availability of cheaper generic ARVs from developing countries ... led to a reduction in prices from over US$10,000 per patient per year to less than US$350 per patient per year for a first-line combination therapy".[37] Today, prices of first generation ARVs have been reduced by more than 99% due to generic competition.[38] As such, developing countries that are not, or not yet, subject to the obligation of full implementation of the TRIPS Agreement may exploit the opportunity to take full advantage of generics to control costs.

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35 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

36 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

37 See C Perez-Cassas et al, "Accessing ARVs: untangling the web of price reductions for developing countries" Médecins Sans Frontières (2001) 3 quoted in *Promotion and protection of all human rights, civil, Political, economic, social and cultural rights* (Anand Grover) (A/HRC/11/12, 31 March 2009).

38 Médecins Sans Frontières, *Untangling the Web of ARV Price Reductions* (11th Ed, 2008) quoted in *Promotion and protection of all human rights, civil, Political, economic, social and cultural rights* (Anand Grover) (A/HRC/11/12, 31 March 2009).

Resources permitting, some developing countries could beef up their generic drug manufacturing capability[39] to manufacture and export lower-cost generic versions of patented drugs to countries that permit or encourage the import and use of generic substitutes. By its nature, this may not be a long-term solution for some but it remains extremely attractive.

21 Apart from patent issues, generics also face a number of other problems, including acceptance by health physicians and pharmacists that the drug is "therapeutically equivalent to those of the patent owner and the creation of incentives for physicians to prescribe, pharmacists to dispense and the consumer to search for lower priced brands".[40]

22 The use of generics to lower healthcare costs has also recently been debated in developed countries, including the US, for example, in generic biologics. Access to these generic biotech drugs is facing serious impediments, such as equivalence, efficacy, product safety and interchangeability. This is compounded by difficulties in defining and creating a "biosimilar" product which can be dependent on many complex variables including "whether differences in primary amino acid sequence, post-translational modifications, level of impurities, the mechanism of action, and the mode of administration are or can be accommodated".[41] The current debate in the US on regulatory pathways and data exclusivity for generic biologics, biosimilars and follow-on biologics highlights the "enormous economic and political pressures to reduce healthcare costs"[42] and provide access to affordable medicines even to patients in developed countries. Many biotech drugs cost "tens and thousands of dollars a year" and will impose "an unsustainable

39 It may be worth noting that the East Asian market is driven by generic pharmaceutical companies whose current strength lies in their dominance of local markets. A recent survey by Frost & Sullivan Asia Pacific into the generic pharmaceutical markets in Malaysia, Philippines, Singapore and Taiwan showed the following: The total generic pharmaceutical market in the four countries was estimated at more than $500m in 2001 and is expected to reach over $1bn by 2007. See Frost & Sullivan Asia Pacific, "The Asian Generic Pharmaceutical Market" (2002) at <http://pharmalicensing.com> (accessed 5 February 2009). See also Frost & Sullivan Asia Pacific, "The Generic Invasion – An Inside Scoop to the Pot of Gold" (2003) at <http://pharmalicensing.com> (accessed 5 February 2009).

40 Gorecki, "Regulating the Price of Prescription Drugs in Canada: Compulsory licensing, product selection, and Government reimbursement programmes" (1981) (Technical Report No 8, prepared for the Economic Council of Canada).

41 See K Noonan, "Uncertain Future for Waxman Follow-on Biologics Bill" (9 June 2009) at <http://www.patentdocs.org/2009/06/uncertain-future-for-waxman-follow on-biologics-bill.html> (accessed 15 June 2009).

42 See K Noonan, "Uncertain Future for Waxman Follow-on Biologics Bill" (9 June 2009) at <http://www.patentdocs.org/2009/06/uncertain-future-for-waxman-follow on-biologics-bill.html> (accessed 15 June 2009).

burden on patients, employers, and ... the governments"[43] in both the developed and developing world. This is particularly so in countries facing a rapidly aging population where "the burdens on all payors [*sic*] (public and private) can be expected to intensify".[44]

23 Finally, the invention and development of competing drugs and treatment for the same disease condition may be another option to constrain the "monopoly power of patented drugs".[45] It is, therefore, mainly in the new "break-through drugs that face little therapeutic competition in treating critical and widespread disease conditions"[46] that more serious pricing and access concerns arise.

COMPETITION FROM OTHER MEDICINES[47]

A survey found that of the 148 new drugs introduced into the United States market between 1978 and 1987, only 13 (or about 8%) had no close substitute in their therapeutic class.

(2) Parallel imports

24 Parallel imports in patented pharmaceutical products arise "for a variety of factors associated with price differences across markets: price discrimination by manufacturers, vertical price setting within distribution systems and differential systems of price controls".[48] Parallel

43 See K Noonan, "Uncertain Future for Waxman Follow-on Biologics Bill" (9 June 2009) quoting a letter from Congressman Waxman to President Obama at <http://www.patentdocs.org/2009/06/uncertain-future-for-waxman-followon-biologics-bill.html> (accessed 12 June 12009).

44 See K Noonan, "Uncertain Future for Waxman Follow-on Biologics Bill" (9 June 2009) at <http://www.patentdocs.org/2009/06/uncertain-future-for-waxman-follow on-biologics-bill.html> (accessed 15 June 2009).

45 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

46 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

47 Lu & Comanor, "Strategic Pricing of New Pharmaceuticals" (1998) Review of Economic and Statistics 80:108–118 quoted in Scherer & Watal, "Post-Trips Options for Access to Patented Medicines in Developing Countries" Commission on Macroeconomics and Health Working Paper Series, Paper No WG 4: 1, January 2001.

48 See Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* (Report presented to the WIPO under terms of Special Service Agreement, 2001) at p 41. For the potential benefits and costs of permitting parallel imports, see Maskus. See also Wilder, "Market Segmentation: Techniques, actors and incentives – the use of intellectual property rights" (Paper presented at the Workshop on differential pricing and financing of essential drugs, WHO and WTO Secretariats, Norway, 8–11 April 2001). See also CIPR, *Integrating*

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imports therefore affect the maintenance of differential pricing and regulation thereto. It has been referred to as a "form of arbitrage, tending to reduce differences in prices across diverse markets".[49]

25 The TRIPS Agreement leaves each WTO Member free to establish its own regime for the exhaustion of intellectual property rights, subject to the Most Favoured Nation and National Treatment provisions of Arts 3 and 4.[50] The freedom to apply the doctrine of exhaustion of rights to limit the rights conferred by patents has led to a wide variety of national policies on parallel import or "parallel trade". A country may implement a "national exhaustion" regime and prevent parallel imports, a "regional exhaustion" system to limit exhaustion within a "single economic market" or "international exhaustion" to legalise parallel imports.[51]

26 This is another area that developing countries may seek to explore in their search for access to affordable drugs. However, in order to encourage pharmaceutical companies to supply medicines at preferential prices, it is important to address their concerns that these may emerge in other markets through parallel exports. It has been noted that parallel export of "drugs sold at low prices in less-developed nations could undermine the willingness of the pharmaceutical manufacturers

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Intellectual Property Rights and Development Policy (2002) at p 41 at <http://www.iprcommission.org/> (accessed 5 February 2009).

49 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

50 See para 5(d) of the DOHA Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2) at <http://www.worldtradelaw.net/doha/tripshealth.pdf> (accessed 30 August 2008). See also Art 6 of the TRIPS Agreement that provides for exhaustion of rights as follows: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." For a discussion on compulsory licensing and parallel importation, particularly the softening of the US and EU thereto, see IIPI, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000) at <http://www.iipi.org> (accessed 5 February 2009) at pp 14–19.

51 The "exhaustion" doctrine is also sometimes known as the "first sale" doctrine, the exhaustion principle allows a Member State to limit application of a patent right once a product protected by the patent has been sold: see IIPI, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000) at <http://www.iipi.org> (accessed 5 February 2009) at p 30. For a detailed discussion on parallel imports in pharmaceuticals, see Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* (Report presented to the WIPO under terms of Special Service Agreement, 2001). See also Wilder, "Market Segmentation: Techniques, actors and incentives – the use of intellectual property rights" (Paper presented at the Workshop on differential pricing and financing of essential drugs, WHO and WTO Secretariats, Norway, 8–11 April 2001).

to sell at those low prices or even to supply low-income markets at all".[52] Thus, it may be necessary for developing countries to implement satisfactory control measures to prevent subsequent parallel exports of drugs imported at reduced prices.[53] In this context, it has been emphasised that:[54]

> [T]here is an important rationale for restricting parallel exports of medicines from low-income countries to high-income countries, though the former group could remain open to [parallel import]. This idea could be supplemented by regimes of regional exhaustion among poor countries in order to increase market size within which prices are integrated.

27 Measures to prevent parallel exports are also important in ensuring that pharmaceutical products that are manufactured under compulsory licensing are not utilised or re-exported beyond the purposes for which they were granted.

(3) Compulsory licensing

28 The use of compulsory licensing to enhance access to affordable patented drugs is controversial.[55] The threat of compulsory licensing was

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52 See Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

53 The EU Regulation of 26 May 2003 that aims to prevent pharmaceutical products sold to developing countries at reduced prices to be brought back into the European market underscores the need to insulate and track parallel imported drugs within regional blocs of developing countries and strictly enforce against their re-export from their borders. This provides an extra mechanism for protection, which applies irrespective of whether these medicines are IP-protected, in order to encourage companies to supply medicines at reduced prices. See Communications by the EC on the Implementation of the DOHA Declaration on the TRIPS Agreement and Public Health (IP/C/W/402, 2003). This is also echoed by the Royal Society that: "Access to such medicines is critical if society is to fight the major pandemics affecting the third world. Poverty is the critical issue but IPRs must not be used to prevent availability of medicines at low prices. A corollary is that developed and developing countries should cooperate in ensuring legal and practical measures to prevent resale in developed countries of low-priced medicine destined for developing countries." See the Royal Society, *Keeping Science Open: the effects of intellectual property policy on the conduct of science* (2003) at p 15.

54 See Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* (Report presented to the WIPO under terms of Special Service Agreement, 2001) at p 3. This was echoed by Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

55 Take, for example, the fundamental problems that South Africa, Brazil and Thailand now face over the patent system, namely, the problem of the multilateral trading system securing monopoly rights over, among other things, life saving knowledge and technology; see Bank, "Differential Pricing and Politics of Health Development" (2001) at <http://www.twnside.org.sg/title/politics.htm> (accessed 6 February 2009). See IIPI, *Patent Protection and Access to HIV/AIDS*

(*cont'd on the next page*)

successfully used by Brazil in the pursuit of its National STD/AIDS programme in negotiations with pharmaceutical companies.[56] It has also garnered much worldwide attention in recent years. Take, for example, Thailand's use of compulsory licensing in relation to anti-retroviral drugs for HIV/AIDS, cancer and heart disease.[57] This has precipitated similar calls from other developing countries, such as India and the Philippines, for urgent need to lower the cost of medicines and make them more affordable to the sufferers.[58]

29 Compulsory licensing has been said to "introduce the dynamic effects of competition that can pressure prices lower over time".[59] Indeed, the CIPR has opined that they "do not regard compulsory licensing as a panacea, but rather as an essential insurance policy to prevent abuses of the IP system".[60] This has been echoed by the call for Governments, as:[61]

> [C]ustodian of the public interest, [to] closely monitor the activities of patent owners and be prepared to intervene actively with counter-measures where necessary. Compulsory licensing and ... competition laws are the obvious tools ... Governments [should] further facilitate compulsory licensing and application of competition law in situation where single or multiple patents, do on balance, unreasonably affect use and development of inventions.

30 However, the TRIPS Agreement has narrowed the circumstances under which compulsory licensing may be deployed to remedy anti-competitive and other practices.[62] One of the restrictions under Art 31(f) is that the use must be "predominantly for the supply of the

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Pharmaceuticals in Sub-Saharan Africa (2000) at <http://www.iipi.org> (accessed 5 February 2009). See also Rozek, "The Effects of Compulsory Licensing on Innovation and Access to Health care" (2000) 3 Journal of World Intellectual Property 889.

56 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 42 at <http://www.iprcommission.org/> (accessed 5 February 2009).

57 See, for example, Sinfah Tunsarawuth, "Thailand: 20 More Drugs in Pipeline for Possible Compulsory Licences" (2 November 2007) Intellectual Property Watch at <www.ip-watch.org/> (accessed 11 February 2009).

58 See, for example, Tatum Anderson, *India Cancer Patients Seek to Use Courts for Access to Patented Drugs* (3 April 2003) Intellectual Property Watch at <www.ip-watch.org/> (accessed 11 February 2009); Peter Ollier, "Philippines Plans to Follow India in Limiting Patentability" *Managing Intellectual Property Weekly News* (Hong Kong) (6 May 2008).

59 See Statement of Information made by the Consumer Project of Technology ("CPTech") at the Competition Commission of South Africa.

60 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at <http://www.iprcommission.org/> (accessed 5 February 2009).

61 See Royal Society, *Keeping Science Open: the effects of intellectual property policy on the conduct of science* (2003) at p 10.

62 See Art 31 of the TRIPS Agreement and note also Art 40 relating to Control of Anti-Competitive Practices in Contractual Licences.

domestic market" of the authorising State. While this condition may be waived, where the compulsory licence is granted to remedy anti-competitive practices,[63] its effect in curtailing the export of drugs manufactured under such licences will greatly impact on some developing countries that rely on such imports. These are countries that are unable to make effective use of the compulsory licensing option available to them due to the lack of infrastructure and technological capability to "reverse engineer" and manufacture the drugs themselves.

31 This concern was clearly noted in the Doha Declaration (para 6) as follows:[64]

> We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement ...

32 The resulting 2003 temporary waiver of Art 31(f)[65] of the TRIPS Agreement was intended to pave the way for allowing WTO Members to export drugs made under compulsory licensing to countries without domestic manufacturing capabilities. In 2005, WTO Members agreed on the first ever amendment to the TRIPS Agreement which will make the temporary waiver permanent. This development has been hailed as a tremendous breakthrough that will make it easier for developing and least developed countries to import cheaper drugs made under compulsory licensing.

33 Whilst it clearly went some way towards plugging the lacuna in the TRIPS Agreement, it may not be the "miracle solution" that some had thought it would be. Indeed, both developing and developed countries appear to be slow in implementing the process. This may be due to several reasons, including the complexity of the procedural requirements for implementing the waiver which may make the process difficult to exploit; the need for special packaging, labelling and marking of these drugs which may erode the cost-effectiveness and efficiency of the system; uncertainty relating to issues, such as the countries that are eligible to utilise the system; and effective measures to prevent parallel

63 See Art 31(f) of the TRIPS Agreement.

64 See para 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2) at <http://www.worldtradelaw.net/doha/tripshealth.pdf> (accessed 25 July 2008).

65 See WTO Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003). See also Matthews, "From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries" (2006) 2 IPQ 91; Mercurio, "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines" 5 Northwestern University Journal of International Human Rights 1.

export, adequacy of remuneration, *etc.* To date, only Canada and Rwanda have notified the TRIPS Council regarding the utilisation of this procedure. It remains to be seen whether these waivers will be effective in ensuring that countries with insufficient or no pharmaceutical manufacturing capacities can participate fully in a compulsory licensing scheme of which they were clearly intended beneficiaries. This article will not deal further with these issues which have been comprehensively discussed elsewhere.[66]

34 In utilising any compulsory licensing scheme, it is important to seek an appropriate balance between the public interest and the legitimate private interests of patent holders. Whilst the Doha Declaration clearly recognises that public health issues can override private property interests of patent holders and reinforces the right given to each WTO Member State to "grant compulsory licences and the freedom to determine the grounds upon which such licences are granted",[67] there are still outstanding issues that need to be addressed. These include the appropriate remuneration[68] and body for making the determination. It is beyond the scope of this article to propose a detailed guideline for implementing an appropriately balanced compulsory licensing scheme. Several established royalty guidelines may be considered, such as those discussed in the United Nations Development Programme ("UNDP") Human Development Report 2001, JPO 1998, Canadian proposed royalty guidelines 2004 and the Tiered royalty method. These have already been discussed elsewhere[69] and will not be reiterated here. However, it is submitted that adequacy of remuneration should not be based solely on the affordability of the general patient population and the final arbiter on this issue should not lie with the government body that granted the compulsory licence.

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66 See, for example, Andrew Mitchell and Tania Voon, "The TRIPS Waiver as a Recognition of Public Health Concerns in the WTO" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010); Noah Novogradsky, "Beyond TRIPS: The Role of Non-state Actors and Access to Essential Medicines" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010) and Alvin Sim Kia Hong, "Anti-Diversion Measures Under the Trips Protocol on Public Health – A Commentary" [(2008) 20 SAcLJ 217.

67 See Doha Declaration on the TRIPS Agreement and Public Health at para 5. See CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at pp 44–51 at <http://www.iprcommission.org/> (accessed 5 February 2009).

68 See, for example, concerns expressed that such a scheme may "weaken existing marketplace protections" and be used as a "means to access protected technologies without fairly compensating the rights holder". *Per* Caroline Joiner, "Big IDEA: IP Rights key for job creation" (18 May 2009) at <http://www.chamberpost.com/2009/05/big-idea-ip-rights-key-for-job-creation.html> (accessed 27 May 2009).

69 See James Love, "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D" (2007) 40 University California, Davis 679.

35 This author proposes that in determining the adequacy of remuneration for drugs manufactured under compulsory licensing, a "Quota system" based on a percentage of global turn-over may be explored. Such a scheme could be based, for example, on a "progressive computation" of entitlement under a tiered system. Take, for example, Tier 1 (free drug supply based on corporate social responsibility or charity), Tier 2 (0% royalty), Tier 3 (+x% royalty), *etc*. The availability of the tier for WTO Member States could be based on factors such as relative *per capita* income relative to other claimants. Under such a scheme, co-payment by government subsidy *etc* may be needed based, for example, on a means testing of the patients. An independent body will need to be established to monitor and ensure an equitable balancing of the needs of various competing interests. This would unfortunately require considerable funding and diversion of precious resources, which some may argue should be better spent in subsidising the cost of drugs.

36 Be that as it may, as the costs of drugs continue to escalate, particularly for those without cheaper equivalents, patients worldwide (from both developing and developed countries) will be compelled to pay "hundreds and even thousands of dollars for prescription medications ... or do without".[70] It is difficult to ignore the increasing pressure that is being exerted on insurance schemes, States and citizens to "meet ever rising bills for patented drugs".[71] This will be exacerbated by an aging population and the emergence of new diseases which will have a profound impact on the social and economic systems of the world. It is, therefore, submitted that a compulsory licensing scheme that is properly calibrated and utilised within appropriate parameters can play an important role in ensuring an effective balance between the public interest and the legitimate private interest of patent holders.

37 While the threat of compulsory licensing may be a weapon that can "enhance [a nation's] bargaining power",[72] it is certainly far from a "magic wand" for obtaining affordable access to patented medicines in developing countries.[73] In fact, it is noted that "in practice, however,

70 See, for example, Gina Kolata, "'Co-Payments Go Way up for Drugs with High Prices" *The New York Times* (14 April 2008).

71 CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 29 at <http://www.iprcommission.org/> (accessed 5 February 2009).

72 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913. Take, for example, Thailand's experience where it has been said that: "Before we announced compulsory licensing, the companies always said the price they offered us was already a 'no-profit' price. But after our enforcement, they cut their price further." See statement of Sorachai quoted in Sinfah Tunsarawuth, "Thailand: 20 More Drugs in Pipeline for Possible Compulsory Licences" (2 November 2007) Intellectual Property Watch at <www.ip-watch.org/> (accessed 11 February 2009).

73 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913. Note

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compulsory licensing is rarely imposed".[74] However, its impact in facilitating negotiations between the parties merits further studies. The Nuffield Council acknowledges that:[75]

> Opposition to compulsory licensing is particularly strong in the pharmaceutical industry at a time when the costs of research and development are rising and the rate of production of new medicines is falling. Moreover, there is a view more generally that once compulsory licensing is deployed in one sector, the principle will be more readily applied elsewhere. We recognise the dilemma: in the case of medicines generally, there are those that are too expensive to be made available for all of the patients who need them; but the widespread imposition of compulsory licensing could seriously erode the capacity for research and development of the pharmaceutical industry. A careful balance would, therefore, need to be struck so that compulsory licensing is only invoked in those cases in which the existence of a monopoly is creating an unacceptable and unfair situation. The guiding principle here would be that the protection which was granted by the patent system should be commensurate with the contribution made by the inventor. In fact, extensive application of compulsory licensing ... may not be required, as experience has shown that the mere threat of compulsory licensing has been sufficient to encourage industry to devise other solutions.[76] [footnote added]

38 The Nuffield Council concludes it observations by rejecting a "wholesale and indiscriminate use of compulsory licensing".[77] Instead, it supports the further exploration of an Organization for Economic Co-operation and Development ("OECD") suggestion to create a "clearing house" to reduce transactions and obstacles to commercial laboratories seeking licences for "genetic inventions".[78] Pursuing other options, such as charity, has been said to be the "only alternative to

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also the view expressed by the IIPI that "it is not at all clear whether the attempts to abrogate patent protection through compulsory licensing and parallel importation will ultimately result in better access to medicines and healthcare.": see IIPI, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000) at <http://www.iipi.org> (accessed 5 February 2009) at p 20.

74 See Nuffield Council on Bioethics, *The ethics of patenting DNA* (2002) at pp 54–55.

75 Nuffield Council on Bioethics, *The ethics of patenting DNA* (2002) at p 55.

76 Other solutions may include the use of differential pricing of anti-retroviral medicines for the treatment of HIV/AIDS in several developing countries.

77 Further arguments against the use of compulsory licensing include the potential costs and complexity accompanied by a detrimental decrease in the incentive to invalidate or revoke patents as it would be easier to obtain a licence than to dispute the patent.

78 See Organization for Economic Co-operation and Development ("OECD"), "Short Summary Report of the Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices" (Berlin, 24–25 January 2002) at <www.oecd.org/> (accessed 9 February 2009).

death or debility".[79] In this regard, it may be useful for some nations or patent owners to consider granting "voluntary or consensual" licences in appropriate circumstances in the spirit of good corporate social responsibility ("CSR").[80]

(4) Consensual licensing: good corporate citizenship

39 The pharmaceutical and biotechnology industries are major multi-billion dollar conglomerates of international players whose products profoundly affect public health and safety in both the developed and developing world. The licensing of the production and exploitation of drugs by the pharmaceutical industry solely for the promotion and safeguard of public health in appropriate circumstances other than under compulsion of law and single-minded pursuit of profits may ameliorate the lack of access to affordable medicine in some developing countries. This adoption of some degree of voluntary self-regulation will not only constitute another milestone by the stakeholders of patents that will ease some of the tensions that inevitably arise between them and the society at large, but will also greatly enhance their public standing.

40 Today, multinational corporations disregard their social roles in the community at their own peril. It is no longer possible to operate a business globally while remaining totally aloof to social issues around it. CSR has gained increasing prominence and importance as can be seen in its exponential growth in the last decade with more companies than ever engaged in serious efforts to define and integrate CSR into all aspects of their businesses.[81] The idea that business has obligations to society that go beyond, and yet are not inconsistent with, profit and shareholder value is gaining increasing appeal among global corporations. Measured by profit alone, some of the developing countries form such small markets that they have only a small effect on the profit margin of the pharmaceutical industry and so have little or no impact on the industries' research and development, manufacturing and marketing policies.

79 Scherer & Watal, "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" (2002) 5 Journal of International Economic Law 913.

80 CSR has been defined by the World Business Council for Sustainable Development ("WBCSD") as "the continuing commitment by business to behave ethically and contribute to economic development while improving the quality of life of the workforce and their families, as well as the local community and society at large". See World Business Council for Sustainable Development, *Corporate Social Responsibility: Making Good Business Sense* (January 2000).

81 See "Corporate Responsibility News" Global Ethics Monitor at <http://www.globalethicsmonitor.com> (accessed 9 February 2009).

41 The adoption of good CSR may be an ideal response to the growing calls by leading institutional investors for pharmaceutical companies to take a more proactive stance towards the public health crisis, "whether from a reputation, market development or corporate citizenship perspective".[82] Indeed, a group of Europe's largest institutional investors[83] has put forward a "Statement of good practice" calling on companies – including AstraZeneca plc, GlaxoSmithKline plc and Novartis AG to:

> (a) establish "sustainable, differential pricing for relevant product ranges in relation to the disease burden"[84] based on capacity to pay in the various markets,
>
> (b) enforce patents "with sensitivity to local circumstances"[85] (*eg* "not enforcing patents" in the poorest countries, such as "LDC countries")[86] and
>
> (c) take measures "to protect and ... segment markets"[87] to prevent "re-importation" or diversion of "differentially priced products"[88] back to the developed world.
>
> [footnotes added]

42 The International Federation of Pharmaceutical Manufacturers Associations ("IFPMA") has highlighted the significant contributions of the pharmaceutical industry's programmes towards the improvement of public health in many countries, particularly developing countries.[89]

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82 See "Investor statement and framework on pharmaceutical companies and the public health crisis in emerging markets" issued by the Pharmaceutical Shareowners Group ("PSG") in March 2003 at p 2 at <http://www.ethosfund.ch/pdf/InvestInitiative_PSG_Framework_Final_EN.pdf> (accessed 18 May 2009) also quoted in the UK Department for International Development ("DFID"), "Increasing people's access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry" (March 2005) at <http://www2.dfid.gov.uk/pubs/files/pharm-framework.pdf> (accessed 18 May 2009).

83 Representing £600bn (US$940bn) in assets. They include Henderson Global Investors, ISIS Asset Management, Morley Fund Management and Schroder Investment Management.

84 See PSG March 2003 at p 3 at <http://www.ethosfund.ch/pdf/InvestInitiative_PSG_Framework_Final_EN.pdf> (accessed 18 May 2009).

85 See PSG March 2003 at p 3 at <http://www.ethosfund.ch/pdf/InvestInitiative_PSG_Framework_Final_EN.pdf> (accessed 18 May 2009).

86 See PSG March 2003 at p 3 at <http://www.ethosfund.ch/pdf/InvestInitiative_PSG_Framework_Final_EN.pdf> (accessed 18 May 2009).

87 See PSG March 2003 at p 3 at <http://www.ethosfund.ch/pdf/InvestInitiative_PSG_Framework_Final_EN.pdf> (accessed 18 May 2009).

88 See PSG March 2003 at p 3 at <http://www.ethosfund.ch/pdf/InvestInitiative_PSG_Framework_Final_EN.pdf> (accessed 18 May 2009).

89 The International Federation of Pharmaceutical Manufacturers Associations ("IFPMA") has noted that from 1998 to 2002, the ten largest pharmaceutical companies contributed US$2.2bn for health-related programmes in the least developed countries, see Director-General of IFPMA's statement on the

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However, recent anti-competitive conduct by some pharmaceutical companies has been regarded by some as examples of "bad corporate citizenship". Yet, does labelling yield result? It remains an "open" question as to what constitutes "bad" conduct in a voluntary scheme. Where there are violations of the law, legal avenues of redress already exist.[90]

43 Moving forward, the industry would have to develop a framework to strike a delicate balance between the preservation of the stakeholders' immediate economic interest through strict enforcement of patent rights and the provision of access to affordable life-saving drugs for the poor. That balance may be expressed in the form of consensual licensing, the actual form of which is a matter that requires further consideration.

(5) Limiting patentability

44 Finally, developing countries may also utilise the flexibilities within the TRIPS Agreement to limit the patentability of inventions that may impact on public health. These may include a more rigorous application of the patentability criteria (*eg*, novelty, inventive step, industrial application or utility); tools for challenging patent validity; permissible specific exclusions, such as those relating to methods of medical treatment, namely, diagnostic, therapeutic and surgical methods for the treatment of humans or animals;[91] and general limited exceptions provided that "such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".[92] However, regard should be given to the basic requirement that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".[93] The difficulty in balancing these various competing interests has generated controversy in recent years where some developing countries have sought to limit the patentability of new

pharmaceutical industry and corporate social responsibility at <http://www.responsiblepractice.com/english/insight/ifpma/> (accessed 18 May 2009). See also the Tamiflu Reserves program at <http://www.bloomberg.com/apps/news?pid=20601203&sid=aaDCDmzyrBWE> (accessed 8 July 2009).

90 See, for example, Abbott Laboratories at <http://www.ago.state.co.us/press_detail.cfmpressID=13.html> (accessed 8 July 2009). However, is there such a concept as "bad Samaritan"?

91 TRIPS Agreement, see Art 27.3.

92 TRIPS Agreement, Art 30.

93 TRIPS Agreement, Art 27.1.

forms or derivatives of known substances[94] to address concerns, including the "ever-greening" of patents.

45 While it is submitted that the patent regime can rise to the challenge of improving the accessibility of some medicines and treatment, particularly to the poor, and possibly differential pricing for costly treatments that often accompany new medical breakthroughs,[95] there is also an urgent need to consider corresponding enhancements in incentivising research and development in "third world/neglected" diseases.

IV. Incentives for research and development: "third world/neglected" diseases

46 Some may argue that a stronger patent regime may provide the incentive[96] for pharmaceutical firms to discover new treatments for some "third world" diseases.[97] However, the public health crisis has focused international attention on its lack of ability to generate research and development into diseases where patients lack the financial ability to pay the price necessary to allow private sector recovery of research

94 See s 3(d) of the Indian Patents Act. See also the Universally Accessible Cheaper and Quality Medicines Act of the Philippines (discussed in Peter Ollier, "Philippines Plans to Follow India in Limiting Patentability" *Managing Intellectual Property Weekly News* (Hong Kong) (6 May 2008)).

95 See also the World Bank, "Intellectual Property: Balancing incentives with competitive access" (2001) 128 at <http://siteresources.worldbank.org/INTGEP 2002/Resources/gep2002complete.pdf> (accessed 23 April 2009) at pp 129–150.

96 This has been noted by the World Bank to be "marginal", see the World Bank, "Intellectual Property: Balancing incentives with competitive access" (2001) 128 at <http://siteresources.worldbank.org/INTGEP2002/Resources/gep2002complete.pdf> (accessed 23 April 2009).

97 Such as Type III diseases. Type III diseases (*eg*, Chagas disease, dengue and dengue haemorrhagic fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis and human African trypanosomiasis) are overwhelmingly or exclusively incident in developing countries. Compared with Type II diseases (*eg*, HIV/AIDS and TB) which are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries; and Type I diseases (*eg*, diabetes, cardiovascular disease and cancer) which are incident in both rich and poor countries, with large numbers of vulnerable populations in each. See definition by the WHO in the "Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property" WIPO Doc A/PHI/IGWG/ 2/INF.DOC./6 (31 August 2007) (Intergovernmental Working Group on Public Health, Innovation and Intellectual Property – Provisional Agenda Item 3). See also Katharine Young, "Securing Health Through Rights" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010) where the author discusses issues relating to the "right to health" and the political economy of health financing and delivery.

and development costs.[98] Indeed, the "reality is that private companies will devote resources to areas where an optimal return can be made".[99]

47 The dearth of investments into this much-needed area of research and development has generated international concerns which have prompted, *inter alia*, the involvement of the World Health Organization ("WHO") in discussions relating to intellectual property. Some have argued that these issues may more appropriately be within the domain of the WTO and WIPO.[100] Be that as it may, it is worth noting that the WHO has embarked on a global strategy and plan of action on public health, innovation and intellectual property, which is focused on the public health needs of developing countries. These include questions relating to "appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries".[101] The WHO initiative seeks to examine whether the international patent system is providing adequate incentives for private sector investment into research and development into "Third world/neglected" diseases.[102]

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98 See, for example, WHO, "Draft Global Strategy and plan of action on public health, innovation and intellectual property" WIPO Doc A/PHI/IGWG/2/INF. DOC./6 (31 August 2007) (Intergovernmental Working Group on Public Health, Innovation and Intellectual Property – Provisional Agenda Item 3); Margaret Chan, "Opening Remarks at the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property" (Geneva, 28 April 2008).

99 See CIPR, *Integrating Intellectual Property Rights and Development Policy* (2002) at p 33 at <http://www.iprcommission.org/> (accessed 5 February 2009). See also Banda, "The Transactional Role of Patents: The Case of Product Development Partnerships" (Paper presented at the Global Governance of HIV/ AIDS: Intellectual Property and Access to Essential Medicines Conference, University of Liverpool, UK, 8 October 2008) where the author argued that in relation to diseases of the developing world, patents do not operate primarily as incentives due to the lack of the availability of lucrative markets; Palombi, "Encouraging R & D doesn't have to mean more patents" (Paper presented at the CIPL Symposium, ANU, Canberra, 26 May 2008) where the author argues for a new IP paradigms that will create incentives for pharmaceutical research and development and access to medicines for all.

100 See Kaitlin Mara & William New, "WHO Members Inch Toward Consensus on IP, Innovation and Public Health" (2 May 2008) Intellectual Property Watch at <http://www.ip-watch.org/weblog/index.php?p=1024> (accessed 10 February 2009).

101 WHO, "Draft Global Strategy and plan of action on public health, innovation and intellectual property" WIPO Doc A/PHI/IGWG/2/INF.DOC./6 (31 August 2007) (Intergovernmental Working Group on Public Health, Innovation and Intellectual Property – Provisional Agenda Item 3).

102 See WHO, "Draft Global Strategy and plan of action on public health, innovation and intellectual property" WIPO Doc A/PHI/IGWG/2/INF.DOC./6 (31 August 2007) (Intergovernmental Working Group on Public Health, Innovation and Intellectual Property – Provisional Agenda Item 3) and Margaret Chan, "Opening Remarks at the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property" (Geneva, 28 April 2008). See also Kaitlin Mara & William New, "WHO Members Inch Toward Consensus on IP, Innovation and Public Health" (2 May 2008) Intellectual Property Watch at <http://www.ip-watch.

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The draft global strategy and action plan has been hailed by the WHO Director General Margaret Chan as:[103]

> ... a unique opportunity for public health. An agreed framework can make the cycle of product discovery, development and delivery more efficient and more sensitive to health needs in the developing world ... [T]he international community will have a common tool, and an agreed way to tackle some of the most pressing problems in public health ... forging ways to tackle the gaps in access to health care and, in so doing, to reduce the gaps in health outcomes ... making the benefits of advances in medicine and science more inclusive.

48 The usage of prizes as a possible incentive for research and development was debated at the recently concluded WHO negotiations.[104] Other proposals that have been mooted elsewhere such as innovation prizes and grants,[105] Private and Public Partnerships ("PPPs") scheme (*eg*, Bill and Melinda Gates Foundation sponsored projects),[106] advance market commitments ("AMCs"),[107] patent buy-out,

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org/weblog/index.php?p=1024> (accessed 10 February 2009) and Kaitlin Mara & William New, "WHO IP and Health Group concludes with Progress; Tough Issues Remain for Assembly" (6 May 2008) Intellectual Property Watch at <www.ip-watch.org/> (accessed 10 February 2009).

103 See Margaret Chan, "Opening Remarks at the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property" (Geneva, 28 April 2008).

104 See Kaitlin Mara & William New, "WHO IP and Health Group concludes with Progress; Tough Issues Remain for Assembly" (6 May 2008) Intellectual Property Watch at <www.ip-watch.org/> (accessed 10 February 2009).

105 *Prizes to Stimulate Innovation*, Knowledge, Ecology International ("KEI") at <http://www.keionline.org/index.php?option=com_content&task=view&id=4&Itemid=1> (accessed 10 February 2009). See also WHO, "Draft Global Strategy and plan of action on public health, innovation and intellectual property" WIPO Doc A/PHI/IGWG/2/INF.DOC./6 (31 August 2007) (Intergovernmental Working Group on Public Health, Innovation and Intellectual Property – Provisional Agenda Item 3), Art 5(3)(a). Aidan Hollis, *Prize, Advanced Market Commitments and Pharmaceuticals for Developing Countries* (2007) at <http://www.iprsonline.org/ictsd/Dialogues/2007-10-22/7%20ThinkPiece_Hollis.pdf> (accessed 10 February 2009). See also Matthew Rimmer, "The Lazarus Effect: The (RED) Campaign and Creative Capitalism" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010). Prizes have also been used to stimulate innovation in other areas, such as in the field of water, see, for example, the Lee Kuan Yew Water Prize.

106 See, for example, WHO, "Draft Global Strategy and plan of action on public health, innovation and intellectual property" WIPO Doc A/PHI/IGWG/2/INF. DOC./6 (31 August 2007) (Intergovernmental Working Group on Public Health, Innovation and Intellectual Property – Provisional Agenda Item 3), Art 7(2); and Mercurio, "Resolving the Public Health Crisis in the Developing World: Problems and Barriers of Access to Essential Medicines" 5 Northwestern University Journal of International Human Rights 1.

107 Note the report in Intellectual Property Watch that the WHO IGWG negotiations that were concluded in May 2008 have apparently removed advance market commitments; see Kaitlin Mara & William New, "WHO Members Inch Toward Consensus on IP, Innovation and Public Health" (2 May 2008) Intellectual

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open sourcing,[108] patent pools,[109] health impact fund,[110] stronger domestic initiatives, and financial or fiscal incentives to encourage more effective participation by the pharmaceutical industry should also be considered to ameliorate this problem. In this context, some pharmaceutical companies have started to focus on "diseases of the developing world"[111] through the setting up of "dedicated groups" within their "R&D organization"[112] or research institutes. Take, for example, the Novartis Institute for Tropical Diseases ("NITD") which was established in Singapore to develop medicines for some third world diseases.[113]

Property Watch at <http://www.ip-watch.org/weblog/index.php?p=1024> (accessed 10 February 2009) and Kaitlin Mara & William New, "WHO IP and Health Group concludes with Progress; Tough Issues Remain for Assembly" (6 May 2008) Intellectual Property Watch at <www.ip-watch.org/> (accessed 10 February 2009). See also Owen Barder, Michael Kremer & Heidi Williams, "Advance Market Commitments: A Policy to Stimulate Investment in Vaccines for Neglected Diseases" (2006) Economists' Voice at <http://www.bepress.com/ev> (accessed 10 February 2009); Aidan Hollis, *Prize, Advanced Market Commitments and Pharmaceuticals for Developing Countries* (2007) at <http://www.iprsonline.org/ictsd/Dialogues/2007-10-22/7%20ThinkPiece_Hollis.pdf> (accessed 10 February 2009).

108 See Matthew Rimmer, "The Lazarus Effect: The (RED) Campaign and Creative Capitalism" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010); Krishna Ravi Srinivas, "Open Source Drug Discovery: A Revolutionary Paradigm or a Utopian Model?" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010).

109 See, for example, Dianne Nicol & Jane Nielsen, "Opening the Dam: Patent Pools, Innovation, and Access to Essential Medicines" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010).

110 This initiative propounded by Thomas Pogge of the Centre for Applied Philosophy and Public Ethics ("CAPPE") is an option for pharmaceutical innovators to forgo patent exclusivity worldwide in exchange for a treaty-backed payment stream proportioned to the actual global health impact of the inventions. See Thomas Pogge, "The Health Impact Fund: Boosting Innovation without Obstructing Free Access" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010) See also Kathy Liddell, "The Health Impact Fund: A Critique" in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Thomas Pogge, Matthew Rimmer and Kim Rubenstein eds) (forthcoming 2010), for a critical analysis of the Pogge/CAPPE initiative.

111 See, GSK Corporate Responsibility Report 2005 at <http://www.gsk.com/responsibility/cr_report_2005/access-to-medicines/dc-research-development.htm> (accessed 26 May 2009).

112 See GSK Corporate Responsibility Report 2005 at <http://www.gsk.com/responsibility/cr_report_2005/access-to-medicines/dc-research-development.htm> (accessed 26 May 2009).

113 See Novartis Institute for Tropical Diseases ("NITD") which was established in Singapore in 2003 at <http://www.corporatecitizenship.novartis.com/patients/access-medicines/nitd.shtml> (accessed 26 May 2009). The Institute develops

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V. Conclusion

49 The public health issue involves a complex milieu of competing legal, political, economic and social interests. These will be compounded by the emergence of new pharmaceutical innovations, such as biopharmaceuticals and biologics, which will further strain the patent, regulatory and healthcare systems of both developed and developing countries. Whilst it is important to avoid abuse by both patent owners and users (*eg*, through exorbitant pricing and free-riding respectively), it is also essential to encourage good governance, accountability, as well as reciprocity (*eg*, through participation in clinical trials, sharing of disease information, *etc*). The WHO's Member States' (particularly Indonesia) sharing of human and animal specimens from avian influenza A ("H5N1")[114] is a timely example. A review of the entire matrix of developments to ensure coherence with existing schemes, such as parallel imports, differential pricing, generics, compulsory licensing, drug donation, government and international aid, and corporate social responsibility, merits further studies.

50 There is an urgent need to reconcile and effectively manage the competing policy interests to facilitate better access to drugs in certain circumstances. In searching for meaningful solutions to alleviate the suffering generated by the global health crisis, the scope of access to affordable medicine and medical treatment should be broadened to include preventive and defensive medicine and treatment, as well as better dissemination and sharing of new medical knowledge. We should accelerate defensive treatment issues to generate a more defensive disease management scheme. A good example is the case of small-pox where access to vaccination globally, coupled with international resolve and efforts, led to the eradication of the disease. In recent years, there has also been increasing usage of emotive labels, such as "charity", to appeal to sympathy and "lifestyle medicine" to connote luxury to which the poor should not be entitled. The use of these labels does not advance any cause and obscures the serious issues that need to be addressed and effectively managed. This article has proceeded on the basis of an urgent need to resolve some of the tensions and imbalances which have garnered much worldwide attention in the field of public health. There

medicines for third world diseases, such as dengue fever, malaria and tuberculosis, which will be "made available without profit to poor patients in those countries where they are most needed."

114 See, for example, WHO's Member States' (particularly Indonesia) sharing of human and animal specimens from avian influenza A (H5N1) between 2003 and 2007 at <http://www.who.int/csr/disease/avian_influenza/TrackingHistoryH5N1_20080131.pdf> (accessed 12 May 2009). See also WHO Director-General's report on Pandemic Influenza Preparedness: "Sharing of influenza viruses and access to vaccines and other benefits" at <http://apps.who.int/gb/pip/pdf_files/PIP_IGM_13-en.pdf> (accessed 27 May 2009).

are many other challenging issues and solutions beyond those highlighted here.

51 Moving forward, further dialogues and research will be fruitful in prioritising key common concerns aimed at enhancing access to affordable medicine for some and health for all. It is important, therefore, that the patent system strikes an effective balance between the public interest and the legitimate private interest of patent holders, and averts the perception of prioritisation of private rights over public welfare. Unless these are satisfactorily addressed and articulated, tensions and imbalances are likely to be exacerbated. Faced with these grave international concerns, it is vital that the international patent system adapts and evolves to meet the public health challenge by holding to its core principles that have the "public interest at their center".[115]

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115 See WIPO Patent Agenda (A/36/14); WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6).