Intellectual Property or Intellectual Poverty? Between Colonialism and Empire in the Context of AIDS and Public Health Crises

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> He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me.

> > -Thomas Jefferson

I do not myself think that anything should be patented by either physician or pharmacist.

-Dr Edward Robinson Squibb, founder of Squibb Corporation, a precursor to pharmaceutical giant Bristol-Meyers Squibb.¹

• Introduction

The incorporation of the global intellectual property (IP) agenda into the free trade forum of the World Trade Organization through the TRIPS (Trade-Related Intellectual Property Rights) agreement has raised a number of important ethical issues regarding the AIDS pandemic and the global enforcement of pharmaceutical patents on essential medicines, many of which are held by multinational pharmaceutical corporations (Big Pharma) in the industrialized world.² This move from the more political and democratic forum of WIPO (World Intellectual Property Organization) to the more norm-generating and industrialized-country dominated

¹ Cited by Judge Finkelstein of the Australian Federal Court in *Bristol-Myers Squibb v. FH Faulding* (1998) 41 IPR 467, who for his part stated in the judgment: "The important question: 'is it ethical to patent a pharmaceutical substance or a method of medical treatment?' admits of no satisfactory answer."

² The terms 'industrialized world' and 'industrialized countries' as used in this paper are synonymous with 'developed countries' denoting primarily the USA, Switzerland, Japan, Canada, Australia and other MEDCs (more economically developed countries) with a strong pharmaceutical industry and lobby.

WTO is symptomatic of a general tendency by the industrialized world to depoliticize trade related issues and impose on the developing world (and on those less fortunate in the industrialized world itself) norms that serve its own immediate economic interests and goals. As Stiglitz notes, the Uruguay round of negotiations from which TRIPS resulted "overwhelmingly reflected the interests and perspectives of the producers, as opposed to the users, whether in developed or developing countries." The Doha declaration on the TRIPS Agreement and Public Health adopted at the WTO ministerial conference in 2001 resulted from an effort by developing states to reaffirm their right to circumvent patents in order to gain access to essential medicines by issuing compulsory licences to generic manufacturers – permitted by TRIPS but actively discouraged by industrialized countries through economic and political pressure and even re-negotiation of agreements. This latter behaviour of the industrialized world and pharmaceutical companies has had a definite impact: according to one World Health Organization (WHO) spokesperson, the complexity of the 2003 WTO agreement has resulted in "no country [having] issued a demand for a compulsory license [to manufacture generic drugs] as authorised in the agreement". 4 Meanwhile, according to UNAIDS and WHO 25.4 million people in Sub-Saharan Africa were living with AIDS in 2005, just over 70 percent of those afflicted globally, and 2.3 million died of the disease in 2001 alone.⁵

The position of the industrialized world reflects a considerable amount of hypocrisy in relation to both its own historical origins and some contemporary practice when it has found itself 'in the shoes' of the developing world, whether faced with public health crises or at earlier phases of development. Realizing that any arguments in favour of patent protection based on 'natural rights' are untenable in the context of the AIDS pandemic or any similar health crisis⁶, the pro-patent camp has turned instead to justifying exorbitantly high drug prices and stringent patent protection using utilitarian rationales that boil down to one simple message: without patent protection, important research and development (R&D) would simply not get done.⁷ As will be shown, many of the specific arguments advanced in this vein – i.e. in relation to the costs of R&D as opposed to marketing – misconstrue the very facts

³ Stiglitz, p 8.

⁴ Andreasson, p 16.

⁵ Whiteside et al, p 15.

⁶ Sterckx (2004).

⁷ Kettler; Resnik (2005); both cited below.

they rely upon, or exhibit a wilful ignorance of the obvious. But more importantly, they rest on one highly doubtful crucial assumption that is never explicitly or elaborately defended: that the only feasible model for financing R&D into life-saving treatments is the existing corporate model.

This paper will argue for the *right* of developing nations to resist the imposition of a 'common standard' for all patents, and to implement patent systems suited to *their* immediate needs, by expanding the following four interdependent and consecutive points:

- 1. The history of patents in the industrialized world shows that the patent system has always been and remains at its core a crude political mechanism deployed and withdrawn arbitrarily from time to time to serve the immediate political or public goals of states (i.e. public health crises) and its character at any time is therefore contingent (in part) on the stage of development of the society in question and on the nature of the public good protected. In relation to the pharmaceutical and chemical industries in particular, it is clear that many industrialized countries have engaged in extensive 'piracy' in order to develop their industries, just as developing countries are attempting to do today.
- 2. The global R&D model that the industrialized world seeks to universalize by sweeping away these historical precedents is clearly not suited to the needs of the developing world:
 - (i) the utilitarian argument that attempts to justify the maintenance of high prices through extreme patent protection (particularly 'product' patents) in order to fund R&D disregards the relatively straightforward notion that this is the *default* justification for patents and intellectual property, and that the ethical questions that arise in public health crises such as that in relation to AIDS in Africa demand a *different* approach to patents for pharmaceutical products; (ii) arguments in favour of patent-induced high prices based on the need to conduct R&D and the risks associated with this process misconstrue the evidence for their position and even ignore the implications of, for example, the 'super-normal' profitability of the pharmaceutical industry in light of this astounding profitability, it is misleading to speak of pharmaceutical companies

- taking 'losses' due to lax patent regimes in the developing world, or of patents as artificial monopolies of denoting property rights equivalent in statute to any other property rights, or other rights;
- (iii) pharmaceuticals further mislead in their justifications by obscuring the real relationship of R&D costs to marketing costs (it being more justified to pass on the former to consumers than the latter), while providing no evidence that ever tighter patent protection leads to more innovation, or more useful innovation. Even if this is the case, the high prices that patent monopolies lead to make any resulting research useless to the poor who constitute the majority of those afflicted in the AIDS epidemic, or any public health crisis for that matter. A different R&D model is needed.
- 3. A Better model: Public institutions already play a significant role in R&D in industrialized countries, and the behaviour of pharmaceutical corporations reflects a failure to acknowledge this debt; (the current R&D model does not depend on the contribution of developing countries by protecting patents, given that it is already super-profitable in spite of the fact that the least developed countries constitute a negligible share of the market; developing countries benefit from it only to the extent that their public health problems coincide with those of the industrialized world;) many of the arguments in favour of the corporate R&D model rest on the unfounded assumption that it is the only workable model that can provide for public health needs. This is a gross oversight, given the positive example that Cuba provides for other developing countries in combating health crises, taking into account both its success in public health and biotechnology, and its socio-economic similarity to other developing countries, irrespective of the political context it is implemented in.
- 4. The patent system as a policy tool (going back to point 1) can only be properly conceptualized in its historical and socio-political context. The effort by industrialized countries to impose a one-size-fits-all common global standard represents a hegemonic process that threatens to deprive us of the extra-legal ethical language by which we measure their legal actions, by erasing both the historical roots of the patent notion and the historical debt owed to the developing world by the industrialized world. This process of 'Empire' (a notion borrowed from Hardt and Negri) runs

counter to the 'natural' process of adapting and implementing patent policy that industrialized countries themselves have undergone. This is a violation of *ethical* norms that underlie the juridical notion of patent and therefore a violation of the juridical notion itself, especially in the international law context; a notion which in fact incorporates or is subject to among other things international human rights norms such as the right to health. By working towards a common standard in patent protection industrialized countries have got the wrong end of the stick, so to speak. Ethically (and juridically in the sense outlined), they should instead be working from the *opposite* end, that is, towards a common standard in public health, not through mere charity and *ad-hoc* measures but by addressing the root causes of the AIDS epidemic in Africa and investing in the development of self-sustaining and self-sufficient public health and R&D networks in the developing world. This in turn may in time organically produce greater confluence in patent protection norms such as exists today among industrialized countries themselves.

1 A Short History of Patents:

A great irony lies in the fact that the global enforcement of pharmaceutical patents has been incorporated into the neoliberal free-trade agenda. The notion of a patent is anathema to any concept of free trade, in both historically contingent and practical terms, and it is no surprise that a number of prominent economists, including Joseph Stiglitz, Jagdesh Bhagwati and several senior World Bank economists have recently denounced pharmaceutical patents on precisely this ground, referring to them as 'unfair, inefficient, and inconsistent with the free trade agenda'. In the 1870s *The Economist* similarly railed against the protectionism of the patent system at a time when Britain came close to abandoning it altogether. A closer look at the history of patents illustrates very well this self-indulgent hypocrisy at the core of policymaking in the industrialized world.

⁸ Loff and Heywood, p 624. Also, *Developing World Bioethics* 1(1) 2001, News Section, "World Bank Economist Gives Thumbs Up To Generic Producers" as reported in *The Times of India*, December 11, 2000. The economist in question, Hans Binswanger, believes developing countries should not negotiate price discounts, but produce generics, which will lead to price reductions by pharmaceutical companies. Jagdish Bhagwati has also criticized the TRIPS agenda as turning the WTO into a "royalty collection agency." (Sterckx (2004), p 74)

The origin of patents varies slightly between legal systems, but the one feature common to all is the idea of monopoly. A patent is at bottom a grant of monopoly rights over the production of a specified product for a specified period of time to a specified entity. In Elizabethan England, the English concept of patent originated in the grant of 'letters patent' to merchants over commodities such as salt or coal, giving them the exclusive right to trade in the relevant goods in exchange for cash payments. Such 'patents' were not tied to invention in any sense and were monopolies pure and simple, in the modern sense of the term. They were used purely as a means of raising revenue for the Crown or in some cases "rewarding royal favourites at the public's expense". This type of patent was outlawed by the Statute of Monopolies 1624. In France a similar scheme operated until the revolution, when it was replaced by a modern patent law based on the idea of invention.

The first modern patents granted in England and other European countries for genuine technological inventions were clearly motivated by the policy concerns of states in wishing to attract inventors or stimulate invention on their soil.¹³ This may seem obvious, but highly important to reconsider in the light of global enforcement of pharmaceutical patents, particularly as against poor developing countries who gain little from registering such patents besides nominal access to life-saving drugs that most of their citizens can hardly afford. One of the earliest – if not the earliest – measures of this type, which according to Grubb 'still sounds very modern today' was a Venetian decree of 1474 which notably for our purposes gave patent protection to [my italics] "each person who will make in this city any new and ingenious contrivance...so that it can be used and exercised..." Thus here at the earliest sign of what we may call the modern, invention-based notion of patent, we have what is clearly a proclamation by a sovereign and autonomous city-state, decreeing what is in its best interest: if the inventor has any intellectual property 'rights' as such, they do not exist here or are not recognized in any deontological sense. They are not human rights, not even to the extent that real property can be so termed – they exist only insofar as they serve what the state and society in question perceive to be their

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¹⁰ Brennan and Baines, p 30.

¹¹ Grubb, p 8.

¹² *Ibid*, p 12.

¹³ *Ibid*, p 9-11.

¹⁴ *Ibid*, p 10-11.

immediate policy interests, and only insofar as they are defined in the decree, which can be viewed as a kind of contract.

Some examples from more recent times illustrate well not only that the interests at stake are political, but that the gradual development of the notion of patent into what it is in the industrialized world today has not truly been a 'development' – that is, it has not followed a steady, progressive timeline in any sense. It is particularly interesting to note how today's patent-pushers have dealt with patents in the past during prolonged economic or health crises or simply earlier stages of development. In a number of countries that are now part of the industrialized world, patent laws have at times for decades-long periods been repealed, or substantially modified to reduce patent protection in the public interest, and later reinstated, at least partially.¹⁵ England, for example, came close to abandoning the patent system entirely in the 1870s, having *previously* enjoyed very strong patent protection – not due to a public health crisis, but largely due to pressure from economists and industrialists that the system was too protectionist. ¹⁶ Still later, in 1919 the British chemical industry under pressure from competition in Germany, in turn pressured the British government to abolish 'product' patents on chemicals. The government acted on this, going even further to allow compulsory licensing on demand for all patents relating to medicine. These changes were not reversed until after WWII.¹⁷ According to VanGrasstek,

England escaped its status as an economically backward nation during the Middle Ages in large measure because it practised a successful form of industrial piracy...The economic history of the United States demonstrates a similar [evolution], albeit along a somewhat different route...American businessmen attempted to bypass British controls on technology, by illicitly importing state-of-the-art intellectual property...It was only after the nation grew in economic and political stature, and developed an important indigenous industrial base and a local class of successful innovators, that its practices came closer to the liberal paradigm.¹⁸

Switzerland, one of the modern giants of the pharmaceutical industry, came to prominence as a 'patent piracy' haven where German patents were safely imitated. J

¹⁵ Grubb, pp 17-35, "Historical Developments in Industrialized Countries"

¹⁶ *Ibid*.

¹⁷ *Ibid*, p 19.

¹⁸ VanGrasstek Communications, pp 88-92.

Geigy-Merian, founder of Geigy AG, a precursor of Ciba-Geigy and Novartis, "denounced patents as a 'paradise for parasites', (by which he seems to have meant patent lawyers..." This patchy history is not limited to what are today 'developed' countries. In Brazil, patents enjoyed very strong protection before 1945, when 'product' patents for pharmaceuticals were abandoned, leading eventually to complete exclusion of patent protection on pharmaceuticals by 1969.²⁰

As Heywood puts it, [my italics] "historically, the granting of a patent was a reward, bestowed by the state, to an inventor in return for making the invention available to the public."²¹ Even Kettler, though taking a pro-patent position, concedes that "in the past, countries used IPR legislation as part of a package of policy tools...to develop their industries,"22 noting however a current move towards a "global standard". The irony and hypocrisy of this global move is entirely lost on Kettler. Having gained a firm foothold both economically and technologically the industrialized world now seeks to maintain its superiority by preventing developing countries from taking the same approach to develop their industries and public health networks. To Kettler this is merely an earlier phase of global development, not an indication of an ambiguity at the heart of the very notion of patent with respect to each global player. Put more simply in playground terms, the situation is analogous to a group of older kids bullying the younger kids to change the rules of the game once the older kids have benefited from them to a standard that now suits them better in their dominant position. This hypocrisy is not limited to history, either. As recently as the post-September 11 anthrax scare, the governments of the United States and Canada forced Bayer, makers of ciprofloxacin, to sell the drug at substantially reduced prices after both governments threatened to issue compulsory licences to generic manufacturers.²³ This in the case of what cannot be termed a 'public health crisis', or even an imminent public health crisis (given that it never took place) but merely a wave of fear following a string of highly-publicized incidents.

Kettler (or the study by Lacetera and Orsenigo to which she refers) only manages to present a seemingly uniform timeline consisting of three neat, progressive phases by limiting historical breadth and focusing on the second half of the 20th

²⁰ Loff and Heywood, p 622.

²³ Loff and Heywood, p 627.

¹⁹ Grubb, p 25.

²¹ Heywood, p 223.

²² Kettler, p 662.

century.24 This allows her to conclude that "The organization of R&D and the role of IPRS have evolved over time in the pharmaceutical industry", avoiding any inconvenient (for her argument) parallels between the current state of patent protection and 19th century protectionism; and the rather contrary conclusion that the process in question is better described as a 'regression' than an 'evolution'. The low level of patent protection which the study finds at its starting point in the pre-WWII period was arrived at from a previous state of high protection, as discussed above. Thus the present "global move to a common standard" represents in some ways a return. But the more important point is to draw out the logical implications of Kettler's description of patent systems as a 'policy tool' – a concession which undermines some of Kettler's own conclusions. As Sterckx puts it "differences in national priorities, which are closely connected to different levels of economic development, justify a different approach to intellectual property protection"26 Industrialized countries have historically designed at the national level patent systems that suit their best immediate interests individually; the global system they are trying to foist on the developing world today is designed to suit their collective interests, but as the next section will show, fails to provide for the needs of the developing world.

2 Utilitarian Ethics?

2.1 Are high prices justified?

Given the political history of patents outlined above it seems wholly incongruous that in the African AIDS context many patented drugs are "substantially *higher* priced in developing countries than they are in some developed countries."²⁷ This is partly due to price caps imposed on pharmaceuticals in many industrialized countries, as Schüklenk and Ashcroft note, contending that self-imposed price reductions by pharmaceuticals with no real incentive to reduce their prices and in the absence of

²⁴ Kettler, p 661.

²⁵ Ibid.

²⁶ Sterckx (2000), p 73.

²⁷ Schüklenk and Ashcroft, p 134.

price caps is problematic – not least because it still leaves developing countries' healthcare planning at the "goodwill of commercial organizations" and "represents as charitable what is actually sound business policy."²⁸ Overpricing pharmaceuticals to the extent that they are beyond the reach of most patients in the developing world actually prevents the pharmaceutical companies themselves from getting the optimal use out of their patents, in other words – so it is in their best business interest to reduce prices to some extent. This could be a response to the argument made by Brennan and Baines in favour of pharmaceuticals, claiming that the high level of drug prices is in principles justified and advocating an ethical managerial egoism that amounts to charitable giving, private-public partnerships and similar initiatives that in turn "maximize long term shareholder value."29

But in a deeper sense many of the proposed and somewhat implemented solutions (price reductions, private-public partnerships) are ad-hoc and fail to address and even tend to avoid the fundamental ethical questions that cast doubt on the very validity of granting patents for life-saving pharmaceutical products. It is clear that in terms of real or physical property, most if not all legal systems distinguish between different types of things in terms of how or whether they can be owned at all. Different rules apply to land and chattels, and this is not merely for practical reasons, for often there are reasons of moral or natural rights that inform such distinctions. There must be a distinction between the rights that pertain to one's home and the rights that pertain to a book or stereo or car that one 'owns'. We do not own our bodies. There are certain physical assets or public goods that are for reasons of public interest – moral and ethical reasons – excluded from private ownership. Why then should the same *legal* regimes and rules, the same basic concepts of ownership pertaining to the rights of patent-holders, apply in the same way to both aerospace and engineering inventions, computer technology, and life-saving pharmaceuticals? The argument, discussed below, that patents and therefore high prices are necessary (some say "essential") to fund R&D into further developments – to the extent that it is valid applies to all patents, pharmaceutical or not. The whole point of the ethical counterargument is precisely that pharmaceuticals should be treated differently – on one hand, that the burden of paying for the R&D that "benefits all humanity" to the

²⁹ Brennan and Baines, p 41.

³⁰ Brennan and Baines - a doubtful claim, discussed below.

extent that it is reflected in and secured by the patent, should not fall entirely on those who purchase or pay for the drugs they need in order to stay alive, whether it be patients themselves, governments of poor countries, or insurance schemes, and the response should not be one of merely implementing *ad hoc* measures of charity and temporary price discounts, but rather uprooting and reforming the very way we think about and implement patents; and secondly, that the price of essential life-saving drugs should not be subject to the purely business costs incurred by corporations (i.e. advertising) which are substantial and outweigh R&D costs, and which are not incurred by wholly publicly financed drug development projects. Ironically, it is precisely pharmaceutical manufacturers who have been at the forefront of the global IP agenda through their influence on governments and supranational organizations such as the WTO in recent decades.³¹

2.2 Super-normal profits

When the case is made in support of corporate patents and more-less in favour of the status quo (with some charitable concessions) with regard to pharmaceuticals, the arguments used function only by blatantly overlooking certain facts, some of them relatively well known. Brennan and Baines argue that the current high prices of drugs are justified so long as corporations practice an enlightened form of managerial egoism, because the prices are necessary to "recoup massive R&D costs" and thus provide the incentive for drug companies to develop new drugs, making all humanity better off.³² Interestingly enough, they do acknowledge that drug companies have for decades reeled in 'super-normal profits' far in excess of Fortune 500 corporations averaging profits more than three times that of other industries,³³ but fail to see the implications of this for their argument, in response only repeating the mantra that "the development and testing of new drugs is an expensive and risky business." Not only that, but "pharmaceuticals have been rated first or second on the list of the most

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³¹ Loff and Heywood, p 622. Brennan and Baines, p 35. Sterckx (2000), p 69.

³² Brennan and Baines, p 35.

³³ *Ibid*, p 35. Also, Schüklenk and Ashcroft, p 136; and O'Manique, p 85.

³⁴ Brennan and Baines.

profitable sectors for more than thirty of the past forty years."³⁵ And in 2001 when there was much talk of sacrifice in the national interest in the United States following the September 11 attacks, and other industries entered a recession, declining by 53 percent, drug companies in fact *increased* their profits by 32 percent.³⁶ It is very difficult to see how an industry that performs so astonishingly well in economic terms consistently over decades can justify yet further net gains based on "risk".

A further question that begs asking here is in what way are pharmaceutical companies experiencing 'losses' due to lack of patent protection in the developing world, as many authors – even those somewhat well-intentioned, such as Resnik³⁷ unquestioningly and casually state? The current move toward a global 'common standard' for patents began in the 1980s when "several US industry associations (in particular the chemical, pharmaceutical, electronic and information technology industries) prepared reports for various Congressional committees, quantifying the losses they suffered [due to infringement of IP rights]." This resulted in a shift in US trade policy through the office of the Trade Representative.³⁸ What notion of 'loss' is at stake here? It cannot be loss in any ordinary sense of entitlement, given the 'supernormal' profits earned by pharmaceutical companies. Once they have made a net profit, let alone a *consistently* 'super-normal' net profit over an extended period of time, they cannot claim to be *losing* anything they are entitled to, especially by virtue of an artificial monopoly on the production of a good. But it is not only for this reason that it is misleading to use the term 'loss' here. As has been noted by many writers, most of these drugs are unaffordable to patients in the developing world anyway³⁹ – so to speak of 'loss' as a result of generic manufacturing is tantamount to, or at least a very small remove from saying that luxury car manufacturers such as Mercedes and BMW experience 'losses' as a result of investments in public transport networks in poor urban ghettoes of the developing world. Both claims are wholly disingenuous.

³⁵ O'Manique, p 85. Hunter, p 36: "pharmaceutical companies remained the most profitable sector of the US economy for the third decade..."

³⁶ Hunter, p 36.

³⁷ Resnik (2005), p 121 (my italics): "It is hard to say exactly how much money pharmaceutical companies *lose* as a result of the failure to recognize patents globally." The corporate patent ideology is thus unquestioningly embedded in the language used by many writers on the subject.

³⁸ Sterckx (2000), p 69.

³⁹ Brennan and Baines, p 35; Buckley and Tuama, p 134; Loff and Heywood, p 621.

Taking this into account, the ethical question about patent enforcement arises before we even take into account the gravity of the epidemiological situation in Africa, and the life-saving nature of the treatments in question. In other words, before we even get to that stage of the inquiry, the existing level of enforcement and protection of patents becomes questionable merely by virtue of the 'super-normal' level of profits in a particular industry. And the argument that the business is a risky one also fails, given that this super-normal profitability has been consistent over several decades. 40 Once all costs to be recouped have been recouped and profits have been made and begin to exceed any normal level of profits, the moral, ethical, and legal-political foundation of the patent begins to crumble. This is another reason why 'ethical egoism' and ad-hoc 'charitable' (but business-wise) solutions to the AIDS problem misconceive the issue – because in a fundamentally moral sense, the resources 'donated' by corporations through such schemes are not theirs to give away in the first place. They are the result of an artificial monopoly imposed for the benefit of society and which has exceeded its usefulness to society: "intellectual property rights are designed to promote innovation in the public interest...where they contravene the public interest, the justification for their enforcement in that context is removed."41 Yet by insisting on charitable 'giving' rather than allowing developing states to exercise their autonomy by producing generic versions of drugs covered by over-exploited patents, the corporations obscure this reality, and deign to occupy the moral high ground.

2.3 Marketing costs

Brennan and Baines hardly mention the fact that pharmaceutical companies spend a substantially larger amount of money on marketing than they do on research and development, in some cases two or three times as much.⁴² (If public enterprises spent money in this way, it would almost certainly be put down to 'government waste') In fact, "much of the cost attributed as R&D cost can be identified as marketing cost, which ultimately contributes to company profits, and is only incurred in the case of

⁴⁰ O'Manique, p 85. Also, Buckley and Tuama, p 132-133.

⁴¹ Schüklenk and Ashcroft, p 137.

⁴² O'Manique, p 84.

successful products."43 Thus a large portion of the 'R&D' that contributes to the high price of pharmaceuticals and is justified because inherently 'risky' is actually not risky, because it is the cost of marketing already successful drugs craftily subsumed under the R&D costs heading. This in a sense gives the lie to Brennan and Baines in holding that "If patents cease to hold their legal power, huge R&D expenditures would be wasted."⁴⁴ Whatever the business rationale or necessity is for enormous marketing expenditure, the ethical implications are clear. The phrase "necessary to recoup R&D costs" is misleading and omits about ½ to 1/3 of the equation: "necessary to recoup marketing and R&D costs" would be more appropriate. This vagueness is necessary, however, to avoid the inconvenience of asking the obvious question: why should impoverished third-world nations pay for the costs of advertising and marketing Viagra to consumers in the industrialized world?

Resnik similarly ignores this reality, claiming that "if companies face limitations on profits and prices, they may cut back on their investments in R&D and focus more on marketing." As a consequence, a lot of important research simply would not get done. 45 The rationale actually *sounds* sensible – with patent protection, companies can charge whatever price they wish for their products, and do not need to spend very much on advertising given that no one else can manufacture the same chemicals, at least in the industrialized world where 'product patents' are enforced and protection is generally strong, and which is where most of their profits lie anyway. 46 Kettler similarly states: "the standard message from research-based pharmaceutical and biotechnology companies is clear: without patent protection, there will be no R&D."47 Why then do pharmaceutical companies spend substantially more on marketing anyway, in spite of growing patent protection, spending most or all of their marketing budget where patent protection is highest and where their monopoly over drug prices is strongest? And moreover why is the gap between marketing and R&D is in fact growing in favour of marketing⁴⁸ just as global patent protection is also increasing in the tendency toward what Kettler calls a 'common standard'?⁴⁹ And why is it the case that contemporaneous with increased patent protection an ever

⁴³ Buckley and Tuama, p 132.

⁴⁴ Brennan and Baines, p 32.

⁴⁵ Resnik (2005) p 118.

⁴⁶ Sterckx (2004), p 73.

⁴⁷ Kettler, p 660.

⁴⁸ O'Manique, p 84-85.

⁴⁹ Kettler.

greater proportion of new drugs that are developed are hardly innovative, falling in the category of what Sterckx calls 'me-too' drugs⁵⁰, existing products that have been slightly modified or 'ever-greened' by competition?⁵¹ 80% of new drugs approved by the FDA in the US are in this 'standard' category, according to Sterckx. This turns Resnik's assertion on its head, but it is no surprise at all when carefully considered – why would Big Pharma, in the face of stronger patent protection, invest *more* in the admittedly 'risky' business of generating more genuinely *new* products, when all that is necessary in order to pursue its best business interests is to maintain the current level of innovation, give a little charity, and invest more in the much less risky business of marketing? On the facts one could easily argue the very opposite of Resnik's assertion: lower patent protection – i.e. the exclusion of 'product' patents for pharmaceuticals – would lead to a *higher* rate of innovation as companies are forced to compete with better and newer products and processes. Braun and Pugatch in their study note that the "shifting of the mode of protection towards the product" is in fact one of the outcomes of the "shrinking pipeline of truly innovative drugs."⁵²

Even if important research is done by pharmaceutical companies that in the immediate context would not be done *at the same rate* without patent protection, how exactly do developing countries benefit from upholding these patents, confronted with the *immediate* reality of the AIDS epidemic, when the medicines in question are beyond the reach of most of those in the developing world⁵³ – not only because they are in the poorest part of the world but because those hardest hit by the epidemic are the poorest segments of the poorest part of the world;⁵⁴ and furthermore when they will never have the chance to close the technological and economic gap unless permitted to avail themselves of the very approach to intellectual property that enabled many industrialized countries to develop *their* industries as discussed above – that is, widespread piracy? The 'trickle-down' claim that the developing world will benefit from patents through 'transfer of technology' is not only hypocritical but false, for as Wade has shown "the knowledge gap between North and South inevitably widens when property rights are applied in a more sophisticated manner." 55 Whatever

⁵⁰ Sterckx (2004), p 62.

⁵¹ Braun and Pugatch, p 620.

⁵² *Ibid*, p 620.

⁵³ Loff and Heywood, p 621.

⁵⁴ Buckley and Tuama, p 134.

⁵⁵ Wade, p 624.

benefits there are in the current corporate model of R&D, they clearly accrue to those who already have a foothold in the technological arena, and severely disadvantage those who do not. The costs of intellectual property regimes are socialized, while the benefits are privatized.⁵⁶ It cannot be in the interest of "all humanity" to uphold patents and high prices when entire swathes of humanity cannot afford the drugs resulting from these patents. This presents an ethical dilemma that in no uncertain terms demands an alternative model for financing and generating research and development into essential cures, one not based on the corporate profit agenda and not hampered by patents, advertising and marketing costs, shareholder value maximization, and the like.

3 The Public R&D Model

Schüklenk and Ashcroft note that it is quite "conceivable" (in their words) that any gap in research would be filled by universities, charities, and even governments. Much of the research on which pharmaceutical companies profit in fact already takes place at universities and other publicly funded institutions who sell it to companies for a paltry fee⁵⁷ – thus the infrastructure is already in place. It is in fact more than conceivable that the gap would be filled either by public institutions or by more enterprising private institutions – it is virtually certain. And it is not only because of the already existing role of public institutions in both conducting and financing research, although this is significant – Sterckx notes that even in the United States, according to the National Institutes of Health, "55% of the research projects leading to the discovery and development of the 5 best-selling drugs in 1995 was performed by researchers whose work had been financed with taxpayers' money."58 Two key HIV/AIDS drugs were developed at Yale University and the University of Minnesota, now licensed exclusively (for a 'paltry fee') to Bristol-Myers Squibb and Glaxo Smith Kline.⁵⁹

⁵⁶ Perelman, p 4.

⁵⁷ Schüklenk and Ashcroft, p 136.

⁵⁸ Sterckx (2004), p 65.

⁵⁹ Buckley and Tuama, p 132.

Resnik and others note that the majority of research done by pharmaceutical companies is on the diseases of the wealthy in the industrialized world. 60 Research that benefits the developing world is simply not very lucrative and therefore unattractive to big pharmaceutical companies. 61 Sterckx: "Of the 1223 molecules that were sold worldwide between 1975 and 1996, less than 1% was intended for tropical diseases."62 Even in the developing world, those hardest hit by disease and malnutrition are the poorest – of the *developing* world. How could they possibly benefit at all from a corporate R&D model built purely on financial incentives, their life and death dependent on the good will and charity of corporate donors half a world away? The pro-patent argument presents the developing world with a false choice, encapsulated thus: "LDC [least-developed countries] governments may feel pressured to choose between an IPR policy that helps support its domestic industry (and arguably further economic development) and one that others have argued is essential for supporting new R&D in global health."63 Kettler distances herself somewhat from the sentiment by inserting the proviso that 'others have argued' the latter point. Nevertheless, the choice presented is a false one – for neither do developing countries benefit greatly from the R&D in question, as argued above (or if they do, as the figures show, it is only to the extent that their diseases also afflict the industrialized world, which account for 99% of R&D), nor does the R&D performed by multinational pharmaceutical corporations particularly 'depend' on their contribution – an outlandish suggestion, to say the least – given that, in the existing climate of already 'super-normal' profits in the pharmaceutical industry, Africa represents only 1 percent of the global pharmaceutical market.⁶⁴

Many of the pro-patent pro-corporate arguments outlined rest on the never-questioned and hardly even defended assumption that the private corporate model is the *only* one that can feasibly support the R&D needed for global health needs. Even when the public model is given some consideration, it seems hardly worth the time. Kettler undertakes to analyse the costs and benefits of three models of R&D – the commercial, the public-private, and wholly public – but while spending a considerable length on the first two, concluding from the outset without any

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⁶⁰ Resnik (2004), pp 46-47. Sterckx (2004). Wade, p 624.

⁶¹ Resnik (2004).

⁶² Sterckx (2004), p 68.

⁶³ Kettler, p 679.

⁶⁴ Sterckx (2004), p 73.

comparative evidence that they "seem to have the greatest prospect of progressing R&D in neglected diseases" spends but one paragraph discussing the 'wholly public' model, amounting to no more than a brief mention of an initiative by *Medicins Sans Frontieres* to create a public research facility to meet global health needs. No mention of existing wholly public models is made; no comparison of costs, especially with regard to the voluminous corporate costs related to competition (marketing, advertising) that public institutions would not be faced with. The discussion ends with a prescriptive suggestion relating to the MSF scheme but which does not even approximate an encapsulation of the issues surrounding the public vs private models: "They must also demonstrate how they will be able to raise the funds necessary to duplicate the industry know-how and resources and that this is a more efficient use of scarce funds than negotiating agreeable terms with companies directly." "66"

This amounts to a gross but not surprising oversight. The reasons why a model such as that implemented in Cuba would be absent from public discourse in the industrialized world, though ironic, are clear – in the charged ideological context, Cuba represents the "threat of a good example." It is worth looking at this example here. Cooper et al note that "modest infrastructure investments combined with a welldeveloped public health strategy have generated health status measures comparable with those of industrialized countries", particularly in the [my italics] "control of infectious diseases, reduction in infant mortality, establishment of a research and biotechnology industry, and progress in control of chronic diseases." A number of common diseases have been entirely eliminated, in some cases (such as Polio) for the first time anywhere in the world. Cooper et al further hold that it is unlikely on close scrutiny that any manipulation of data has taken place, and that "sufficient data now exist in several key areas to demonstrate that skepticism can no longer be the basis for a refusal to engage the question."68 The Cuban biotechnology industry has in the twenty-odd years of its existence⁶⁹ advanced to the point that some of its inventions – well ahead of the 'me-too' drugs that make up the bulk of pharmaceutical patents in many industrialized countries⁷⁰ - are being licensed by foreigners, some of which are

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⁶⁵ Kettler, p 656.

⁶⁶ *Ibid*, p 677-678.

⁶⁷ Spiegel, p 25.

⁶⁸ Cooper et al, p 818-822.

⁶⁹ Randal (12)

⁷⁰ Sterckx, above.

U.S. corporations engaged enough to be willing to overcome the hurdle of getting US government approval to waive the embargo on Cuba. Among these are the world's only type B meningitis vaccine, licensed to SmithKlineBeecham⁷¹, and 3 potentially "revolutionary" experimental cancer drugs licensed to CancerVax, a biotechnology company in California, with special dispensation from the US government.⁷² In the pipeline are also recombinant vaccines against AIDS, hepatitis C and dengue fever.⁷³ Yet as Spiegel notes in spite of these remarkable health achievements, "there has been limited discussion of this in scientific circles." This he terms the 'Cuba taboo' – a symptom of the "strong inclination to narrow the boundaries of what are deemed to be possible approaches."⁷⁴

Cuba clearly provides a far superior model for developing countries to aspire to, compared to the model pushed by the industrialized countries – their own – through TRIPS and WTO. First of all, Cuba is itself a developing country and demonstrates "that economic measures alone are poor predictors of physical well-being within a society." Moreover, it has implemented a highly successful public health programme "at a cost well within the reach of most middle-income countries." Nattrass maintains, for instance, that the successful implementation of a large-scale AIDS treatment programme in South Africa is well within the reach of the government there (not least due to compulsory licensing), but that "a cold-hearted economic calculus on the part of the elite may thus conclude that it is more efficient to let people die than to raise taxes to try and save them."⁷⁶ The obstacles to treatment programmes thus are clearly multiform as some writers suggest, yet given the choice, it is certainly preferable being at the mercy of cold-hearted economists who are accountable to and may be removed by the very populace afflicted by the epidemic, than being at the mercy of cold-hearted economists half a world away who are accountable mainly to their shareholders – not to mention at the mercy of both. The Cuban model can certainly be implemented without replicating its political context – although it is interesting to note that Cuba does honour foreign patents and has a patent office.⁷⁷

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⁷¹ Randal (13).

⁷² "TECHNOLOGY: US Permits 3 Cancer Drugs From Cuba" *The New York Times*, July 15, 2004. Andrew Pollack.

⁷³ Randal (13).

⁷⁴ Spiegel, p 25.

⁷⁵ Cooper et al, p 817-822.

⁷⁶ Nattrass, p 46.

⁷⁷ Randal (13).

This may go to show that simply a better state of public health, and not necessarily a higher stage of economic development, is sufficient to organically produce stronger patent protection in relation to pharmaceuticals.

4 Hegemony or Death?

The central utilitarian claim from the pro-patent corporate lobby as voiced by Resnik and Kettler among others – that any downgrading of patent protection leads to less R&D and is therefore contrary to the interests of all humanity; that without patents, important R&D simply would not get done at all by anyone – amounts to moral blackmail, and presents the poor urban sufferers of the AIDS epidemic in Africa with a false choice: hegemony or death. Either enforce our patents, Big Pharma claims, or there will be no more medicines. This is clearly not the case prima facie, and it is still not the case following a careful analysis. Piracy, as discussed above, is the very mechanism that has enabled industrialized countries to develop their industries, and for many poor developing countries faced with the immediacy of public health crises it has been the primary means of survival thus far, as they have themselves contended. This is not merely a *historical* contingency – it is part of the very notion of legal patents as a policy tool. As Hardt and Negri put it, [my italics]"juridical concepts...always refer to something other than themselves. Through the evolution and exercise of right, they point toward the material condition that defines their purchase on social reality." Moreover, "every juridical system is in some way a crystallization of a specific set of values, because ethics is part of the materiality of every juridical foundation."80 The juridical concept of a patent, too, cannot even in law be anything more than the sum of ethical, moral and political justifications and rationalizations that animate it, combined with the historical and political mechanisms that develop, evolve, and put it into practice.

Thus when Sterckx (2000) argues that a lower level of patent protection is justified by national priorities at a lower stage of economic development⁸¹, this should

⁷⁸ Sterckx (2000), p 84.

⁷⁹ Hardt and Negri, p 22.

⁸⁰ *Ibid*, p 10.

⁸¹ Above, note 26.

not be read as merely a plea for an ethical treatment of patent enforcement or for an ethical concession to the poor *in waiver* of a legal norm. The idea (perhaps unwittingly for Sterckx) goes to the very core of the juridical notion of patent and may effectively turn the tables on Big Pharma and the industrialized world: by attempting to impose global norms and values on developing countries through the international (inter-governmental) trade arena and ignoring their own history, industrialized countries are not merely conducting an unethical hegemonic project, they are in fact violating the very juridical notion of what it means to hold a patent as evidenced overwhelmingly by at least two centuries of state policy and practice, norm-generation, adjustment, and political discussion. When the ethical/political foundation on which a juridical norm is built begins to crumble, the substance of the claimed juridical right disintegrates along with it. As Schüklenk and Ashcroft argue in more euphemistic terms, "intellectual property rights are designed to promote innovation in the public interest...where they contravene the public interest, the justification for their enforcement in that context is removed."82 The ethical debate over the enforcement of patents in developing countries faced with the AIDS crisis and similar public health crises, this essay argues (in what may be seen as a Dworkinian turn), is a debate over the very *meaning* of the notion of patent. Multinational pharmaceutical corporations and the governments of industrialized countries have misconstrued this meaning. This is especially the case given the obvious relevance of general international law to the subject-matter – enforcing pharmaceutical patents through international trade law – where state practice⁸³ is crucial to determining valid and applicable legal norms, and international human rights are acquiring greater importance. In fact, as a matter of international law it has been explicitly stated that "any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other *right* set out in the Covenant, is inconsistent with the legally binding obligations of the State party."84

⁸² Schüklenk and Ashcroft, p 137.

⁸³ Note discussion above on history of patents and recent Anthrax scare.

⁸⁴ United Nations Committee on Economic, Social and Cultural Rights, as cited in Loff and Heywood, p 628: "Human rights bodies inside and outside the United Nations now argue that the regulation of the global economy must not be divorced from global social problems. Intellectual property law should be considered within the body of international human rights law and be implemented consistently with human rights such as the right to health…"

The corporate-industrialized world nexus project in pushing the global IP agenda with a view to adopt a "common standard" or "one size fits all" model for patents regardless of the field of technology (in this case medicine) or socio-economic circumstances in question (AIDS epidemic in Africa) is not only hypocritical but dangerous, and not just to immediate public health concerns. It constitutes an attempt to sever the juridical notion of patent from its material historical source – to deprive us of the language to articulate the *un-ethics* of the situation. It seeks to monopolize the very language and thought-processes that permit us to ethically and effectively question the 'rational' decision-making of world leaders and corporations. This is what Hardt and Negri refer to (in a reading of Foucault) as a 'biopolitics' of control, which permeates below the level of consciousness to the bios in order to manipulate the very limits of what we are capable of thinking.⁸⁷ The sentiment is echoed in the comment cited above by Spiegel regarding the 'Cuba taboo' – a conspicuous silence which reflects an "inclination to narrow the boundaries of what are deemed to be possible approaches"88 to public health. Out of this universalized silence, the global order of 'Empire' unfolds [my italics]:

[T]he problem of the new juridical apparatus is presented to us in its most immediate figure: a global order, a justice, and a right that are still virtual but nonetheless apply to us...our internal moral disposition...tends to be determined by the *ethical*, *political*, *and juridical* categories of Empire...The means of the private and individual apprehension of values are dissolved: with the appearance of Empire, we are confronted no longer with the local mediations of the universal but with a concrete universal itself.⁸⁹

This latter tension represents most faithfully the precise tension between the position of developing nations and that of industrialized nations in relation to pharmaceutical patents. It is the tension between an adaptive conception that is modified as it is historically and socio-economically contextualized or 'locally mediated' – and on the other hand a conception that is in juristic terms rigid and by claiming for itself 'concrete universality' extinguishes all contextualized conceptions. This tendency of

⁸⁵ As approved of by Kettler.

⁸⁶ Lamented by Sterckx (2004), p 74.

⁸⁷ Hardt and Negri, p 22-24.

⁸⁸ Note 76.

⁸⁹ Hardt and Negri, p 19.

Empire to extinguish and erase context and 'local mediation' is not directed merely at the Other – the industrialized world which here is the agent of empire seeks to expunge its own context and history from the record, too, so long as the order that is universalized is the one it dominates at present. The characteristic of Empire is that it is "formed not on the basis of force but on the basis of the capacity to present force as being in the service of right and peace."90 The only truly effective means to resist this process of Empire then is to deny it its ethical foundation by insisting on history, both that of the developed and developing world, and in particular the complicity of the former in the plight of the latter, for example:

Besides introducing new diseases, European colonial incursions created devastating ecological changes in Africa. Mining, plantation agriculture, irrigation schemes, and drainage ditches created good habitats for malariabearing mosquitoes. As Africans died from smallpox and famine, cultivated areas returned to bush, promoting the spread of tsetse flies...⁹¹

That, in short, is the sort of thing European 'transfer of technology' to Africa achieved in the 19th and early 20th century. Hunter goes on to note some further examples, among them this: it took until the 1960s to rid the Serengeti plain of the rinderpest virus brought there by the British and Italians in the 1880s, by which time most of the native domestic cattle and wild ungulates on which the Masai population depended were dead. From 1880 to 1933 the population of the Belgian Congo declined from around 40 million to 9.25 million. In another French colony it went from 20 million to 2.5 million in the space of 20 years, 1911-1931. On the heels of these ravages, "Western medicine matured at just the right time to be used as a 'tool of empire'."92 This configuration, it seems, persists today in what Hardt and Negri call the new 'imperial paradigm', which has migrated from "disciplinary society to a society of control."93 It is the latter that operates at the level of bios, which rather than merely employing physical coercion, attempts to regulate from afar our very thought processes "to narrow the boundaries of what are deemed to be possible approaches."94

⁹⁰ Hardt and Negri, p 15.

⁹¹ Hunter, p 137.

⁹² Hunter, p 140-141.

⁹³ Hardt and Negri, p 23.

⁹⁴ Spiegel, above.

What is taking place here is the transition to an order wherein the agents of Empire need not instruct colonial subjects what to do or coerce them to it, but are able to ensure that goals are carried out merely by limiting the horizons of thought.

• Summary and Conclusions

It is clear that industrialized countries have taken every opportunity to adapt their patent systems and evolve them according to their immediate socio-economic or public health needs in different epochs. Developing countries should be allowed to do the same, especially given the historical complicity of developed countries in their demise and in the retardation of their development. The global model imposed by industrialized countries cannot serve the immediate public health needs of the developing world. In this process and particularly in dealing with existing public health crises such as the AIDS epidemic, Cuba provides the best existing model for developing countries to learn from, given both its success and the country's socioeconomic identity with other developing countries, and there is no reason why this model could not be implemented without replicating its political environment. Over this entire complex, however, looms the hegemonic global order of Empire, with the industrialized world as agent, seeking to universalize its own conception. In order to resist this universalizing process, developing countries should insist as a matter of right on managing their own public health networks matched by suitable patent regimes crafted to their immediate needs (i.e. compulsory licenses, import of generics) – rather than accepting the universalising imposition in return for ad hoc donations and other aid as a matter of charity or good will.

Developing nations should, in other words, reject *ad hoc* utilitarian approaches of enforcing patents unconditionally at the service of the industrialized world designed to alleviate their suffering but never allow them to stand on their own two feet, leaving them always a step behind and at the mercy of corporate and international donors. They should continue to assert their moral rights in the face of the global pharmaceutical lobby and insist on their unfettered discretion to determine the existence of health crises on their territories and design patent regimes appropriate

to their immediate needs. They should implement "social and organizational priorities" shown to produce results toward the "social production of health" – by simultaneously investing (socially and financially) in their public health networks and in publicly financed institutions to conduct R&D programs crafted to their concerns, guided by public health needs and motives and not profit possibilities. The attainment of public health goals is financially well within their reach merely by the implementation of appropriate policies, as discussed above. This of course raises a number of issues relating to the willingness of African officials and governments to deal with the AIDS crisis in an effective way, and the various cultural and political obstacles to this, 96 which cannot be dealt with in this paper. It is suggested in closing however that this only makes the compendium of obstacles to the resolution of the AIDS crisis more complex;⁹⁷ by removing the global obstacles (stringent pharmaceutical patent protection) and reducing the crisis to the level of national politics, the immediate technical responsibility is placed on the shoulders of leaders who in most cases are in one way or another politically accountable to the very populace afflicted by the epidemic, rather than on the shoulders of corporate executives thousands of miles away who answer primarily to shareholders. Thus if there is unwillingness among African politicians and elites to engage effectively with the epidemic (as some writers suggest), a more systematically ethical and less profitoriented approach to patent enforcement by industrialized countries would be much more likely to expose this unwillingness and eliminate such politicians. So long as industrialized countries insist on a 'common standard', they will remain the main scapegoat. If they believe it to be in their interest to produce a greater confluence of norms relating to intellectual property, they should work from the opposite end to where they are now – by investing in the public health networks of developing countries with a view to making them sustainable and self-sufficient both in providing for immediate health needs and conducting R&D in the long term; that is, by working toward a 'common standard' in public health rather than in patent protection, for the former would in turn produce greater confluence in patent systems.

⁹⁵ Spiegel, 825-826.

⁹⁶ Nattrass.

⁹⁷ The fact that there are other obstacles to access to ARVs does not mean that patent protection is *not* an obstacle and should not be removed, although some have by implication made this disingenuous argument, such as Brennan and Baines, p 36.

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