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to the Access to Knowledge Movement

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Intellectual property and global health: from corporate social responsibility to the access to knowledge movement

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Abstract

Any system for the protection of intellectual property rights (IPRs) has three main kinds of distributive effects. It will determine or influence: (a) the types of objects that will be developed and for which IPRs will be sought; (b) the differential access various people will have to these objects; and (c) the distribution of the IPRs themselves among various actors.

What this means to the area of pharmaceutical research is that many urgently needed medicines will not be developed at all, that the existing medicines will not be suitable for countries with a precarious health infrastructure or not target the disease variety that is prevalent in poorer regions. Such effects are commonly captured under the rubric of the "10/90 gap" in biomedical research. High prices will also restrict access to medicines as well endanger compliance to treatment schemes. IPRs are mainly held by multinational corporations situated in the developed world, which not only raises egalitarian concerns, but also severely limits the possibilities of companies in poorer countries to realize improvements on existing inventions, as they cannot financially afford to secure freedom to operate, which systematically shrinks the number of potential innovators. Those inequities lead to an enormous burden for the global poor and since no institution is willing to assume the responsibility to fulfil the right to health and the corresponding right of access to essential medicines, we have to analyse alternatives or additions to the actual intellectual property regimes in order to create new incentives to fill this gap.

Keywords: global justice; intellectual property rights; access to medicines; innovation policy; neglected diseases

Introduction

For slightly more than a decade, the recognition has become increasingly common that there may exist a deep conflict between intellectual property rights (the collective name for a set of rights encompassing patents, copyrights, trademarks, plant breeders rights and the like) and basic human rights. In their campaigns for access to essential medicines, for example, civil-society organizations like Médecins Sans Frontières (MSF) and Oxfam invariably insist that patents should never be put before the human right to health. Likewise, in 2005 Brazil and Argentina and other developing countries supported their proposal to broaden the narrow mandate of the United Nations (UN) agency WIPO (World Intellectual Property Organization) by arguing that “under no circumstances can human rights – which are inalienable and universal – be subordinated to intellectual property protection”¹. The Adelphi Charter on Creativity, Innovation and Intellectual Property that was issued in October 2005 also declared that “[IP] laws must serve, and never overturn, the basic human rights to health, education, employment and cultural life”². And as a final example: The UN special rapporteur on the right to food, Olivier De Schutter, used the human right to adequate food as a normative yardstick for assessing the effects of patents and other IP rights in the field of agriculture and nutrition³.

The human rights that are often invoked against certain IP rights are enshrined in such classical documents as the UN Universal Declaration of Human Rights (UDHR) of 1948 and the UN International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1966. The human right to health is encompassed in a rather broad article of the Universal Declaration: “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”⁴. The International Covenant gives a more specific formulation: “The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”⁵. Rights to participate in cultural life and to share in the benefits of the advance of science are also formulated in both human rights documents. Thus the Universal Declaration states in article 27.1: “Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits”⁶. However, the tenor of this paragraph seems to be counterbalanced by the very next paragraph: “Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”⁷. This might be seen as providing a justification for IP rights as themselves based in fundamental human rights, thus creating a (potential) tension with the human rights of participation and sharing that are stated in the first paragraph. The same tension recurs in the International Covenant: “The States Parties to the present Covenant recognize the right of everyone: (a) To take part in cultural life; (b) To enjoy the benefits of scientific

¹ World Intellectual Property Organization (2005) 17.

² RSA (2006)

³ De Schutter (2009)

⁴ Universal Declaration on Human Rights, 25.1 (1948).

⁵ International Covenant on Economic, Social and Cultural Rights, 12.1 (1966).

⁶ Universal Declaration on Human Rights, 27.1 (1948).

⁷ Universal Declaration on Human Rights, 27.2 (1948).

progress and its applications; (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”⁸.

To escape from the legal deadlock in which one set of human rights might seem to negate another set of human rights, the precise status of IP rights definitely needs to be clarified. Some would argue that such rights must indeed be recognized as fully-fledged human rights, even to the point of overriding any possible claim of patients to have access to essential medicines⁹. However, in 2005 the Committee on Economic, Social and Cultural Rights issued an interpretative comment which cautioned against equating the human right recognized in ICESCR 15.1.c (and in UDHR 27.2) with intellectual property rights as defined in national laws and international agreements. According to the Committee, human rights are “fundamental, inalienable and universal entitlements belonging to individuals and, under some circumstances, groups of individuals and communities”, whereas IP rights are “first and foremost means by which States seek to provide incentives for inventiveness and creativity” and IP regimes “primarily protect business and corporate interests and investments”¹⁰. In short, it would be wrong to grant legally recognized IP rights the full dignity of basic human rights¹¹.

The awareness that IP rights might sometimes clash with basic human rights such as the right to health and the derivative right of access to essential medicines is of fairly recent origin. It is apparent that the issue of a potential conflict was not foremost on the minds of those who were involved in the formulation of the international human rights charters. This general lack of awareness can be attributed in part to the so-called “Westphalian assumption” that it is the national government of each and every country which is primarily responsible for the protection of the human rights of its citizens. Although increasingly contested in recent years, this assumption has been the dominant and often taken-for-granted axiom in international affairs throughout the entire United Nations period. Moreover, before the conclusion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994 as part of the overall WTO package, the design of national intellectual property laws was largely left to the needs, desires and insights of the government of each country. Thus, for example, national governments could, if they wished, exclude pharmaceutical products from patent protection. All of this changed with the arrival of the TRIPS agreement, which imposes relatively high minimum standards of protection for intellectual property rights on all WTO member states. The TRIPS agreement mandates for example that, with few exceptions, “... patents shall be available for any inventions, whether products or processes, in all fields of technology”¹². Countries like India and Brazil that had previously excluded patents for pharmaceutical products (allowing patents on pharmaceutical processes only), were obliged to introduce new legislation by 2005 to allow the patenting of pharmaceuticals (Brazil complied with this requirement already in 1996, India in 2005). More generally, TRIPS created for the first time a *de facto* global IP regime. Only after the establishment of such an international system of protection of intellectual property rights could concerns about human rights and *global justice* vis-à-vis patents and other forms of intellectual property be sufficiently elaborated. A new institutional arrangement on a global scale was needed for such concerns to attain

⁸ International Covenant on Economic, Social and Cultural Rights, 15.1 (1966).

⁹ Cass (2009)

¹⁰ UN Committee on Economic, Social and Cultural Rights (2006)

¹¹ See also Chapman (2009); for a criticism of the Committee’s interpretative comment, see Millum (2008).

¹² Agreement on Trade-Related Aspects of Intellectual Property Rights, 27.1 (1994).

more articulation and a sharper focus. However, it would take some time before these concerns assumed more definite shape.

As a preliminary to the subsequent discussion, we will set out the very useful threefold perspective that has been introduced by the American philosopher Matthew Wayne DeCamp for the ethical scrutiny of IP systems. Any system for the protection of intellectual property rights or IP regime, DeCamp points out, has three main kinds of distributive effects. It will determine or influence: (a) the *types of objects* that will be developed and for which IPRs will be sought; (b) the differential *access* various people will have to these objects; (c) the *distribution of the IPRs themselves* among various actors¹³. Because of these distributive effects, any IP regime can be judged from the angle of (distributive) justice. The claim that it is simply the purpose of an IP system to maximize innovation does not provide an exemption from ethical evaluation, as no regime is distributionally neutral. As we have at present a global IP regime, or at least the incipient forms of a global regime, the relevant standards of judgment must be derived from a credible conception of *global justice*.

There are diverging views on global justice, but a common ground between the most important views is a shared recognition of the importance of *basic human rights*¹⁴. This means that we can pragmatically use internationally recognized and codified human rights (as defined in UDHR and ICESCR) as a proxy criterion for assessing IP systems in terms of their compatibility with global justice. When discussing pharmaceutical patents, for instance, we would obviously want to refer to the human right to health as codified in UDHR 25.1 and ICESCR 12.1, and the derived human right of access to essential medicines. A relevant distributive effect of the current international IP system relates to the prices of the lifesaving drugs it generates, and hence their affordability for various categories of patients. This effect concerns DeCamp's second dimension (b). But we could also wonder what type of innovations will be promoted by the present system: will it primarily stimulate the development of lifestyle drugs like Viagra and remedies against baldness or rather encourage the development of medicines for conditions that afflict the lives of the global poor? This question refers to DeCamp's first dimension (a). This distributive effect is also a hot issue in the international debate on pharmaceutical patents and access to essential medicines. What is often overlooked in the debate, however, is the relevance of DeCamp's third dimension, the distribution of the IPRs themselves. When the IP system functions in such a way that almost all exclusive rights end up in the hands of a few big multinational corporations headquartered in western countries, such an outcome might also be problematic from a global justice angle, even if the performance of the IP system on the two other dimensions were fully satisfactory. Here, other basic human rights beyond the right to health may be at stake, such as the right to take part in cultural life and to share in the advancement of science. Concerns about capacity building can also be subsumed under this rubric.

The TRIPS Agreement and the HIV/AIDS crisis

The TRIPS Agreement was the culmination of years of intensive lobbying by a (predominantly US) coalition of business firms in such IP-intensive industries as pharmaceuticals, software, agricultural chemicals and biotechnology, and the music and movie sector¹⁵. In the early 1980s Pfizer's CEO Edmund Pratt was a key

¹³ DeCamp (2007) 50f. and 315-317.

¹⁴ DeCamp, *ibid.*, 253.

¹⁵ See Drahos and Braithwaite (2003), and Sell and Prakash (2004).

figure in building this coalition. The very notion of ‘intellectual property’ was instrumental in bringing the interests of patent holders (e.g. the pharmaceutical industry) and copyright holders (e.g. the music and movie industry) together under one umbrella¹⁶. The IP coalition thundered against what it considered the “theft” of US-owned intellectual “property” abroad. The unauthorized copying of Hollywood movies and the production of generic equivalents of patented medicines, even if perfectly legal according to foreign laws, were labeled as “piracy” and “stealing from the mind”. The IP coalition used its privileged access to policymakers to institute policies destined to end such practices. By threatening trade retaliations (denying access to the American market), the US government brought enormous pressure to bear on recalcitrant foreign countries that showed insufficient respect for IPRs, in the end more or less forcing them to accept the terms of the TRIPS Agreement. For the IP coalition the insertion of the protection of intellectual property into the WTO framework was of strategic importance, as it would allow sanctioning non-compliant countries with punitive damages. Thus the TRIPS Agreement has real teeth. No wonder then that a leading figure in the pro-IP business coalition, Jacques Gorlin, could declare: “we got 95% of what we wanted”¹⁷. The remaining 5% that they did not get relate to the transition period that the TRIPS Agreement granted to developing countries for introducing product patents for pharmaceuticals and the perhaps somewhat ambiguously defined options for compulsory licensing that the agreement still retained (in articles 30 and 31), a crucial element of the so-called “TRIPS flexibilities” (ibid.).

Ethical judgments about the TRIPS Agreement vary. Bruce Lehman, president of the International Intellectual Property Institute and commissioner of the US Patent and Trademark Office during the Clinton Administration, holds that “the TRIPS Agreement was intended to create a more equitable system of international trade”¹⁸. The philosopher Thomas Pogge, by contrast, arrives at a strongly negative judgment: “The TRIPS Agreement and its imposition are plainly unjust and will, in terms of the magnitude of harm caused, number among the largest human rights violations in history”¹⁹. No less critical is economist Joseph Stiglitz: “When the trade ministers signed the TRIPS agreement in Marrakesh in the spring of 1994, they were in effect signing the death warrants on thousands of people in sub-Saharan Africa and elsewhere in the developing countries”²⁰.

It was the worldwide HIV/AIDS crisis that would put the TRIPS Agreement to a severe test in the years around the turn of the millennium. There is no cure for HIV/AIDS, but in 1996 medical researchers discovered that the progressive advance of the disease could be effectively controlled by a combination treatment of three different antiretroviral (ARV) drugs. The annual cost of the use of the three patented medicines together would be between 10,000 and 15,000 US dollars per patient. Such costs could perhaps be affordable in wealthy countries with robust health insurance systems, but would surely be out of reach for developing countries. In 1997 South Africa passed a new Medicines Act, which would allow the Minister of Health to initiate compulsory licensing or parallel importation of HIV/AIDS drugs. Thereupon 40 international pharmaceutical companies (and the Pharmaceutical Manufacturers Association of South Africa) filed a lawsuit against the South African government, claiming that the new law breached the TRIPS Agreement and even the constitution of the Republic of South Africa. The US government exerted additional pressure by placing the country on the so-called “Section

¹⁶ Kapczynski (2008).

¹⁷ Sell and Prakash (2004) 160.

¹⁸ Lehman (2003) 6.

¹⁹ Pogge (2008) 76.

²⁰ Stiglitz (2008) 1701.

301 Watch List” (enumerating countries that “misbehave” in the IP area as potential targets for retaliatory measures). The European Union also increased the diplomatic pressure. The initiative of Big Pharma led to a strong backlash, however, after HIV/AIDS activists mobilized international public opinion against the lawsuit, which turned into a PR nightmare for the pharmaceutical companies. It also caused the US and EU authorities to withdraw their support²¹.

A decisive turning point in the evolving drama occurred in January 2001, when the Indian generics manufacturer Cipla offered to sell the triple-therapy cocktail to Médecins Sans Frontières for 350 US dollars per patient per year²²: “Cipla’s dramatic price reduction, which received widespread media attention, hammered the message home that the multinational drug companies were abusing their monopolistic position in the face of a catastrophic human disaster. It also focused attention on the effects of generic competition in bringing drug prices down”²³. In April 2001, the pharmaceutical companies dropped their lawsuit against the South African government. The same month UN Secretary-General Kofi Annan announced the creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria. The price drop also led the international policy-makers to change course: earlier they had approved the use of donor funds only for prevention, but not for treatment²⁴.

Finally, in November 2001 the WTO Ministerial Conference assembled in Doha, Qatar issued the famous Declaration on the TRIPS Agreement and Public Health (or Doha Declaration), stating 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*” (our italics). This was at least an ideological victory for the access-to-medicines campaign waged by MSF, Oxfam and several other organizations. Unfortunately, it did not mean that in actual practice developing countries would henceforth be free to use the “TRIPS flexibilities” such as compulsory licensing to the full without having to fear any retaliations from more powerful countries.

Access to medicines: a contested terrain

The worldwide HIV/AIDS crisis has brought the problem of access to life-saving medicines into sharp relief, much to the dismay of the (non-generic) pharmaceutical industry. Drug companies resent the one-sided focus on patents and high drug prices as a major obstacle to access. A more impartial investigation of the situation in developing countries, they insist, would show that access to medicines is actually impeded by a great variety of factors, such as lack of an adequate infrastructure, lack of well-equipped hospitals, lack of well-trained doctors, nurses and pharmacists, lack of clean water and adequate storage capacity, lack of good governance, and so on and so forth – in short, an endless array of factors that can be summed up in the one underlying factor of extreme poverty. Thus the international pharmaceutical industry holds that it is inappropriate and unfair to concentrate on intellectual property protection as if this were the single or decisive factor impeding access to essential medicines. A report issued by the International Intellectual Property Institute (IIPI) in 2000 even stated categorically that “the intellectual property rights and the TRIPS Agreement are not, in themselves, impediments

²¹ ‘t Hoen (2009) 21.

²² see Sell and Prakash (2004) 162, and Love (2009) 17.

²³ ‘t Hoen (2009) 25.

²⁴ Love (2009) 16f.

to the availability of HIV/AIDS therapies in sub-Saharan Africa”²⁵; the focus on patents tended to divert attention away from the “real factors” constraining the availability of and access to drugs in this region. The position that patents do not constitute a major obstacle for access to essential HIV/AIDS drugs in sub-Saharan Africa was further elaborated in an academic article by Amir Attaran and Lee Gillespie-White²⁶; Amir Attaran²⁷ put the argument in the general form that patents do not impede access to essential medicines for all sorts of diseases in the developing world as a whole. However, the methodological assumptions of this work have been severely criticized by NGOs involved in access-to-medicines campaigns²⁸.

In debates on access to medicines, representatives of the non-generic pharmaceutical industry constantly reiterate their mantra that the big problem is not patents but poverty²⁹. Yet there is something disingenuous about this way of framing the problem. By blaming lack of access on the root cause of poverty and arguing that an effective solution should address the “real factors” underlying the problem, the proponents of Big Pharma turn the critical spotlight away from their intellectual property rights. It is an easy way to get off the hook, as no one would contest the desirability of more aid and assistance to tackle global poverty – least of all the NGOs campaigning for greater access to medicines. There are indeed more barriers impeding access, but that would be no excuse not to clear the one particular barrier making patented medicines so expensive as to be unaffordable for poor patients and poor countries³⁰. As a number of NGOs declared in response to the Big Pharma position: “We agree that donor aid is extremely important, and continue our work to advocate for such aid. But it is entirely irrational, and in our opinion, deeply cynical, to pit donor aid against efforts to overcome patent barriers. Everything possible needs to be done. Every barrier for cheaper medicine needs to be removed”³¹.

By robustly protecting their global intellectual property rights and insisting that access to essential medicines should be ensured by increased donor aid rather than by lowering their prices and/or licensing generic manufacturers, pharmaceutical companies effectively shift the burden of solving the access problem onto governments and international donor funds. This approach is vehemently defended by the president of the International Intellectual Property Institute, Bruce Lehman. Thus after first extolling the stimulating effect of the patent system on the development of new medicines, Lehman refuses to blame the same system for the high drug prices: “None of the new drugs in the pipeline, much less the 74 medicines that already have caused deaths from AIDS to plummet in the United States, would have come into existence without the patent incentive and the prospect of a return on investment provided by that incentive. This is not to dismiss the fact that many patients in the world cannot pay for these drugs and do not have access to them. *However, this is not the result of the patent system.* It is the result of lack of a source of funding for the purchase of drugs for those currently too poor to buy them themselves”³². In other words, high prices for patented drugs are apparently an inevitable fact of nature. Lack of access of the world’s poor to such medicines can only be remedied if governments or donor funds are willing to pay the full price for them. Lehman would not be appreciative at all if donor funds like the Global

²⁵ International Intellectual Property Institute (2000) 54.

²⁶ Attaran and Gillespie-White (2001)

²⁷ Attaran (2004)

²⁸ Consumer Project on Technology et al. (2001)

²⁹ Leisinger (2009) 7f.

³⁰ Sell (2007) 45-47.

³¹ Consumer Project on Technology et al. (2001)

³² Lehman (2003) 8, (our italics).

Fund used their limited budgets to purchase much cheaper generics, even if they would thereby reach many more patients³³.

The sad fact, however, is that governments or international charities may sometimes consider the prices of patented medicines prohibitively high to act as a source of funding for the poor. James Love tells us about a meeting he had in 2003 with the Director of the Office of Management and Budget (OMB) under President George W. Bush, Mitch Daniels, who declared that when prices were more than \$1,000 per year, the OMB could not justify spending money on AIDS treatment, but that when the price fell below \$1 per day, he felt they could not justify *not* spending money on AIDS medicines³⁴.

The drop in prices for antiretroviral drugs, mainly thanks to increased competition from generic manufacturers, induced US President George W. Bush in early 2003 to launch a major initiative, the Presidential Emergency Plan for AIDS Relief (PEPFAR). In his State of the Union Address of January 28, 2003, he declared:

“There are whole countries in Africa where more than one-third of the adult population carries the infection. More than four million require immediate drug treatment. Yet across that continent, only 50,000 AIDS victims – only 50,000 – are receiving the medicine they need . . . A doctor in rural South Africa describes his frustration. He says, ‘We have no medicines . . . many hospitals tell [people], ‘You’ve got AIDS. We can’t help you. Go home and die.’ In an age of miraculous medicines, no person should have to hear those words. AIDS can be prevented. Anti-retroviral drugs can extend life for many years. And the cost of those drugs has dropped from \$12,000 a year to under \$300 a year, which places a tremendous possibility within our grasp [T]onight I propose the Emergency Plan for AIDS Relief – a work of mercy beyond all current international efforts to help the people of Africa. . . . I ask the Congress to commit \$15 billion over the next five years, including nearly \$10 billion in new money, to turn the tide against AIDS in the most afflicted nations of Africa and the Caribbean.”³⁵

For all its generosity the PEPFAR initiative would have been unthinkable were it not for the inroads made by generic manufacturers on the patent monopolies of the world’s leading drug companies. In his address to the nation Bush implicitly affirmed the universal right to health and the derivative right of access to essential medicines (note the line: “In an age of miraculous medicines, no person should have to hear those words”). So, for once, the US president did not put patents before patients. His stance represented a remarkable departure from the “patents-are-sacrosanct” position usually adopted by the pharmaceutical industry and also, most of the time, by the US government.

The general thrust of US trade policy during the last fifteen years or so has been to aggressively defend the global IP interests of the pharmaceutical industry. The American government has concluded several bilateral and regional trade agreements containing so-called “TRIPS-plus” provisions aimed at eliminating the “flexibilities” of the TRIPS Agreement and it has also exerted heavy economic and political pressure on Third World countries intent on using these same “flexibilities” (e.g. compulsory licensing) for the sake of protecting public health or

³³ Lehman, *idem.*, 10.

³⁴ Love (2009) 18 n. 36.

³⁵ Bush (2003)

promoting access to medicines for all³⁶. A case in point is the US response to the decisions taken by the Thai government in 2006 and 2007 to issue compulsory licenses for the production of the first-line AIDS drug efavirenz (Stocrin), the second-line AIDS drug lopinavir/ritonavir (Kaletra) and the antiplatelet drug clopidogrel (Plavix), patented respectively by Merck Sharp & Dohme (the UK subsidiary of the US firm Merck), the US firm Abbott and the European company Sanofi-Aventis. Although these decisions were fully in line with the TRIPS Agreement (as reaffirmed by the Doha Declaration), they were branded by the international pharmaceutical industry as illegal appropriations of private-sector property³⁷. US and European ambassadors signaled their strong disapproval of the compulsory licenses to the Thai government. Abbott retaliated by announcing to withdraw all applications to register its new drugs in Thailand. The US Trade Representative placed Thailand under the Special 301 “Priority Watch List Surveillance” and threatened to terminate Thailand’s privileges to export to the US market. According to some legal experts, however, it is not the Thai government’s resort to compulsory licensing, but the contemplated US reprisal against Thailand that is in contravention of international law³⁸.

In its conflict with the US government and pharmaceutical companies, Thailand received support from an unsuspected quarter, namely from Bill Clinton. Accompanying the Thai minister of health during her visit to New York in May 2007, the former US president defended Thailand’s decision to issue compulsory licenses: “No company will live or die because of high price premiums for AIDS drugs in middle-income countries, but patients may”³⁹. For Clinton, affordable drug prices were a life-and-death issue. Since 2002 the William J. Clinton Foundation had been active in making first-line AIDS medicines available to the needy in Africa and elsewhere by striking advantageous deals with generic manufacturers. The relative success of this program created a new financial burden because part of the patients who have been kept alive develop resistance to the first-line drugs and need to be treated by the newer and much more costly second-line AIDS drugs. Typically, patented brand-name versions of the latter are more than 10 times as expensive as the first-line generic drugs, thus causing an enormous strain on the health-care budget. The Clinton Foundation therefore struck new deals with the Indian manufacturers Cipla and Matrix to provide generic versions of second-line AIDS drugs at greatly reduced prices, with average savings of 50 percent in middle-income countries like Thailand. Needless to say that Clinton’s initiative was not welcomed by the big multinational drug companies and the US government, but their demurrals did not deter him. He criticized Abbott’s “hard-line position” over what he considered to be “a life and death matter”⁴⁰.

The human rights obligations of pharmaceutical companies

While states have the primary responsibility for realizing the human right to health and increasing access to medicines, other national and international actors, including private business firms, also share in this responsibility. Although pharmaceutical companies normally have extensive Corporate Social Responsibility (CSR) policies in place and often subscribe to the loftiest humanitarian aims in their mission statements

³⁶ Sell (2007)

³⁷ Limpananont and Kijtiwatchakul (2010) 442.

³⁸ Reichman (2009) 256.

³⁹ Bill Clinton quoted by Dugger (2007).

⁴⁰ Bill Clinton quoted by Osborne (2007).

(typically placing the relief of human suffering before profits), they generally do not want to be strictly held to account with regard to more specific commitments and obligations.

When the previous UN Special Rapporteur on the right to health, Dr. Paul Hunt, undertook to create more clarity on the human rights obligations of drug companies in relation to access to medicines, he found few firms that were ready to participate in the consultation process and his draft and final guidelines met with negative comments from the pharmaceutical industry⁴¹. The drug firms felt that the human rights obligations that had conventionally been placed on the nation state (and the international community) were illegitimately shifted onto their shoulders, and they rejected this move: “Most companies will argue that it is not their role to step in when those first in line of responsibility fail to perform their duty”⁴². Let us have a closer look at Hunt’s guidelines to see whether or to what extent this response is warranted.

Hunt’s definitive list contains no less than 47 guidelines, grouped into 14 themes. Some of the guidelines refer to such general requirements as the need for transparency, monitoring and accountability. It is further held imperative that companies disclose all their advocacy and lobbying activities and their attempts to influence public policy (guidelines 17 and 18). Companies are also called upon to respect the letter and spirit of the Doha Declaration (guideline 27) and not to impede those states that wish to use the flexibilities of the TRIPS Agreement (guideline 28). There are also interesting requirements on licensing and pricing. Thus drug companies “should issue non-exclusive voluntary licenses with a view to increasing access, in low-income and middle-income countries, to all medicines” (guideline 30). With a view to ensuring that a company’s medicines are affordable to as many people as possible, the former UN Special Rapporteur suggests that it should adopt differential pricing between countries and within countries (guideline 33), charging lower prices in poorer countries and for poorer patients and communities. Drug companies should also do more research and development on neglected diseases and make public commitments in this respect (guideline 23). Hunt recognizes that drug companies also have a responsibility to enhance shareholder value (preamble) and thus are no charities, but he insists that they should do everything they reasonably can to help realize the human right to health: “The seminal right-to-health responsibility is to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need, within a viable business model”⁴³. Moreover, companies have to make themselves accountable in this regard by having their efforts to enhance access to medicines monitored and reviewed by independent agencies.

While working on the guidelines, Hunt also undertook a mission in 2008 to the headquarters of the UK-based drug firm GlaxoSmithKline (GSK) to interview several senior managers on the company’s policy with regard to access to medicines. GSK is widely recognized as a strong exponent of Corporate Social Responsibility policies within the pharmaceutical industry. In 2008 it ranked first on Access to Medicine Index and in 2010 it came out on top again. As GSK’s policy might be considered as constituting ‘best practice’ in this area, Hunt’s findings are particularly interesting⁴⁴. While he thinks some aspects of GSK policy are indeed admirable and commendable, he still concludes that across the board the company fails to live up to its human rights

⁴¹ See Hunt (2008) and Hunt and Khosla (2010).

⁴² Leisinger (2009) 10f.

⁴³ Hunt and Khosla (2010) 2.

⁴⁴ Hunt (2009)

obligations. GSK does quite a lot of research on so-called “neglected diseases” with special relevance to developing countries. The company also has made a commitment to offer its antiretrovirals and anti-malarial treatments to least-developed countries and all of sub-Saharan Africa at not-for-profit prices (which cover costs including insurance and freight). These price reductions are in line with GSK’s right-to-health responsibilities, but Hunt observes that they have been forced by competition from generic producers: “Crucially, generic competition played a vital role in driving down these prices. In most cases, generic companies have pushed their prices below the NFP [not-for-profit] prices of innovator companies”⁴⁵. The former UN Special Rapporteur also notes that the price of GSK’s HPV (human papilloma virus) vaccine against cervical cancer, Cervarix, remains so high (US \$ 300) as to be beyond the reach of most people in developing countries.⁴⁶ Although GSK grants licenses for some of its products in some markets, Hunt holds that the company is too reluctant to use this instrument and that it should enter into voluntary licensing (both commercial and non-commercial) on a much wider scale across a range of medicines and markets. GSK has also experimented with a new marketing approach of differential pricing between countries and within countries. This approach would hold much interest and promise, Hunt remarks in his report, if it could be extended considerably beyond its present far too modest scale. Hunt is also critical of GSK’s lobbying activities to discourage the full use of the TRIPS flexibilities by countries like India, Indonesia and the Philippines and its support for the inclusion of “TRIPS-plus” provisions in bilateral and regional free trade agreements. Finally, the company has not lived up to standards of accountability by failing to provide for external review of its *Corporate Accountability Report* for 2008.

Hunt’s recommendations (not to say prescriptions) to GSK and the pharmaceutical industry in general are based on the assumption that drug firms have definite human rights obligations in relation to access to medicines. It is precisely this assumption that is bluntly rejected by the pharmaceutical industry. In this regard GSK’s response to Hunt’s report on the company’s policies is highly significant: “The ‘right to health’ is an important issue, though not well defined, especially as it relates to non-state actors. Therefore we do not accept the suggestion – implicit in the development of this Report – that GSK’s programme and ongoing commitment is in any way required by international legal norms, whether in the human rights or other areas.”⁴⁷. In other words, the company prefers to see its Corporate Social Responsibility policies as “good works” that are supererogatory and

⁴⁵ Hunt (2009) 18.

⁴⁶ Hunt states in his report: “As a patent holder of a life-saving medicine, GSK has a right-to-health responsibility to do all it reasonably can to put in place, as a matter of urgency, mechanisms that enhance access to Cervarix in middle-income and low-income countries [...]”, Hunt (2009) 18. However, beyond being financially unaffordable, Cervarix is also not the most appropriate HPV vaccine for use in developing countries. The same holds for the other HPV vaccine that is currently on the market, Merck’s Gardasil. Both vaccines have actually been designed and developed with a view to be used in developed countries. They are expensive to produce; require refrigeration and a cold chain for storage; they require delivery by intramuscular injection in three doses over a six-month period; they work against HPV16 and HPV18, but not against virus variants such as HPV35 that are more prevalent in sub-Saharan Africa; they may be less effective in women with other infections (like HIV); their ideal target group is females in early adolescence, but this may make them culturally inappropriate in some developing countries. For all these reasons, Cervarix and Gardasil are not optimally designed for use in developing countries, despite the fact that more appropriate alternative options would have been possible, see Intemann and de Melo-Martín (2010). Thus, these two HPV vaccines not only illustrate the problem of access to existing medicines or vaccines due to their high prices, but also show the biased orientation of the global R&D effort towards the demands of affluent markets. It is not just that HPV vaccines are “largely unaffordable where [they are] most needed”, Hunt (2009) 18; as Hunt notes, but *appropriate* forms of HPV vaccines are not even *available* where they would be most needed.

⁴⁷ GlaxoSmithKline (2009)

not required by international legal norms. The implication is that a pharmaceutical company cannot be held to account for not living up to any alleged human rights obligations in relation to access to medicines.

GSK's position is in fact representative for the entire pharmaceutical industry. The editors of *PLoS Medicine* argue that pharmaceutical companies "blunt their own responsibilities by instead emphasizing their corporate social responsibility initiatives" and that by persistently claiming that "the primary responsibility for delivering the right to health lies with the State" the industry allows "to exculpate itself from its own human rights responsibilities"⁴⁸. Business ethicist Richard De George also points out that the Corporate Social Responsibility initiatives in which pharmaceutical companies engage seem to imply that they are not to be held accountable for failing to live up to any commitments: "In their various programs, many pharmaceutical companies give a variety of drugs away free to the needy, be they AIDS victims in Africa or poor people in the United States. These are most often presented as meeting part of the company's social responsibility. So framed, it sounds as if these are voluntary, non-obligatory programs that the companies adopt as good citizens or through their philanthropic foundations. They might be considered supererogatory, or good works that are not required, and ones for which they deserve praise; but failure to engage in them would deserve no blame. This approach puts the actions of pharmaceutical companies in the realm of charity, and portrays them as generous and caring"⁴⁹. The language of social responsibility, he also observes, "carries with it no non-self imposed obligations and so no broader accountability beyond what the company defines its responsibility to be"⁵⁰.

Pharmaceutical companies often cite the reduced prices for antiretrovirals or other essential medicines that they charge in developing countries, or their willingness to engage in differential pricing schemes on a case-by case basis⁵¹, as proof of their good intentions to help enhance access to medicines. It is doubtful, however, whether such price reductions are always of an entirely voluntary nature. In many cases, as Paul Hunt also pointed out in his report on GSK, prices have been driven down by increased competition from generic producers and pharmaceutical companies were simply forced to follow suit (although Hunt noted that GSK's not-for-profit prices were still above the prices of generic versions). It might be naïve to expect that drug companies would introduce drastic price reductions entirely on their own accord, without being pressed to do so by strong external forces. In their study of Brazil's successful policy of securing access to low-cost AIDS medication, William Flanagan and Gail Whiteman also show that pharmaceutical companies were only willing to concede drastic price reductions in the face of strong pressure from NGOs and especially from the Brazilian government, which credibly used the threat of compulsory licensing. They conclude: "Action undertaken in terms of voluntary CSR alone may be insufficient"⁵².

In view of the fact that pharmaceutical companies generally reject the notion that they have definite obligations flowing from the human right to health and that their CSR initiatives are often just a reaction to NGO campaigns and other external pressures, it would seem that a direct moral appeal to their sense of social responsibility is not the best approach to realize global justice with regard to access to and availability of medicines. One may also insist that "all pharmaceutical companies have a responsibility to take reasonable measures to redress the historic

⁴⁸ PLoS Medicine Editors (2010)

⁴⁹ De George (2005) 557f.

⁵⁰ De George, *idem.*, 557.

⁵¹ Leisinger (2009)

⁵² Flanagan and Whiteman (2007) 65.

neglect of poverty-related diseases”⁵³, and it would of course be nice if companies would do more research on “neglected diseases”, but this moral appeal remains rather futile as long as the profit opportunities of wealthy markets exercise a powerful pull in the contrary direction. It might be too much to expect that companies, which also have a responsibility to enhance shareholder value, would resist this pull.⁵⁴ In short, a more structural approach may be called for.

Thomas Pogge and the Health Impact Fund

The German philosopher Thomas Pogge has thought long and hard about the working of the international patent system from the perspective of global justice. He is also concerned about the human right to health, but he thinks it is inappropriate and unhelpful to assign the responsibility for realizing this right to national states or to individual business enterprises. Instead, he holds that this right is to be secured by a just global institutional order. Pogge also holds that the right of access to essential medicines, as a derivative of the right to health, not only demands that existing essential medicines are accessible to all, but also that a fair allocation of research efforts ensures that work is being done on the right kind of diseases (e.g. also for life-threatening diseases that are currently being “neglected” due to lack of profitable markets). Thus Pogge pays special attention to the first two distributive effects of IP systems distinguished by DeCamp: (a) the *types of objects* that will be developed and for which IPRs will be sought; and (b) the differential *access* various people will have to these objects⁵⁵. What is more, Pogge holds that any attempt to re-design the international patent system according to principles of global justice has to deal with these two dimensions together and to solve the twin problems of availability and access *simultaneously*. Any solution alleviating the one problem at the expense of aggravating the other must be avoided.

Pogge starts with a fairly conventional economic analysis of the role of patents. Patents are intended to address a well-known “market failure”, namely the lack or insufficiency of innovative activities on the part of firms in the absence of legal protection for the results of their efforts. If any inventions could be easily copied by “free riders”, firms would not be able to recoup the expenses incurred in their innovative efforts and would therefore have no incentive to engage in such pursuits in the first place. The patent system helps to overcome this problem by providing the inventor a temporary monopoly on the use of the invention for which he is granted a patent, currently for a period of 20 years from the date of filing the patent application. This amounts in effect to solving one “market failure” (the undersupply of innovations) by creating another “market failure”⁵⁶. As any economics textbook explains, a monopoly will lead to a static inefficiency or welfare loss that is known as a “deadweight loss”. A patent on a drug allows the patent holder to charge what the market will bear, that is, to set the price at the level where his profits will be maximized. Because the monopoly price is so much higher than the marginal cost price, this will prevent transactions with all those potential users who are able and willing to pay more than the marginal cost but not the full monopoly price of the patented medicine. Some quantitative calculations indicate that the deadweight loss in the US pharma market may be no less than 60 percent of sales revenues and

⁵³ Hunt (2009) 23.

⁵⁴ Here is a concise expression of this viewpoint: “Pharmaceutical companies prosper by catering to the affluent; and they would be violating their responsibilities to their shareholders if they purposefully served poor patients at the expense of their bottom line.” Hollis and Pogge (2010) 12.

⁵⁵ See DeCamp (2007) 50f.

⁵⁶ Pogge (2005) 186.

that the relative share in developing country markets may be even higher⁵⁷ – thus it is clear that, simply in economic terms, enormous amounts are involved. In the case of patents for essential, life-saving medicines, this “market failure” leads to morally unacceptable situations, as deadweight losses in economic terms translate here to dead bodies in human terms.

In theory, the deadweight loss of a monopoly could be mitigated or even overcome if the monopolist were able to charge different prices for different customers, according to their respective ability and willingness to pay, instead of charging a single price for all customers. This solution requires that the monopolist can differentiate his customers into different “classes” and also that any re-sale of the product between these different “classes” can be prevented – conditions that in practice may be extremely hard to fulfill⁵⁸. Nonetheless, we have seen that the former UN Special Rapporteur on the right to health, Paul Hunt, strongly urged pharmaceutical companies to use differential pricing schemes, both between and within countries, on a wide scale in order to fulfill their human rights responsibilities. Some drug firms have indeed made modest attempts in this direction (examples are GSK and Novartis), but most are very reluctant to engage in deliberate price differentiation at all for fear of spoiling their markets in affluent countries. It is not just that they are afraid that medicines will be diverted from low-price markets in poor countries to high-price markets in rich countries. It is also because of the practice of *reference pricing*: “some high-income and middle-income countries try to use, as benchmarks for the prices at which they buy, the preferential prices offered to low-income countries”⁵⁹. For all these reasons Pogge concludes that differential pricing is not a workable solution to the deadweight-loss problem, or in other words, to the problem of access to essential medicines⁶⁰. He also holds that it is unreasonable to expect drug companies “to systematically lower prices in developing countries on the basis of altruism”⁶¹. In his eyes it is even unfair to impose such a requirement on the pharmaceutical industry “when other industries (which do nothing for poor people) have no such expectations placed on them” (ibid.).

It thus becomes apparent that Pogge does not wish to go along with all those NGOs that relentlessly continue to press pharmaceutical companies to lower their prices in developing countries ever further in the belief that this is the right way to proceed in the search for solutions to global health problems. He also highlights the limitations of compulsory licenses, noting not only the fierce opposition of the pharmaceutical industry and the risk of political retaliation but also pointing out that their widespread use might undermine the incentivizing effect of patents: “But [...] compulsory licensing, especially if it were to become more common, brings back the first market failure of undersupply: Pharmaceutical companies will tend to spend less on the quest for essential drugs when the uncertainty of success is compounded by the additional unpredictability of whether and to what extent they will be allowed to recoup their investments through undisturbed use of their monopoly pricing powers”⁶². It is almost as if we hear the well-known mantras of the pharmaceutical industry. Drug firms also tend to emphasize that it is incorrect to look at the prices of patented medicines only from a static point of view. After all, patents are temporary monopolies that are precisely intended as incentives to stimulate the search for new

⁵⁷ Grootendorst (2009)

⁵⁸ Lipsey and Steiner (1972) 258-263.

⁵⁹ See Hunt (2009) 16 and also Hollis and Pogge (2008) 85.

⁶⁰ See Pogge (2005) 187 and Hollis and Pogge (2008) 98f.

⁶¹ Hollis and Pogge (2008) 95.

⁶² Pogge (2005)188 and see also Hollis and Pogge (2008) 99f.

medicines. No patents, no innovation. Higher prices in the present (until the competition of generics after the expiration of the patent brings them down), the industry argues, are simply the “price” we all have to pay to enjoy the fruits of progress. A substantial erosion of price margins might well endanger pharmaceutical innovation.

Pogge agrees that one should not consider the problem exclusively from the point of view of static efficiency but also take into account the dynamic role of the patent system to foster innovation. In so far he subscribes to the industry position. However, one cannot simply trade off static efficiency (wide access to existing medicines) against dynamic efficiency (innovation). Pogge insists that access to essential medicines is a human right that is to be secured by a just international system. This human right cannot be sacrificed on the altar of pharmaceutical innovation. Even more, when looked at from a dynamic perspective, the international patent system does not meet the requirements of global justice either: it generates innovations, indeed, but it does not generate the right kind of innovations. As financial incentives, patents operate by orienting research towards the needs of the wealthy and the affluent, that is, those who exercise effective demand backed up by purchasing power, and not towards the needs of the poor and needy who are unable to do so. The result is an enormously skewed distribution of the global pharmaceutical research effort. The well-known “10/90 gap” illustrates this effect: “Only 10 percent of global health research is devoted to conditions that account for 90 percent of the global disease burden”⁶³. There are therefore many “neglected” diseases, especially in the Tropics, which fail to receive adequate attention from the international research community.⁶⁴

Pogge concludes that any proposal for a re-design of the international patent system in the field of medicines has to solve the access problem (cf. deadweight loss) and the availability problem (cf. the 10/90 gap) simultaneously. He has proposed his own institutional solution for dealing with these two problems, the so-called *Health Impact Fund*, which has been further elaborated with the help of economist Aidan Hollis⁶⁵. Irrespective of how one judges the merits of his reform proposal, Pogge certainly deserves credit for bringing home so clearly that these twin problems define a major part of the task-set for any attempt at institutional re-design.

In Pogge’s view, an international public fund based on obligatory contributions (mostly) from developed countries, the *Health Impact Fund*, should be established to create the possibility of rewarding pharmaceutical

⁶³ Drugs for Neglected Diseases Working Group (2001) 10.

⁶⁴ Actually, we use the notion of the “10/90 gap” as a shorthand to denote the skewed allocation of worldwide medical and pharmaceutical research effort over diseases and conditions differentially affecting various parts and populations of the globe. This stylized formula may be appropriate as a first-order indication of global imbalances, but needs to be refined in a more thorough scrutiny of the problem. The WHO’s Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) offers a more sophisticated approach. It distinguishes between *Type I diseases* (incident in both rich and poor countries, with large numbers of vulnerable population in each), *Type II diseases* (incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries), and *Type III diseases* (overwhelmingly or exclusively incident in the developing countries). Diseases that disproportionately affect developing countries would thus by definition be Type II and Type III diseases. However, this approach may be too simplistic, as some Type I diseases (like cardiovascular diseases) may be expected to rise in importance in developing countries while showing decreasing mortality rates in developed countries. As the CIPRH report rightly remarks: “The criterion should be diseases or conditions of significant public health importance in developing countries for which an *adequate* treatment does not exist for use in resource-poor settings – either because no treatment exists whatsoever, or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable” CIPRH (2006) 26.

⁶⁵ Hollis and Pogge (2008)

companies for developing essential medicines, the size of their reward being proportional to the impact of their invention on the global disease burden. In essence, the scheme means that companies are offered a choice. Once they have taken out a patent for a new drug, they can either attempt to earn money on it in the usual way by exploiting the monopoly and setting prices that affluent markets can bear, or they can choose the option of registering with the Fund and being rewarded according to a formula that is geared to the health impact of the new drug (measured in terms of QALYs, i.e. the number of quality-adjusted life years saved worldwide). In the latter case the drug will have to be made available at an administered price that is set by the Health Impact Fund to reflect average manufacturing and distribution cost. In return the registrant will receive, after market approval of the new medicine, annual reimbursements from the Fund that are proportional to the global health impact of the drug for a period of 10 years. (The absolute size of the reimbursements will be determined by the size of the Fund and the measured health impacts of the other registered products.) After this period the medicine will be freely available for generic producers. The second option would entail a different *metric of success* for the drug company. Success will not be measured then in terms of net sales to those who can afford to pay the high prices of a monopolized invention, but in terms of the reduction of the global disease burden, irrespective of the purchasing power of those who suffer from it. In this way it is hoped that the Health Impact Fund will redress the existing imbalance of availability (epitomized by the “10/90 gap”) by providing incentives that are not geared to purchasing power but to medical need. Setting an administered price at roughly the level of average manufacturing and distribution cost will ensure that the problem of access is also addressed, at least for drugs registered with the Fund.⁶⁶

According to Pogge, there is a strong moral obligation for the governments and citizens of affluent countries to support the Health Impact Fund (HIF). He holds that the citizens of affluent countries are indirectly responsible for the international institutional order which their governments have the power to impose on the entire world. In his eyes, the status quo of the TRIPS system of IP protection, which “*foreseeably* and avoidably deprive[s] human beings of secure access to the object of their human right”⁶⁷, is thoroughly unjust. Given the claim that a large part of these human rights violations *can* in principle be avoided by installing the HIF, the ethical conclusion is that they *should* be avoided: “Maintaining SQ [= the status quo] without the HIF constitutes a massive violation of the human rights of the global poor. So long as there will be poor people in this world – whether in poor or rich countries – who are unable to obtain expensive medicines still under patent, SQ will gravely harm, and kill, many of them”⁶⁸. The SQ + HIF option drastically changes the moral landscape and is even ethically preferable, in Pogge’s judgment, to a return to the pre-TRIPS era.⁶⁹

Criticism

Several commentators have questioned the political and practical feasibility of the Health Impact Fund. One critical issue is funding. The whole initiative needs initially some 6 billion dollars from governments or other contributors to take off. Will such funds really be forthcoming and can pharmaceutical companies base their long-term R&D decisions with any confidence on government pledges to provide funds over a longer period of

⁶⁶ For a detailed exposition of the whole scheme, see Hollis and Pogge (2008) and Singer and Schroeder (2010).

⁶⁷ Pogge (2005) 199.

⁶⁸ Hollis and Pogge (2008) 60.

⁶⁹ Hollis and Pogge, *idem.*, 54.

time? “Providing public funds to drug companies is unlikely to be politically popular: competing demands will always seem more urgent and desirable”⁷⁰. It has also been pointed out that the measurement procedure for assessing the impact of a new medicine on the global disease burden is rather complex, which would make the assessment vulnerable to corruption⁷¹.

In many respects the Health Impact Fund is similar to the *prize fund* that has been elaborated by James Love and others as an alternative system for rewarding pharmaceutical innovation.⁷² Love’s ideas have also inspired the legislative proposals introduced by US Representative Bernard Sanders from Vermont in 2005 and 2007 to create a Medical Innovation Prize Fund in the United States. The HIF as well as James Love’s prize fund aim to break the link between incentives for R&D and product prices, or in other words to separate the market for innovation from the product market. However, there are also important differences. Whereas the HIF allows registrants to retain their IP and only requires them to accept the price to be set at average cost as a condition for being eligible to reimbursements from the HIF, Love’s scheme would make the patented invention on registration available to generic competitors through open licensing⁷³. The consequence is that this scheme actively harnesses the forces of economic competition to bring the prices of new medicines down. Furthermore, while the HIF is a voluntary *complement* to the existing pharmaceutical innovation system, Love’s prize fund ultimately aims to become a complete *replacement*. An obvious drawback of a voluntary system like the HIF is that it would not address the access problem if the patent owner chose the traditional patent monopoly rather than the HIF option⁷⁴. Finally, Love and Pogge also strongly disagree about the role of compulsory licensing. For Love, this option continues to be vital to secure access to medicines in poor countries by relying on the potential of generic competition. Pogge, by contrast, is rather critical of this option and emphasizes that “compulsory licenses weaken the innovation incentives that were supposed to result from the extension of strong intellectual property rights into the less developed countries”⁷⁵. In Love’s view, this alleged ‘trade-off’ between innovation and access is extremely overstated as the potential demand from poor countries does not provide much of an incentive at all, with or without patent protection. Love refers to the report of the WHO’s Commission on Intellectual Property Rights, Innovation and Public Health, which concluded that strong global IP protection (without compulsory licensing) is unlikely to boost pharmaceutical research on diseases disproportionately affecting developing countries (i.e. Type II and Type III diseases), given insufficient market incentives.⁷⁶ Love fears that Pogge’s statements may readily play into the hands of patent-owning companies opposing compulsory licensing.⁷⁷

⁷⁰ Buchanan et al. (2011) 326. This lack of trust in governments’ commitments is shared by Philip Hedger, executive managing director of international affairs at Pfizer: “The sustainability of a government-funded reward system has various areas of uncertainty. Governments change, as do their objectives and their funding mandates. Totally unpredicted issues can arise, as the world is currently witnessing. These and more reasons provide plenty of opportunity for governments to review their commitments, whatever the nature of the original agreement.” quoted in Schulz (2008).

⁷¹ Sonderholm (2010)

⁷² See Love and Hubbard (2007) and see Gombe and Love (2010).

⁷³ Compare Hollis and Pogge (2008) 105f.

⁷⁴ Love and Hubbard (2007) 1535.

⁷⁵ See Hollis and Pogge (2008) 54 and also 99f.

⁷⁶ CIPIH (2006) 85

⁷⁷ Love (2008)

It is a notable feature of Pogge's reform proposal that the whole scheme still relies very strongly on the "incentivizing" effect of patents.⁷⁸ The main problem with the present patent system, in Pogge's view, is that the incentives are geared to (potential) market demand in wealthy countries that is backed up by purchasing power. The "trick" of the HIF scheme is to leverage the unmet medical needs of the South by backing them up with additional funds, so that they too carry some weight in the market pull directing pharmaceutical innovation. It is all a matter of setting the incentives "straight" – but by the same token the scheme still counts on the role of patents as incentives. In this regard Pogge's ideas are clearly out of sync with the emerging "A2K" (Access to Knowledge) movement, which radically questions the need for exclusive intellectual property rights as a condition for stimulating creativity and innovation.⁷⁹ The success of free and open-source software provides the paradigmatic example for the A2K movement: "The production process of free and open-source software is central to the imaginary of the A2K mobilization because it offers a model of collaborative, distributed innovation that does not rely on the incentivizing effect of IP rights"⁸⁰. Another plank of the "A2K" platform is that "under no circumstances can human rights be subordinated to intellectual property protection"⁸¹. The A2K movement is however concerned with a wider range of human rights than the right to health and the right of access to essential medicines that constitute the major focus of Pogge's concerns.

The pharmaceutical industry is usually seen as a sector where patents are indispensable for innovation, due to high investment costs of R&D and the relative ease to reverse engineer any resulting product. Lately, however, the presumed "incentivizing" effect of patents even for the pharma sector is increasingly called into question. For one thing, the track record of the industry over the recent period is not particularly impressive (even apart from the global imbalance epitomized in the 10/90 gap). Official figures show that in the last three decades "the productivity of the pharma R&D enterprise – the number of new molecules brought to market per dollar spent on R&D – has declined markedly"⁸². This productivity slowdown occurred in a period when new technologies like genomics, combinatorial chemistry and knock-out mice were supposed to make the drug discovery process more rapid and more efficient. The conditioned reflex of the pharma industry to a drying pipeline of new inventions is to clamor for more patent protection, but the fact of the matter is that their wishes on this score have been answered rather well during the past decades. Ironically, some hard-boiled economic analyses locate the root of the problem in the patent system itself and the very high profit margins that it generates. Grootendorst sums up the social costs that are caused by the current system of pharmaceutical innovation centered on patents: (1) the costs to the healthcare system of medication non-compliance due to higher drug prices; (2) the resources consumed in the battle over the innovator's profits; (3) the resources spent by the innovator to expand unit sales and extend patents; (4) the increased costs of pharma R&D when this R&D builds on patented upstream discoveries; (5) the distortions in research direction caused by non-patentability of certain compounds; and (6)

⁷⁸ As Singer and Schroeder explain: "The Health Impact Fund leaves intact strong incentives for the pharmaceutical industry around the globe, thereby preserving the TRIPS advantages, whilst mitigating its main challenge, namely to block access to life-saving medicines to the poor. By registering a patented medicine with the Fund, a firm would agree to sell it globally at cost. In exchange, the firm would receive, for a fixed time, payments based on the product's assessed global health impact. The arrangement would be optional and it would not diminish patent rights, it therefore aligns the interests of pharmaceutical companies with the interests of poor patients. Such a win-win situation has to be welcomed!" Singer and Schroeder (2010) 17.

⁷⁹ See Kapczynski (2008) and Kapczynski and Krikorian (2010).

⁸⁰ Kapczynski (2008) 869f.

⁸¹ Kapczynski (2008) 866.

⁸² Grootendorst (2009) 2.

the administrative costs of the patent system.⁸³ To this list can be added the unknown but most likely very considerable extent of bias and distortions in the medical literature due to widespread practices like “ghost management” and “publication planning” that result from the dominance of marketing imperatives over the research process.⁸⁴ Thus there is every reason to question Pogge’s assumption that patents are indispensable as incentives for innovation.

A broader panorama

Looking at Pogge’s ideas and proposals through the lens of the emerging A2K movement reveals some conspicuous blind spots. While concentrating his attention on the human right to health (or rather, more narrowly, on the derived human right of access to essential medicines) and on the design of a workable patent-based system that is able to address the twin problems of access to and availability of medicines, Pogge tends to ignore or dismiss other areas of science, technology and culture and other forms of intellectual property that may raise issues of global justice. There is of course no denying that access to essential medicines is extremely important, but it would be rather weird to suggest that it is the *only* issue in which basic human rights are at stake. Proponents of the A2K movement typically bring into play a wider range of human rights, as transpires from the following statement from the Adelphi Charter already quoted above: “[IP] laws must serve, and never overturn, the basic human rights to health, education, employment and cultural life”⁸⁵. The rights to participate in cultural life and scientific advancement are also enshrined in the Universal Declaration (UDHR 27.1) and other official human rights charters. Pogge’s narrow focus on the right to health may also explain why he pays no attention to what DeCamp refers to as the third distributive effect of an IP system, beyond the effects on access and availability, namely the distribution of the IPRs themselves⁸⁶. For Pogge it seems to present no particular problem of global justice when most pharmaceutical patents are possessed by a handful of western drug companies. Access to knowledge, however, is crucially about *participation* in the global networked knowledge-and-information economy. The key issue is “whether information production will be primarily centralized and proprietary or whether large parts of it should be decentralized and participatory”⁸⁷.

While Pogge may sound fairly radical when he criticizes the restrictive effects of patents on access to medicines, his judgments are rather timid when he occasionally turns to other forms of IP and to other areas of science, technology and culture. He even deems the exclusion brought about by “other categories of intellectual property (for example, software, films, and music)” perfectly “acceptable”.⁸⁸ Proponents of free and open-source software and of the A2K movement hold a different view. Brazil’s former Minister of Culture, Gilberto Gil, saw free

⁸³ Grootendorst, *idem.*, p. 32. In Grootendorst’s paper, each of these rubrics of social costs is further specified and discussed in detail. A very interesting category is the second rubric. When a patent allows very high profit margins on a certain drug, this will attract others seeking their share of the spoils. A lot of effort is simply wasted on keeping these rent-seekers at bay: “The innovator will need to spend resources fending off counterfeiters, resellers, competing drug companies (both generic and branded me-toos), and negotiating with and lobbying price regulators and drug insurers ...” (*idem.*, p. 32).

⁸⁴ Sismondo and Doucet (2010)

⁸⁵ RSA (2006)

⁸⁶ DeCamp (2007) 318.

⁸⁷ Balkin (2006)

⁸⁸ Pogge (2005) 187. The conflict between participation in scientific advancement in general and the principle behind the Health Impact Fund is further explored in Timmermann and van den Belt (2012) and Timmermann (2012).

software as central to Brazil's collective sovereignty ("a cultural question par excellence") and as an essential contribution to the promotion of skills and knowledge that will enable historically disenfranchised Brazilians to participate in various forms of cultural production such as music, design, publishing, software development and photography.⁸⁹ One could think here of the fourth category, called 'Senses, Imagination, and Thought', in Martha Nussbaum's list of central human capabilities, representing a key element of human flourishing.⁹⁰ In this connection worldwide access to educational materials and scientific publications, often effectively blocked by copyright protections, also comes to mind as an issue of global justice.⁹¹

Access to knowledge can refer to four different things: (1) human knowledge (education, know-how, embodied skills); (2) information (news, data, reports); (3) knowledge-embedded goods (KEGs) like drugs and computer software; (4) tools for the production of KEGs (e.g. research tools, materials and chemical compounds, computer programs).⁹² Sectors like the multinational biotechnology and pharmaceutical industry try to control the production of knowledge-embedded goods by using IPRs and monopolizing the tools of production. Sometimes, however, attempts are made to wrest control from the hands of the few oligopolistic companies dominating the industry. Special importance in this regard accrues to the initiative taken by the molecular biologist Richard Jefferson to set up *BiOS* (Biological Innovation for Open Society or Biological Open Source) at CAMBIA in Australia. His aim is to make and to keep the basic techniques of agricultural biotechnology, the "tools" and the "technology platforms", accessible to everybody. Freeing the tools from the stranglehold of patents would make the development of numerous potential applications benefiting the poor and needy of the world economically viable. It would also facilitate the active participation of developing countries in the process of biotechnological innovation. Interestingly, in an interview Jefferson declared that "the most fundamental human right is the freedom, or the capability, to make and use tools to solve problems"⁹³.

It might seem just wishful thinking to expect that in the foreseeable future developing countries could build the capacity to undertake fully-fledged drug research and to become actively involved in such a complicated, knowledge-intensive and capital-intensive industry as pharmaceuticals. However, there are some considerations that mitigate this skepticism. For one thing, the established shape of the pharmaceutical industry and the corresponding pattern of innovation are by no means set in stone – if only because of the widely recognized productivity crisis of the current R&D model. It is also notable that middle-income countries like Brazil, India and China (the so-called BIC countries) have built up quite formidable industries for producing generic medicines (although their continued survival will crucially depend on maintaining the "flexibilities" of the TRIPS agreement). It would be inappropriate to consider generics production simply as a "copycat" industry (the image that the non-generic pharmaceutical industry wants to convey). As Amy Kapczynski notes, "it was Indian [generic] firms that first incorporated all of the necessary anti-HIV drugs into one pill, thereby making it easier

⁸⁹ see Schoonmaker (2007) 1015f.

⁹⁰ "Being able to use the senses, to imagine, think, reason – and to do these things in a 'truly human' way, a way informed and cultivated by an adequate education, including, but by no means limited to, literacy and basic mathematical and scientific training. Being able to use imagination and thought in connection with experiencing and producing works and events of one's own choice, religious, literary, musical, and so forth ..." (Nussbaum 2006) 76.

⁹¹ Willinsky (2006)

⁹² Balkin (2006)

⁹³ Richard Jefferson quoted by Poynder (2006).

for patients to adhere to treatment and prevent viral resistance”⁹⁴. The need to drive production costs down also requires skills to effect incremental process innovation.

The international pharmaceutical industry is definitely in flux. Companies are casting around to find new models for drug research and development. Under the leadership of its new CEO, Andrew Witty, GlaxoSmithKline is embracing a model of “open innovation” – which involves making a library of 13.500 compounds freely available for testing against malaria, granting access to patents and know-how of the company, and creating broad-based partnerships around a so-called “Open Lab” where researchers are allowed to access GSK’s expertise and infrastructure – all in the name of breaking down barriers to innovation and access to medicines and vaccines⁹⁵. Jeffrey Sturchio, former vice-president of Merck and currently president of the Global Health Council, also sketches a broad panorama of the changing landscape of innovation in the international pharmaceutical industry which in his view heralds a “new era for intellectual property”⁹⁶. Sturchio notes that more and more companies, just like GSK, are adopting an “open innovation model built around licensing and alliances”, and he also refers to the rise of partnerships between non-generic pharmaceutical companies and generic firms, an increased interest in innovation and IP among the latter, and finally to the rise of PDPs or product development partnerships (e.g. the Medicines for Malaria Venture, the Drugs for Neglected Diseases Initiative, the International AIDS Vaccine Initiative, and the Malaria Vaccine Initiative). The upshot of all these trends: “IP is still important, but it is being used now as a tool to foster more open innovation, rather than an end in itself”⁹⁷. The reason Sturchio gives for the increasing popularity of the open innovation model among pharmaceutical firms is also revealing; it is “the realization that they cannot hope to generate or control within their four walls more than a small fraction of global biomedical research in areas of interest”⁹⁸. It thus seems that the days of pharmaceutical laboratories as closed bulwarks of research and innovation are numbered.

During the last decade Product Development Partnerships (PDPs) and other forms of Public-Private Partnerships (PPPs) have been proliferating in the area of neglected diseases. Although this new wave of activity is of course highly welcome, its institutional setup is not without criticism. Hollis and Pogge have pointed at some of the problems inherent in PDPs such as the difficulty to monitor contractual compliance among partners and the lack of sufficient incentives to push products through regulatory approval and promote their use by healthcare personnel⁹⁹. Their claim is that these problems could be alleviated if a Health Impact Fund were in place. Shortcomings related to local participation have escaped their critical notice, however. Complaints have been raised about the lack of indigenous (in most cases here: African) representation on the boards of these partnership organizations, which is said to result in a perpetuation of “neo-colonial” dependency relationships, with monies being channeled through first-world head offices and decisions taken in the USA or Europe¹⁰⁰. A related complaint is that the ethical acceptability of drug trials and other projects carried out in developing countries is often judged by the criteria set up by ethical committees in the USA or Europe rather than by local

⁹⁴ Kapczynski (2008) 872.

⁹⁵ Witty (2010)

⁹⁶ Sturchio (2010)

⁹⁷ Sturchio, *idem.*, 5.

⁹⁸ Sturchio, *idem.*, 4

⁹⁹ Hollis and Pogge (2010)

¹⁰⁰ Tucker and Makgoba (2008)

standards.¹⁰¹ Another complaint is that a large part of funding for PDPs originates from a single source, the (admittedly very generous) Bill and Melinda Gates Foundation, which thereby gains enormous power to set priorities.¹⁰² Rumors are circulating that decision-making on the malaria research agenda has been effectively “captured” by the Gates Foundation and that the WHO feels threatened by the latter’s growing influence.¹⁰³ However that may be, it would seem that developing countries in Africa and elsewhere desperately need to build indigenous clinical, research and regulatory capacity in order to better set their own priorities, advance their own ethical standards and secure their own interests.¹⁰⁴ Otherwise they will continue to find themselves at the receiving end of decisions taken by companies and agencies headquartered in first-world countries.

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¹⁰¹ Lexchin (2010). For a detailed case study, see Crane (2010).

¹⁰² Lexchin, idem.

¹⁰³ See McNeil (2008).

¹⁰⁴ Cf. McNeil (2008).

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