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Access to medicines, market failure and market intervention: a tale of two regimes

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To date, much of the academic and policy literature has focused on the impact of intellectual property rights (IPRs) on the governance of access to medicine, and in relation to various property rights associated with the regime governing international trade, and other associated bilateral and regional agreements. The paper rehearses how IPR/trade regime has generated particular sets of problems for access to medicines. At the same time, the growth of new actors in global health, and their specific roles in the global governance of access to medicines, has in contrast received limited attention with respect to their role in access. These new actors include Global Health Partnerships (such as GAVI and the Global Fund), major philanthropic foundations (such as the Gates and Clinton Foundations) and new access initiatives (such as UNITAID). The paper problematises these actors' governance roles with respect to the overarching authority of the IPR/trade regime. It argues that new actors and initiatives can be described as a 'pro-access regime,' concerned with widening access to medicines, and that, contrary to popular and political understanding of these agencies wider role in global health, their baseline functions are to intervene in a dysfunctional global drug market.

Keywords: access to medicines; global health; intellectual property rights; trade regimes; global drug market

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Introduction

Access to medicines (hereinafter AtoM) has emerged in recent decades as a totemic problem in global health. Some one-third (or roughly two billion) of the world's population lack

access to drugs (UN Millennium Project 2005) yet are afflicted by, or even die from, diseases which are either preventable or curable, or suffer each day from often debilitating and painful symptoms of disease that can be managed and ameliorated by existing treatments. Others simply suffer or die from diseases for which no drugs have yet been created, often because they are too poor to provide an adequate economic incentive for biomedical research and development (R&D) into new medicines for their particular disease burden. AtoM is therefore clearly one of the most pressing and morally compelling problems we face as humanity.

Whilst HIV/AIDS has served to crystallise many of the issues associated with AtoM, and has spurred the creation of numerous initiatives to increase the supply of antiretroviral treatments (ARTs), it is still the case that only 50% of those who need them have access to them (WHO/UNAIDS 2010). For other diseases (especially tropical and water borne diseases) the problem of access is even more acute (Ravvin 2008). Often, no drugs or formulations exist to treat these diseases, the pathologies of which have in some cases been known for decades, and there has been a failure, and some would say a market failure (Kremer 2002, Rosiello and Smith 2004), to incentivise the necessary R&D to generate appropriate drugs. In global terms, this failure in the system of pharmaceutical innovation has been labelled the 90/10 gap, in which 90% of pharmaceutical and biomedical R&D is targeted at just 10% of the global burden of disease (Troullier *et al.* 2002).

This paper seeks to examine how we have sought to ‘govern our way out’ of the problem of AtoM, and does so by providing an overview of the activities of the new health initiatives and partnerships which are addressing the access issue. These actors are rarely analysed as being primarily associated with AtoM, nor are they viewed as having, in essence, a basic functions of intervening in markets. The most prominent of these actors are Global Health Partnerships (GHPs), and new and old philanthropic foundations (Rushton and

Williams 2011). Widening access to medicines represents the fundamental pillar of their interventions, and lowering drug process and stimulating R&D are their common policy mechanisms. It is argued here that their role in intervening in a dysfunctional global pharmaceutical market – effectively constituting a ‘pro-access regime’ – is a fundamental characteristic of their systemic role in contemporary global health governance. Moreover, despite bringing vast resources to bear on the problem of access (Ravishankar *et al.* 2009), the new actors are neither the only nor the most important actors engaged in governing AtoM. Whilst we should view the new initiatives, partnerships and foundations as constituting a new modality of health governance in AtoM (Rushton and Williams 2011), they are best understood as being only *one of two* major regimes governing and determining outcomes in the area of AtoM. In fact, these new actors operate in the context of a cluster of agreements/rules, institutions and actors associated with international trade and intellectual property rights (IPRs), and are often reactive, and only partially corrective, to some of the negative outcomes this ‘IPR/trade regime’ has generated for AtoM.

This paper traces both how the IPR/trade regime has exacerbated certain (economic) problems associated with AtoM, and how the pro-access regime has sought to intervene to either solve or ameliorate these problems. Although these new actors often do not frame their activities in terms of this market intervention role, it is argued here that their governance roles and health investments should properly be understood in terms of their inter-relation with and response to the IPR/trade regime, and not as separate from it.

The first part of this briefly paper explains some of the fundamental economic problems that characterise pharmaceutical production, innovation and drug markets. Whilst all IPR regimes (and specifically patents) seek to respond to a basic economic problem associated with knowledge production under market conditions, their interaction with pharmaceutical markets creates further sets of problems for AtoM. So whilst ‘solving’ a

particular problem of free riding, and providing a system of incentive for the invention of drugs, the IPR/trade regime creates knock-on problems. And despite disastrous impacts on peoples' access to drugs, proponents of the regime have consistently used what are often very simple economic arguments to frame strong global patents on drugs as a positive force for drug development, and ultimately for the availability of new and improved medicines in developing countries.

Whilst the economic framing of drug patenting has been counter-framed by rights-based, development and public health discourses (Helfer 2004), and more recently by critical economic arguments that undermine the basic economic assumptions that support the IPR/trade regime (Hollis 2004), this paper argues that the economic justifications for patents on pharmaceuticals are particularly powerful and durable. Whilst there exists no single or coherent school or version of economics associated with such justifications, the proponents of strong IPRs have been able to appeal to common sense assumptions about the virtues of the market mechanism with respect to efficiency, price and allocation of goods, and the necessity of protecting inventions in order to capture and maintain the social benefits of private innovation.

The second part of the paper contends that the global 'pro-access regime' can be characterised as responding to the challenges presented to AtoM by the IPR/trade regimes' interaction with pharmaceutical markets. As will be detailed, these new actors are often intervening in these markets in a number of basic ways (lowering prices and stimulating innovation) – yet this basic market intervention function is rarely present in framings that lay stress on their development or humanitarian role in global health. Despite this, these new actors are therefore often responding to problems that the structure of pharmaceutical markets and global patent rights generate for AtoM. I argue that the pro-access regime, and its donors and supporters, have generally failed to frame its role with respect to market intervention, nor

have they problematised the contradictions of their work in the context of a monolithic IPR/trade regime. Whilst these actors routinely frame their activities in terms of rights, public goods, development or humanitarian duty, these frames are not deployed to challenge the economic justification of patents on drugs, nor the wider global political economy of pharmaceutical production and innovation. Thus, it is argued, the new actors, and the loose development-oriented framing of their role in global health, fails to offer a challenge to the status quo in AtoM, whilst possibly offering legitimacy and durability to the IPR/trade regime.

The IPR/trade regime and its framing

The IPR/trade regime responds to a fundamental economic problem associated with the production of knowledge (and knowledge based goods such as drugs) which arises from its non-rivalrous nature and the ease with which it can be copied and replicated after its invention (Stiglitz 1999, 2008). This generates a social need to reward invention in order to ensure there are economic and social incentives for the generation of future knowledge. The prevention of copying (and free-riding) and the need to provide incentives for innovation provide the basic starting points in the argument that IPRs are appropriate and necessary legal frameworks to achieve these objectives (Draho 2003, Stiglitz 2008).

This framing of IPR systems as a solution to a fundamental economic problem has characterised their social role and evolution in various early industrialising countries, and the presence of these systems are often held to be a key to the technological and economic progress enjoyed by the Global North (Braga 1989). In creating such systems governments were essentially attempting to capture a balance between the private rights of the inventor to reward, and the wider public good. Yet pharmaceutical patents are perhaps *the* classic example of a technology which many countries chose to exclude from their patent laws

because of the competing social value placed on human health and the primacy of public rights in this particular balance of rights (Lanjouw 1998). Indeed, even many developed countries were notably late in adopting patent laws for drugs exactly because of these rationales (Drahos and Braithwaite 2002).

The 1994 World Trade Organization's Agreement in Trade-Related Aspects of Intellectual Property Rights (TRIPS) served to globally 'harmonise' IPR laws, including patents, making rights available in all WTO member countries, and subject to that organisation's powerful dispute settlement body. For patents, a term of 20 year protection was awarded (surpassing the duration then available even in many developed country legal systems), and the agreement made patents available for 'all fields of technology' (WTO 1994, Article 27), and for all processes for production of such technologies. Crucially, the agreement specifically included medicines and biotechnological products and processes (and indeed plant varieties), and severely limited the so-called 'flexibilities' that member countries could exercise to obviate patent rights in either special or sovereignly determined circumstances, limitations which were subject to challenge in the WTO's 2001 Doha Declaration (WTO 2001, Abbott, 2002)

TRIPS gave global scope to patent rights for drugs. Scholars have traced how successive framings of the economic rationale for global IPRs (Odell and Sell 2006), and horizontal institutional and issue linkages (Helfer 2004, Muzaka 2010,.) were made to justify the new global regime. These included: the linkage of IPRs to 'free' international trade and increased foreign investment in the South; the institutional shift of international IPRs from WIPO (a 'weak' regime) to the WTO (a 'strong' regime) linked to disciplinary powers based on trade sanctions; the framing of IPRs and patents via a narrative of 'universal' private rights (Kinsella 2001, Sell and Prakash 2004); the linkage of patents to increased rates of global medical innovation (Mansfield 1986, Grabowski 2002); and the linking of generic

drugs with global piracy and counterfeiting. These framings contributed to the formation of a regime which substantially eroded the treatment of medicines as global public goods, shifting the frame of reference to a discourse of private goods whose allocation and production are subject to the global market mechanism, with the purported benefits of that mechanism, namely higher rates of innovation and lower prices via competition, lurking in the background as supporting economic assumptions (Drahoš and Braithwaite 2002).

These initial economic framings of the TRIPS agreement have recently developed new life, and have been transposed to yet other ('TRIPS-plus') regimes and policy initiatives, all directed at raising the levels of protection and private rights that are available for medicines and other technologies (Drahoš 2003, Sell 2007). Indeed, they are readily detectable in debates regarding so-called 'TRIPS-plus' regional and bilateral trade agreements, as they are in initiatives such as Anti-Counterfeiting Trade Agreement and 2009 EU customs seizures of generic drugs in transit.

However, another success of the economic framing of TRIPS lay in the deceptively simple extension of economic justifications of national systems of IPRs to a global level, and as being equally necessary across global markets. In turn, rather than being framed as having negative consequences, the regime was held to herald longer-term benefits in the form of a genuine basis for innovation in as 'yet to' develop countries (see Braga *et al.* 2000). As I argue below, such assumptions are highly problematic for AtoM, not least because the *legal treatment* of these markets as undifferentiated belies the fact that global pharmaceutical markets are in fact massively differentiated both across and within national markets (Kremer 2002, Flynn *et al.* 2009), and also because many of the predicted benefits in terms of technology transfer and new medicines are not emerging.

The knock-on effects of the IPR/trade regime for AtoM

TRIPS, and the associated national and international instruments which make up the IPR/trade regime, have interacted with and exacerbated certain problems that were already apparent with regard to the oligopolistic structure of the global pharmaceutical sector, and pharmaceutical markets that are characterised by huge inequalities in incomes both within and between markets. More recently, especially in the post-Doha era (2001-), these ‘knock-on’ problems have led to counter-framings of the relationship between the patents and drug innovation and price, which have largely drawn on economic arguments emerging from ‘critical’ economics and innovation studies (Hollis 2004, Ravvin 2008, Selgelid 2008, Pogge 2009, Hollis and Pogge 2010).

The first problem for AtoM is the most obvious and relates to prices of patented drugs. A patent confers, after all, a monopoly and the ability to set an artificially inflated price for a fixed period of time. Such prices are routinely set at rates where the poor cannot afford from out of pocket payments and developing country governments cannot subsidise consumption. Patented drugs are in some cases up to 400% more expensive than generic counterparts (Baker 2004), and the exclusion of generic competition, which would bring down prices close to the marginal cost of production, is after all one of the principal functions of the patent system. TRIPS and other associated agreements have either more narrowly circumscribed the opportunities for compulsory licensing by confining it largely to ARTs, or have headed off avenues by which generics can be introduced to markets by introducing new tiers of legal complexity (Johnston and Wasunna 2007), as is the case when limitations are placed on access to clinical trial data in some ‘TRIPS-plus’ bilateral trade agreements (Sell 2007). These obstacles to generic entry obviously create particular problems for people who cannot afford to pay who are nonetheless affected by an illness which an on-patent drug can prevent, cure, or alleviate the symptoms of. It is certainly the case that

generic entry permits competition that lowers prices, as has been the case with ARTs (see Waning *et al.* 2009).

The effects of globalising patent rights are particularly acute when we appreciate that the global pharmaceutical market is highly differentiated in terms of governments' and individuals' ability to pay high prices. Scholars have also identified that many developing countries are also highly differentiated *within* national markets (as are many developed country markets), not least by high levels of income inequality (Flynn *et al.* 2009). These market structures interact with patents to keep prices high. Flynn *et al.* (2009) found in South Africa that high levels of income inequality mean that firms can target upper deciles of income earners, and achieve prices close to or exceeding prices charged in developed country markets without threatening (deadweight) losses from those consumers priced out of the market. In short, because of huge disparities in income, there is often no incentive to lower prices of patented products and increase the volume of sales (Danzon and Towse 2003).

The second major knock-on problem of the interaction of IPRs with pharmaceutical markets relates to innovation. Whilst the patent system supplies an incentive to invent in the presence of effective demand; in its absence it does nothing. Many scholars have noted that the world's poor often simply do not provide sufficient demand for drug firms to include them in their R&D and production strategies (Troulier *et al.* 2002, Hollis 2004). This has been variously described as market failure (Kremer 2002) in the context of critical economic discourses of AtoM, or as, perhaps more accurately, the problem of missing or non-markets (Rosiello and Smith 2004). 80% of the global market for drug sales lies in North America and Europe (Rosiello and Smith 2004), and this creates a clear incentive for firms to develop and target drugs for those, and the particular diseases affecting those populations. Generally, this had led to a preponderance of drugs being developed for so-called lifestyle diseases, or non-

communicable diseases – such as cancers, cardiovascular diseases, diabetes, and stress-related disorders.

Two clear issues arise from these knock-on problems. The first is the moral and human health hazards of leaving the development of medicines to the market mechanism alone, when it is clearly not sufficient or effective in so many cases. The second is linked to this, but seems to undermine the framing of the global patent system as the answer to all innovation needs in medicines: It is not, and cannot be, as long as poor people and their governments fail to provide incentives to invent via their purchasing power.

Even so, the patent system can also create knock-on problems for innovation even when demand is present. Two examples of this negative influence are worth citing. It has been widely noted that the patent system provides a legal structure or criteria by which incremental innovation of medical technologies is encouraged, rather than meaningful new drugs and treatments. In short, companies have strategies that seek to extend patent life (and profits to gained from a product) by marginal tinkering with the chemical composition or method of drug delivery. Likewise, yet other achieve similar gains by incrementally improving on an existing products to gain a patent so-called ‘evergreening’ and ‘me-too’ inventions, or the legal complexity and uncertainty engendered by multiple and dense patenting of drugs – so called patent thickets (Barton and Emanuel 2005, Faunce and Lexchin 2007, Stiglitz 2007).

The Rise of the ‘Pro-Access Regime’ and New Approaches to AtoM

As the issue of AtoM became prominent in the wake of the 1994 TRIPS Agreement, the range of governance initiatives and new actors involved in tackling the AtoM problem have increased exponentially. As a result a perception emerged that the authority of the IPR/trade regime with respect to ATOM had been effectively politically neutered, and that the AtoM

issue had been substantially reframed in terms of development and global public goods (see Sell 2002, Odell and Sell 2006) and/or in terms of human rights to health (see for example Helfer 2004). At the same time, new initiatives emerged in an effort to ‘govern our way out’ of the fallout of a double market and IPR/trade governance failure with respect to drug innovation and price. Many of the new hybrid public-private Global Health Partnerships and key philanthropic foundations are essentially responding to these problems, albeit in different ways. These actors intervene in the global pharmaceutical market either with respect to drug prices (either through subsidisation, negotiation, or other forms of financing), or in terms of innovation and R&D, and sometimes with combinations of these two basic strategies. In doing so, they have created an elaborate and multifaceted global ‘pro-access regime’ for AtoM.

Before tracing the basic functional characteristics of the pro-access regime’s responses to the economic problems of AtoM, it is worth noting that their activities have rarely been explicitly framed in terms of supplying policy responses to what are basically economic problems associated with patents, pharmaceutical production and markets. Nonetheless, this basic market intervention function with regard to AtoM is very rarely far from the surface of framings of these new actors’ governance roles, nor, indeed, far from the centre of at least 10 years of rapid institutional development and unprecedented financing in global health more widely (Ravishankar *et al.* 2009). Rather than economics, it is international development which has most commonly represented the framing of their activities in increasing AtoM.¹ The rapid emergence of the pro-access regime in the early years of the 21st Century was part of a wider development policy zeitgeist, and was closely associated with the Millennium Development Goals. The G8 (and World Bank) played an instrumental role in the development in the new global health governance regime, most notably via a series of high-profile summit commitments to health and development

programmes which gave birth to initiatives such as the Global Fund and GAVI. These new institutions were presented as providing the basis for an essential ‘step-up’ toward (economic) development and poverty alleviation (see Woodling *et al.*, this volume).

However, the new actors and initiatives have not only framed their activities in terms of MDG-directed development, but have also portrayed themselves as representing a new modality of health and aid (Rushton and Williams 2011). Whilst being part of the wider state-funded and multilateral drive to development, both GHPs and foundations have sought to involve and draw upon the expertise, management skills, reporting and accounting practices, and best practices of a range of stakeholders, and most prominently the private sector (Rushton and Williams 2011). In particular, close collaboration with pharmaceutical firms is viewed as central to the success of the model. Industry representatives have been incorporated into both foundations and GHPs, and a revolving door of personnel has emerged between many of the institutions and drug companies. Furthermore, their programmes have often needed to produce results in short order, not least to satisfy donors and lend themselves output legitimacy. These pressures have further entrenched the pivotal status of widening the medicines coverage in the disease areas they respond to, but also reflects the technical and biomedical bias embedded in the MDG health blueprint, and a basic belief in the power of the power of pharmaceutical sector to supply magic bullet fixes to health problems, given the right amount of stimulus and incentive (Black *et al.* 2009). Thus ‘success’ for the pro-access regime has been framed in terms of the necessary involvement of pharmaceutical firms, and a reliance on their products and innovation. Whilst in key disease areas such as HIV/AIDS there has been a gradual shift to a greater reliance on the generic sector, more widely the focus is on innovator firms as either key partners in publicly funded R&D programmes, or as the sole sources of drug supply (Youde 2011).

Finally, part of the reason for the twenty-first century surge in new institutions and health financing has clearly been ideational, and indeed resulted partly from arguments and counter-frames used to challenge the IPR-trade regime, especially in the period between the coming into force of the TRIPS agreement and 2001, the year that saw both the Doha Declaration and the Millennium Declaration (Sell 2002). The civil society, patient groups and developing states involved in the counter-framing of the IPR/trade regime as impacting negatively on the either human rights or the public goods qualities of drugs had an obvious and instrumental role in the genesis of the pro-access regime. However, whilst being doubtless part of the spur for action, these framings did not lead to a fundamental challenging of the power of the IPR/trade regime over ATM. Instead, the global the governance response has been limited to intervention in markets to either to widen access to treatments, either by securing lower prices, incentivise innovation, or in some cases both. Here I briefly discuss the activities of the pro-access regime in relation to, first, instruments and policies aimed at price interventions (including financing, tiered pricing, donations, pooled procurement, and negotiation), and, second, those aimed at innovation.

Price interventions

Financing partnerships and foundations clearly seek to increase drug availability via the disbursement of money. Organisations such as GAVI and the Global Fund, as well as foundations such as the Gates Foundation, have poured huge resources into financing greater access for certain types of medications, effectively subsidising drug interventions for select diseases in selected countries. In practice, the disease focus of the major GHPs means that financing is disproportionately targeted at medicines and health technologies directed at the ‘big three’ diseases (HIV/AIDS, TB and malaria). Although agencies such as the Global Fund and GAVI are able to point to considerable success in increasing access, their activities

– and the model they represent – have not been immune from criticism. Concerns about the sustainability of financing have become acute in the context of the financial crisis, but also preceded it (Williams and Rushton 2011). Also, questions about accountability plague these actors, not least with respect to accountability to patient groups and developing countries given the weight of donor state and philanthropic largesse (Birn 2005). The distorting effect of massive injections of finance on local drug manufacturers and national health systems have also received attention, as have instances of corruption, waste, endemic local parallel markets, and cost-raising middle men involvement in supply chains (England 2008, Shiffman 2008). Although it has improved access to some medications, the huge increase in finance has not served to challenge or solve long-term dynamic problems associated with drug production and supply (Kapczynski 2009). However, two positives are present in the financing function of the pro-access actors, which might hold longer term positives for AtoM more widely. The first relates to the widespread use of generics by these programmes, and the effects this has had on competition and price, and also the development of the generic sector, particularly in India. The second positive is the establishment of Unitaid in 2006 as a redistributive financing mechanism for the purchase of ARVs, an initiative which holds the promise of wider and innovative sustainable resourcing of pro-access initiatives.

These agencies have not, however, merely provided the financing for the purchase of drugs at existing prices; they have also sought to lower drug prices in order to increase the benefit that their resources can produce. In doing so, they have been joined by a number of other ‘access organisations’ (Caines 2004) and UN/WHO joint programmes with firms, such as the Accelerating Access Initiative (AAI). These have led to the development of a range of price intervention strategies including differential pricing, drug donation schemes, and pooled procurement and price negotiations, as well as an increasing use of generics (see Oxfam 2007, Waning *et al.* 2009, Youde 2011).

Differential (or tiered) pricing schemes are in essence specific responses of pharmaceutical firms to differentiated pharmaceutical markets, and are corporate responses to particularly morally and politically charged cases. The best example is the AAI, a partnership of nine pharmaceutical firms and five UN bodies, established in 2000 and directed at bringing down the price of ARVs. Both the AAI specifically, and differential pricing as a strategy, have received criticism from a number of sources (Danzon and Towse 2003, Oxfam 2007), mainly over their dependence on the sustained commitment of firms, which has not always been steadfast. A recent and influential study by Waning and others (2009) has also highlighted the fact that price reduction gained by generic entry of ARVs dwarf those sustained by differentially priced equivalents. Differential prices can also have the function of short-term discounting to prevent the entrance of completion, or to secure market dominance of a particular drug.

Donation programmes are perhaps the most extreme form of price reduction, effectively lowering the cost of the drugs involved to zero. Donation programmes to date have been restricted to some high-profile examples: Pfizer's Diflucan donation, Merck's Mectizan donation, the Boehringer donation of Viramune, and so on. These programmes are managed by a corpus of partners, charities and NGOs. However, such programmes have also had their critics, notably because of their effects on generic producers, their suitability for use or relative efficacy, and the effect on the choice of treatment available to public health bodies (WHO 1999). However, such programmes also chime well with corporate social responsibility, generate good PR, and do not often represent balance sheet busting donations of drugs with high market value.

Pooled procurement is mainly undertaken by clusters of states or organisations seeking to purchase high volumes of a particular drug. Examples include consolidated drug purchasing schemes managed by PAHO, or the vaccine purchasing strategy of UNICEF,

which is responsible for a 40% share of the total global vaccine market. In terms of partnerships, some successes have been witnessed under the Stop TB Global Drug Facility, and the WHO's intervention in the artemisinin supply crisis, leading to huge reductions in price and increased volumes of global availability of artemisinin and ACTs. More recently, the Global Fund has established its own coordinating function – a scheme called Voluntary Pooled Procurement - with respect to block purchasing of ARVs (Kazatchkine *et al.* 2009). Whilst this system has not as of yet had time to bed-down, Waning *et al.* (2009) note its potential to profoundly restructure the global ARV market.

In some ways linked to these high volume/low price strategies, are the negotiated price strategies pursued by the Clinton Foundation (Youde 2011). Whilst confined to relations with generic ARV producers, the Clinton Foundation prides itself on taking a business approach to the problem of price, and uses a series of techniques – such as demand forecasting – to lower the uncertainties involved for generic firms in matching investments in reverse engineering and production runs on the one hand, with predictable market size and sales volumes on the other (Youde 2011). The Clinton Foundation thus seeks to correct imperfect information (asymmetries) endemic to the ARV markets thereby lowering uncertainties as the basis for lower prices. Again, these strategies have scored some important successes in lowering price, and the Clinton approach could hold real promise in reducing deadweight losses to consumers and producers if applied to other disease areas.

However, a number of more general problems for AtoM are apparent from the price interventions of the pro-access regime. The first simply relates to the need for continued financing, or intervention in the form of bargaining with obvious political clout, in order to keep prices low. Often these interventions offer only short-term price reductions to patients who have long-term need for treatment (as with ARVs). Problems will recur if either the money or the will to negotiate disappears. Second, it is clear that in most cases the entrance

of generic production (especially in ARTs and ACTs) has had a dramatic impact on price, but that impact is only really systemic in a select few diseases (and childhood vaccines have fortunately proven to be a unique exception to the wider pattern of drug prices). In many senses, this reflects the success of the human rights and public goods reframing of ARVs specifically within the post-2001 (Doha Declaration) IPR/trade regime. Since then, the question of ARV compulsory licensing has largely proven to be ‘exceptional’, both with respect to corporations (and developed states) turning a blind-eye to the enforcement of patent rights, and to the willingness of developing countries to enact compulsory licenses on them. As countries like India (accounting for 80% of the global ARV generic supply) have acceded to TRIPS in 2005, and as TRIPS-plus agreements (including a current EU-India FTA) ratchet up global IPRs, it could be that price interventions based on generic entry into the global ARV market – the change which has brought about by far the biggest reduction in prices – might prove to be only a temporary and ‘exceptional’ mechanism for AtoM. Other diseases and pro-access strategies will have to factor in higher prices to subsidise, and longer durations to wait before generic competition permits the type of business-orientated, and innovative solutions offered by Clinton and others.

Innovation interventions

R&D and Product Development Partnerships (PDPs) are fairly straightforward to understand with respect to AtoM, as they bring together public and private medical research capabilities to provide the basis for innovation in neglected and other diseases. They thus correct market failure with respect to innovation. Their innovation incentive function falls into two categories of activities: those organisations that supply push incentives (Kremer and Glennister 2004) at the input side of R&D; and those that provide pull mechanisms – or offer alternate incentives for R&D and product development (Hecht *et al.* 2009).

Push mechanisms are often in the form of financing of research efforts comprising both public and private bodies. Organisations such as the Gates Foundation, national governments, and advocacy organisations (especially Rockefeller), have played pivotal roles in both the financial inputs and partnership necessary for PDPs to work. PDPs mostly rely on push incentives – often in the form of grants – and include actors such as: IAVI; the Drugs for Neglected Diseases Initiative; the Malaria Vaccines Initiative; the Global Alliance for TB Drug Development; and the Medicines for Malaria Venture. In the instance of the Program for Appropriate Technology for Health (or PATH), it receives some 63% of its budget from foundation sources, with the Gates Foundation injecting a massive \$1.3 billion into its work on vaccines (and crop research) in 2009 (McCoy *et al.* 2009). These actors are clearly important where missing markets are a problem, with Moran (2005) finding that PDPs accounted for three quarters of all neglected disease R&D projects, and others (Moran *et al.* 2007) noting considerable success in product development, with a staggering increase in the development of malaria vaccines being an exemplar. Similar R&D gains are reported by IAVI on trial candidates for HIV vaccines (Moran *et al.* 2007), with capacity building in developing countries (for example in laboratory personnel) being a real positive externality of its R&D focus (Chattaway *et al.* 2009).

In an alternative approach to stimulating R&D, Unitaid has created a structure under which pharmaceutical companies can voluntarily contribute patents on ARVs, thereby allowing others to research combination therapies for which patent rights and patent thickets otherwise present an obstacle to (Unitaid 2007). The push element here derives from removing the considerable transaction, legal and financial costs that cross-licensing of multiple patents would otherwise involve, and, by this, eliminating a principal knock-on problem of patents. The new ARV combination therapies that emerge from the pool will be sold on a non-profit basis, with the patent holders gaining royalties only if their component

drug is used, with reward determined and financed by Unitaid. Thus it combines both push and pull incentives for patent donation. In 2010 the Medicines Patent Pool Foundation was established to administer the pool. Despite this positive initiative, it is clear that patent pools require financing and the largesse of the donating firms if they are to succeed.

Pull mechanisms are less evident in global health to date, although proposals for incentive structures to replicate the systemic function of IPRs are now legion. The most high-profile of these ideas are those centring on the Health Impact Fund (HIF) and prizes (Hollis 2004, Pogge 2009). The basic idea of such schemes is to reward inventive activity in health by means of the impact of a new medicine on the global disease burden, with the intention being of decoupling innovation from price and patents, whilst still supplying an incentive structure. Such systems and proposals have been intrinsically economically framed, both in terms of their critique of inefficiencies engendered by the patent system, and in identifying the essentially short-term nature of some of the static interventions on innovation present in push mechanisms described above. However, to date global health has only generated one significant pull mechanism, in the form of the Advanced Market Commitment, established in 2007 using developed country, World Bank and Gates Foundation finances to secure a market (and guarantee a volume of sales) for a pneumococcal vaccine (Barder *et al.* 2006).

Part of the problem with push and pull mechanisms to date, is that they fail to offer a systemic and stable means of generating innovation (Hollis, 2004, Selgelid 2008). This is exactly the systemic incentive structure that profits and patents *do* achieve, albeit, as we have seen, with unpalatable effects for AtoM. The IPR/trade regime is also financially stable (in that it is underwritten largely by political will and higher consumer-end drug prices), and is not dependent on foundation or state donations, as is the pro-access regime (Ravvin 2008, p. 10). Push mechanisms can also introduce inefficiencies associated with the award of grants to the input end of R&D (Hollis and Pogge 2010), a stage at which successful end products are

never guaranteed. Decisions about who gets the grants and which product lines to pursue can also be subject to bias and other problems associated with front-loading decisions about R&D (Hollis 2005, Ravvin 2008). Grant seeking by grant dependent consortia can also further distort R&D and lead to waste.

The criticisms of these activities are not presented here in order to discount or undermine the successes of the price and innovation interventions developed by the pro-access regime. However, in the main, these initiatives they are piecemeal, disease-by-disease, and static responses to long-term and systemic economic problems of AtoM. Only the HIF shows real merit as an economically efficient and practicable incentive system. Yet at present the plans for a global HIF remain only that – plans – and the transition to a parallel or replacement global system of AtoM governance will require significant financing to constitute a similar with a level of rewards similar to that currently conferred by monopoly prices.

Conclusion

The obvious questions arising from this discussion concern how these two regimes (inter)relate with regard to AtoM, and what are the positive and negative consequences of their attempts to respond to the particular problems of pharmaceutical production and innovation. Moreover, what does the evolution of governance responses to the issue area tell us about social contestation and the uses of framing in the formation of global health policy?

First, in relation to the interaction of the two regimes examined here, a wider critical assessment suggests some limited grounds for optimism. It is clear that at the time of the Doha Declaration in 2001 the IPR/trade regime was facing crisis with respect to the legitimacy of global drug patents. Sustained opposition by a sophisticated coalition of states, NGOs and HIV/AIDS activists promoted a substantial reframing, recasting the issue at stake

in terms of development, human rights and public goods, rather than private rights. This produced a new policy momentum that coalesced around the select health interventions targeted by the MDGs, which were framed as (economic) development orientated 'investments' in health, and especially HIV/AIDS. The disease specific and pro-access interventions of the 'new actors' that were born as a consequence of this new policy momentum have led to the huge expansion of coverage of select diseases (most especially HIV and malaria).

Yet, arguably, this pro-access regime has given new legs and legitimacy to the IPR/trade regime, and has helped to head-off its internal crisis by smoothing off some of the rougher edges of its impact on AtoM, particularly in the most politically charged case of access to ARVs. The pro-access has served this function (by design or accident) as a result of its failure to substantially challenge the discourse that presents drug patenting as necessary for innovation, or to problematise the basic political economy of global pharmaceutical production and markets. Business here is very much as usual. Whilst gains *have* been made in access, the vocal opposition to TRIPS and associated regimes which was present in the period 1996-2001 is no longer the force it was. And as that opposition has receded the IPR/trade regime has reinvigorated itself by shifting the forums through which strong patents on medicines could be achieved (for example in bilateral FTAs and new initiatives on piracy and counterfeiting), whilst continuing to employ framings of the (economic) necessity of patents on drugs that are strikingly similar to those used to justify TRIPS over two decades ago. Levels of protection are being 'ratcheted-up' at a time when political and financial commitment to even the big three diseases appears to be under challenge.

However, in more positive series of developments it is clear that the pro-access regime is beginning to develop (at least in theory) a genuine and creative basis for incentivising drug innovation, most clearly in the area of neglected diseases. Whilst many of

the PDPs, prize funds and other push and pull mechanisms are reliant on continued donor funds, there are also signals present, in Unitaid for example, that new redistributive sources of financing might allow for a sustainable parallel system of incentives to fund new drug discovery. If these types of approach were expanded, they could offer a route out of the economic problems that currently plague AtoM.

Finally with regard to the contested framing of AtoM, it is worth noting that the economic framing or justification of the IPR/trade regime has proven particularly resilient. From the mid-1990s (and even to the present), the IPR/trade regime was ‘successfully’ counter framed in terms of its negative human rights consequences for AtoM; its undermining of global public goods; and its negative impact on international development. But despite legal victories for AtoM campaigners within the WTO, TRIPS, new platforms, forums and levels of governance have been deployed to strengthen the wider IPR/trade regime. However, now a growing body of literature and policy initiatives (such as HIF, PDPs, and even UNITAID) are increasingly challenging the basic assumptions of the economic case for both global and national drug patents, focussing on their negative impact on rates of innovation and price. Indeed, these quintessentially economic critiques are increasingly emerging from actors and individuals closely associated with the first wave of human rights and development counter-framings of the IPR/trade regime. The arguments which have been used by proponents of strong drug patents are now being challenged on their own (economic) grounds, highlighting the fact that those arguments are often internally inconsistent, dysfunctional and deeply flawed with regard to innovation and AtoM. New policies and governance arrangements have only recently responded to the economic problems associated with this dysfunctional system. Whilst there are promising signs of genuine change, these developments operate only at the margins of an IPR/trade regime which remains the only truly systemic form of governance in the AtoM issue area.

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Notes

- (1) A perspective borne out by extensive interviews conducted with UN and other organisation personnel as part of the ERC project.

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