New Political Economy
Publication details, including instructions for authors and subscription information:
http://www.informaworld.com/smpp/title~content=t713439457

Shaping Global Rules: Proprietary Pharmaceutical Companies as Global Political Actors

Valbona Muzaka [a]
[a] Department of Politics, University of Sheffield, Sheffield, UK

Online Publication Date: 01 June 2009

To cite this Article Muzaka, Valbona(2009)'Shaping Global Rules: Proprietary Pharmaceutical Companies as Global Political Actors',New Political Economy,14:2,289 — 301
To link to this Article: DOI: 10.1080/13563460902826039
URL: http://dx.doi.org/10.1080/13563460902826039

New Political Economy, Vol. 14, No. 2, June 2009

GLOBAL MONITOR

Shaping Global Rules: Proprietary Pharmaceutical Companies as Global Political Actors

VALBONA MUZAKA

In a book published recently, *AIDS Sutra: untold stories from India*, 16 of India's most influential writers try to cut through the stigma that surrounds acquired immune difficiency syndrome (AIDS) and document the human story behind the epidemic that currently affects around 3 million people in India. Their aim is both noble and timely: if AIDS continues to be stigmatised as it seems to have been until now, the likelihood of the epidemic reaching proportions surpassing those experienced by some African countries is apparently quite high. Stigma is obviously not the only factor preventing AIDS victims in India and across the world from improving their lot. Lack of information, lack of suitable healthcare facilities, poverty and lack of access to appropriate and affordable medicines are also important factors. Some of these and other factors are regularly mentioned in various AIDS studies, each arranging and ordering the elements that constitute the complexity of the endemic in an order that highlights certain elements at the expense of others. When the finger has been pointed at the high price of patented antiretroviral drugs, proprietary pharmaceutical companies (PPCs) have responded quickly with reports and studies that downplay the importance of their patents to patients' access to (affordable) medicines, blaming poverty and limited healthcare spending by governments instead as the main barrier to access.[1]

The issue of pharmaceutical patents and access to medicines was highly politicised during the late 1990s and early 2000s and it denotes a recent display of the longstanding political agency of PPCs at the national and international level. At the very least, the notion of a (political) actor implies some sort of unity of purpose and one key set of issues around which otherwise competing pharmaceutical companies have joined forces has been that of securing favourable industry regulation, whether at the national or international level, in conjunction

Valbona Muzaka, Department of Politics, University of Sheffield, Elmfield, Northumberland Road, Sheffield S10 2TU, UK.

ISSN 1356-3467 print; ISSN 1469-9923 online/09/020289-13 © 2009 Taylor & Francis
DOI: 10.1080/13563460902826039

with or independent of governments. In terms of pharmaceutical regulation, pharmaceutical intellectual property rights (IPRs) have certainly been *the* key issue towards which most of the political agency of proprietary companies has been directed. Indeed, proprietary or research-based pharmaceutical companies stand alone in the extent of their involvement with the IPRs system and have done much to ensure that the latter meets their requirements.

IPRs are essentially about how the 'new' capital – knowledge – is owned and controlled. The shape that the system of global IPRs is currently taking has the potential to alter, for better or for worse, the future of the global economy and the positioning of various economic and political actors therein. This being the context, this essay presents a brief overview of the political agency of pharmaceutical companies and their role in shaping, alongside other actors, the system of global IPRs and, more specifically, that of global pharmaceutical IPRs. To do so, we start by contextualising this political actor through providing a background of the pharmaceutical industry and its main characteristics, not least because the latter provide the main rationale for the degree of involvement of these companies with the system of IPRs. In the next section we highlight briefly the role that pharmaceutical companies played in the negotiation of the World Trade Organization (WTO) Trade-related Aspects of Intellectual Property Rights (TRIPs) Agreement during 1986–94. The third section focuses more specifically on their role in the highly politicised IPRs–public health contests that took centre stage in 2001 and the 'solutions' that were negotiated thereafter. The last section concludes by bringing some of the key issues together and pointing at other areas of IPRs and regulation which will continue to engage PPCs politically in the future.

The modern pharmaceutical industry: trends and characteristics

To be clear, the focus of this essay is on PPCs that have developed and stable in-house research capacities, rather than generic pharmaceutical companies. Although the origins of the modern pharmaceutical industry stretch back as far as the 1800s, it was only during the 1970s and 1980s that some PPCs, seen previously as special branches of large chemical companies, became prominent and large enterprises on their own right. The term Big Pharma is often used to refer to large PPCs and includes names such as Pfizer, Johnson and Johnson, GlaxoSmithKline, Novartis, Sanofi-Aventis, Hoffman-La Roche, AstraZeneca, Merck, Abbott Laboratories and Bristol Myers Squibb, whose revenues in 2007 were US$20 billion or above.[2] Most of the top 50 PPCs are based in the USA, Europe and Japan, which, incidentally, together made up over 80 per cent of the world pharmaceutical market in 2007 according to industry data (European Federation of Pharmaceutical Industries and Associations – EFPIA 2004, 2008). Global pharmaceutical sales in 2008 were projected to be around US$735 billion, only around 10 per cent of which consists of generic sales (IMS Health 2008). In any case, the distinction between patented and generic medicines and companies is becoming increasingly blurred as many PPCs have developed their own generic medicines or sought acquisitions and joint ventures with generic firms to extend their markets and their dominant position after

patent expiration. As a result, a considerable proportion of generic medicines in the market today is actually manufactured by PPCs themselves. Conversely, several generic companies, such as Ranbaxy Laboratories (India), have started to invest in innovative medicines and become transnational in nature (Von Braun and Pugatch 2005).

Compared with late 1980s figures, the pharmaceutical market has become highly concentrated, with the 10 largest PPCs having increased their share of the global sales from 12 per cent to around 50 per cent in the early 2000s (Danzon *et al.* 2003). This increased market concentration is in large part the result of a series of mergers and acquisitions (M&A). Indeed, this period of increased market concentration coincides with the largest M&A activity within the pharmaceutical industry, the value of which was estimated to be above US$514 billion (in 1999 US dollars) between 1988 and 2000 (Danzon *et al.* 2003). This M&A activity was mainly driven by the relaxation of anti-trust policies in the USA and elsewhere, the phenomenal growth of the US pharmaceutical market, the emergence of biotechnology and the reduced rate of growth of pharmaceuticals in the 1990s. Cross-border M&A were particularly common and have had the overall effect of transforming the largest PPCs into some of the most transnationalised companies in the world. The shape of the industry continues to change; in addition to the factors mentioned above, higher costs of developing new medicines, patent expirations, an increasingly 'dry pipeline' and the significant growth and success of biotech companies have continued to motivate new M&A deals throughout the 2000s.[3] In addition, recent market data indicate that there is considerable growth in the research capacities of some emerging economies such as China and India, accompanied by the rapid growth of the share of pharmaceutical market in what are referred to as the seven 'pharmerging' markets: China, Brazil, Mexico, South Korea, India, Turkey and Russia (EFPIA 2008; IMS Health 2008). These developments are expected to change the shape and overall direction of the pharmaceutical industry further in the years to come.

What is clear for now is that the pharmaceutical industry is undergoing a transitional phase caused, in large part, by an unfortunate combination of increased research and development (R&D) expenditure, reduced R&D productivity and increased number of patent expirations of the 'blockbuster' drugs of the late 1980s and 1990s.[4] In other words, one of the main reasons why the stellar performance enjoyed by the PPCs until recently seems to have waned relates, in essence, to the nature of the pharmaceutical R&D process, as does the PPCs' extensive involvement with the IPRs system. In a nutshell, the pharmaceutical R&D process unfolds in four stages that start with the screening of thousands of compounds in the first phase, continue with testing a few hundreds compounds *in vitro* or animals in the second, moving to clinical trials of a few compounds on humans in the third, lengthier and costlier stage and, finally, to the marketing of the successful drug in the last stage. Two key concerns for the PPCs are the length and cost of the R&D process. Compared with the 1970s, when it took on average 6.7 years and around US$138 million to bring a new drug to the market, in 2001 it took on average 12 years and no less than US$800 million (comparison in constant 2000US$) (DiMasi *et al.* 2003). According to industry data, this cost soared to over US$1 billion in 2007 (EFPIA 2008).

Although strongly rejected by PPCs, some studies have pointed out that PPCs spend more on marketing and promotion (sometimes over 30 per cent of their annual sales) than on R&D activities (well under 20 per cent of annual sales) (Ballance *et al.* 1992). Another key issue with the R&D figures above is that they are mainly based on information from industry, which has a strong interest in inflating R&D costs for at least two reasons: first, substantial, higher than average profits are justified by PPCs as being vital to funding future R&D and countering the high-risk nature of the process; second, increasingly higher R&D costs, accompanied by the easily codifiable nature of pharmaceutical innovation, form the basis of PPCs' continuous demands for 'better' and stronger pharmaceutical IPRs. As PPCs representatives put it, pharmaceutical IPRs are the 'lifeblood of our industry – we literally could not exist without them' (Von Braun and Pugatch 2005: 604; also Bale 1998). Pharmaceutical IPRs are varied and complex but pharmaceutical patents remain one of the main layers of intellectual property (IP) protection for PPCs, although more recently pharmaceutical test data protection and various patent extension certificates are increasingly gaining currency.

As will become clearer in the following section, the 1995 TRIPs agreement improved global pharmaceutical IPRs substantially, but better IPRs do not necessarily guarantee more productive R&D processes. If anything, the strengthening of global pharmaceutical IPRs has been accompanied by less innovative R&D, alongside the worrying growth of the number of 'me-too' drugs – slightly improved or modified versions of previously successful 'blockbuster' drugs – and an increased level of pharmaceutical IPRs litigation cases, particularly in the USA. In their defence, PPCs have argued that less innovative R&D is due to, among other things, the fact that 'easier' medicines have already been discovered and regulatory requirements regarding the safety and efficacy of new medicines are far tougher than before (Matraves 1999). To be sure, phase three clinical trials have become lengthier and costlier as a result of, in part, more extensive regulation. Because a pharmaceutical patent is granted before phase three tests begin, this regulatory burden effectively shortens the length of the patent term for successful medicines in the market from 20 years down to 10 or 12 years. However, PPCs themselves have no other way of determining drug efficiency and safety other than conducting the clinical trials required for marketing approval by the authorities. In any case, PPCs have been successful in key markets in securing IP legislation that grants them extensions of the patent term for up to five years to make up for regulatory review delays (Danzon and Keuffel 2005).

The pharmaceutical industry is subject to intense regulation, but some industry arguments that PPCs should operate in a free market fashion (IPRs protection aside) sit at odds with the fact that the ordinary principles of demand and supply do not readily apply to the pharmaceutical sector. Starting with the R&D process, basic research, which is also the riskiest, is largely underwritten by public funds and conducted in university laboratories, with PPCs becoming involved mainly when promising results become visible. Further, as we have seen, on the supply side, the market structure is not exactly competitive; indeed, it is highly concentrated and in individual therapeutical classes it is clearly oligopolistic (Tarabusi and Vickery 1998). The demand side can also be described as an oligopsony; each medicine is purchased by a limited group of

patients with a specific disease and patients are not like customers in other markets as they do not choose which medicine to purchase. This decision is taken by the physician and, often, neither the physician nor the patient pays the (full) market price of the selected medicine. Consumers' purchase of prescription medicines is often reimbursed in whole or in part by insurance, be that private, public or both. This is certainly true for the majority of the developed countries, although reimbursement schemes vary widely. While it may appear unfavourable at first sight, it is this very structure that provides pharmaceutical companies with a substantial and virtually guaranteed market and assured cash flow. Recent efforts by governments to contain rising healthcare spending by increasing the use of generic medicines has certainly impacted upon the rate of growth of PPCs but, as we have seen, the latter have responded early on by penetrating the generics market.

To conclude this section, it is well to acknowledge the close and symbiotic relationship between PPCs and governments, particularly in key pharmaceutical markets. Governments underwrite large parts of basic research bills, buy a large part of pharmaceutical products and protect PPCs' private IPRs. In addition, these governments are only too aware of the need to maintain and promote profitable high-tech industries, while governments almost everywhere consider securing a stable supply of new and improved medicines a matter of their responsibility, one which has considerable repercussions in national wellbeing, productivity, competitiveness and security.

Proprietary pharmaceutical companies and the making of TRIPs

Without a doubt, the WTO TRIPs agreement is the most significant development in the international IP regime during the twentieth century, at least insofar as it set in motion the global harmonisation and enforcement of private IP rights. All the current 153 WTO members are subject to binding rules of IPRs mandated by TRIPs, as will be any acceding countries; although this will not necessarily mean uniform laws of IPRs globally, once transitional periods expire, it will mean high, enforceable and harmonised minimum IP protection across most of the world. Such protection covers patents, copyrights, trademarks, geographical indicators, industrial designs, integrated circuits and trade secrets. Negotiated during the Uruguay Round (1986–94), it was championed largely by key developed countries with a relative (if not absolute) competitive advantage in IP matters: particularly the USA, Switzerland and the European Union (EU). Most developing countries, which, incidentally, are IP net-importing countries, accepted TRIPs through a combination of economic coercion and deployment of a discourse that linked stronger protection of IPRs with accelerated foreign direct investment flows and economic development, as well as through using it as a bargaining chip whereby concessions in one area (IPRs) were exchanged for gains expected to accrue in others (such as agriculture and textiles).[5]

However it is justified, TRIPs was essentially the 'solution' to a 'problem' framed by business actors whose private IPRs the agreement ultimately protects. These business actors are highly reliant on IPRs and include companies from the high-tech (including the pharmaceutical), brand-name goods and entertainment sectors. By the late 1970s and early 1980s, changes in the economic activities

and organisation of some key advanced developed countries, and the concomitant shift towards a more knowledge-based economic make-up, helped to bring to the fore these industries as the most promising sectors capable of delivering in economic terms when most other traditional industrial sectors were in relative decline. These sectors were also (and continue to be) global in nature and the existence of an atomised international system of IPRs with various levels of IP protection and weak standards of enforceability worldwide was soon recognised as a formidable barrier, a problem, to their future growth. TRIPs provided the solution to this particular problem by essentially extending worldwide the level of IP protection these sectors enjoyed at home.

TRIPs, then, is about protecting certain business actors' private rights and is the direct result of these actors' political agency. The strategies deployed by the latter are beyond the scope of this section and have been dealt with elsewhere (Sell 2003; Matthews 2002; Watal 2001; see also Drahos and Braithwaite 2002). Here we want to highlight briefly the role the PPCs played and their success. Pfizer, one of the largest PPCs, was among the first to raise concerns about 'theft' and 'piracy' of its IP property abroad, particularly in promising markets where pharmaceutical IPRs were either not recognised or only extended protection to processes rather than pharmaceutical products (Sell 2003; Matthews 2002; Watal 2001; Drahos and Braithwaite 2002). Pfizer's chief executive officer, Ed Pratt, raised these issues himself at the World Intellectual Property Organization (WIPO) in the late 1970s and later emerged as one of the key individuals to push forward the TRIPs agenda at the WTO (Matthews 2002). It is worth noting that the TRIPs initiative was initially a US affair, but, as we noted above, PPCs are highly transnationalised and almost all of them have a presence in the US market. When the Intellectual Property Committee (IPC), the key business actor generally accredited with TRIPs' 'success', was created in the USA just months before the Uruguay Round, it included a number of the largest world PPCs such as Pfizer, Johnson & Johnson, Bristol Myers and Merck. From then on, the IPC cooperated closely with both European and Japanese business representatives, initially with the aim of putting IPRs firmly into the Round's agenda and, later on, ensuring that the concerns of its member companies were dealt with 'appropriately' therein.

More generally, PPCs were organised through their associations, PhRMA (the Pharmaceutical Research and Manufacturers of America) in the USA, EFPIA in the EU, and their international federation, IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), in Geneva. One key document that was distilled from extensive meetings between these associations and individual companies in various IP-reliant sectors in the USA, EU and Japan, was the 1988 Basic Framework on General Agreement on Tariffs and Trade (GATT) Provisions on Intellectual Property, which provided nothing less than the blueprint of what eventually became the TRIPs agreement (Drahos and Braithwaite 2002). Issues important for PPCs such as pharmaceutical patents' subject matter, terms, coverage, length and extensions, protection of pharmaceutical test data and compulsory licensing rules were all included, although not without some compromises made along the way. For instance, one related to compulsory licensing, which the PPCs strongly opposed but conceded to keep the European and Japanese industries on board, while another related to the proposed transition periods for developing

countries (in order to induce broadest possible participation to an eventual IP agreement), again urged by European business (Sell 2003). It is worthy of note that provisions over compulsory licensing and transitional periods continued to galvanise PPCs during the TRIPs negotiations until the very end, when last minute efforts were made by the USA to tighten the former and reduce the length of the latter, as well as provide 'pipeline' protection for pharmaceuticals that were patented (but not marketed) before the entry into force of the TRIPs agreement (Sell 2003). In the end, only a more limited 'mailbox' protection was achieved and transition periods remained unchanged.[6] Despite such 'losses', however, TRIPs dealt well with pharmaceutical IPRs; as one strategist of a key business actor summarised it, 'we got 95% of what we wanted' (Jacques Gorlin, quoted in Sell and Prakash 2004).

In addition to working closely with other IP-reliant business actors, with state officials and negotiators and GATT/WTO Secretariat to secure an IPRs agreement at the multilateral level, PPCs were also active in pursuing the unilateral route, particularly through the more accessible (from the perspective of PPCs) US Trade Representative Office (USTR). The USTR Section 301 and Special 301 procedures provided a channel through which the PPCs, alongside other IP-reliant business actors, could put pressure on and achieve IP protection laws in certain developing countries of interest to them. Even before the start of the Uruguay Round, pressure was successfully put on South Korea through the USTR Section 301 and further in the late 1980s on Brazil, Argentina, Korea (again), Mexico and China (among others) for 'inadequate' pharmaceutical IP protection (Ryan 1998; Watal 2001). The EEC (European Economic Community, later EU) also moved against Korea, Indonesia and Thailand in the late 1980s on behalf of concerns raised by its IP-reliant companies, including the PPCs (Dutfield 2003; Drahos and Braithwaite 2002). Nevertheless, it was the USA who continued to use the unilateral route more aggressively throughout the 1990s, even after TRIPs was concluded at the WTO. Countries such as Brazil, Chile, Colombia, Pakistan, India, Argentina, Turkey and the Philippines continued to be targeted by the USTR on behest of PPCs regarding complaints of 'inadequate' and 'ineffective' IP protection for pharmaceuticals.[7] Whether at the multilateral level or through exerting unilateral pressure via state actors, PPCs and their associations were highly active in ensuring that their IPRs were better protected and enforced globally; a reading of the TRIPs text certainly testifies to the success of PPCs in this respect.

Once TRIPs came into force in 1995, PPCs assumed two new roles: TRIPs guardians and 'TRIPs-plus' advocates. In other words, the focus of their political agency shifted towards ensuring that TRIPs obligations were implemented 'properly' across the world, as well as on securing higher and wider IP protection in areas dealt with ambiguously or not at all by TRIPs. Some such areas of interest to PPCs included, not surprisingly, pharmaceutical data protection, 'mailbox' provision for new drugs in the pipeline and certain issues related to patents such as extensions for administrative delays and parallel importing.[8] In addition to continuous unilateral pressure mentioned in the previous section, PPCs played these two roles through strategies aimed at both the multilateral and bilateral level. At the multilateral level, the WTO dispute settlement mechanism

provided an obvious platform from which to strengthen pharmaceutical IP protection across the world. Clearly, PPCs cannot officially be part of WTO disputes but, ultimately, it is infringement of their IPRs that would prompt governments to bring cases of inadequate IP protection in other countries before WTO dispute settlement panels (May 2000). Indeed, it was on behest of complaints by PPCs that the USA or the EU (or both) brought cases against Canada, India, Pakistan, Brazil and Argentina in the short five years following the end of the Uruguay Round.[9]

In addition, a bilateral route was opened up with the negotiation of Free Trade Agreements (FTAs) between the USA or EU and a number of developing countries, a trend that has become more visible within the trade regime from the mid 1990s onwards. Such FTAs have often included separate IP chapters that deal specifically with pharmaceutical IPRs (among other issues) at the behest of PPCs; this has been particularly the case with US FTAs and less so with the EU ones, at least until recently (Santa Cruz 2007). At the behest of PPCs, some FTAs have included TRIPs 'plus' provisions for pharmaceuticals such as provisions that expand the scope and term of pharmaceutical patents, provide stronger protection for pharmaceutical test data, prohibit parallel importation and add conditions on the use of compulsory licences (Drahos 2001). As mentioned earlier, the WTO cases brought against Brazil, India and other countries were based on concerns of PPCs over some of these and related issues. Indeed, as the next section shows, the issues of compulsory licences and parallel importing for pharmaceuticals (both closely related to patent rights) were at the core of the IP-access to medicines controversy of the early 2000s.

PPCs and the controversy over IP access to medicines

Up until the late 1990s, PPCs were on the offensive with respect to IPRs, simultaneously making use of unilateral, bilateral and multilateral channels available to them in order to enhance and strengthen the standards and enforceability of their IPRs worldwide. As suggested, TRIPs bears witness to their success, as does the upward global IP ratchet that was set in motion afterwards. However, at the same time, awareness about the nature and extent of TRIPs obligations and their (real and potential) impact upon access to cheap and affordable medicines was increasing. Amid growing global concern about the appalling proportions the HIV/AIDS crisis had assumed by the mid 1990s, a network of health non-governmental organisations (NGOs) including CPTech, Health Action International, *Médicins sans Frontières* (MSF) and others, were particularly successful in raising awareness about the impact of globally enforceable pharmaceutical IPRs on access to affordable medicines and public health, particularly so in the developing world. Framed in 'patents vs patients' terms, the IP access to medicines debate grew stronger by the late 1990s, fuelled in part, and inadvertently, by the very post-TRIPs strategies of the PPCs referred to above. One particular event which substantially raised the profile of the IP-access to medicines debate was the infamous South African lawsuit of the late 1990s. As is well known, around 40 pharmaceutical companies, including some of the largest PPCs, sued the South African government in 1998 for certain provisions of its Medicines Act related

to compulsory licensing and parallel importing. The case was withdrawn in 2001, amid strong criticism by an ever-growing number of actors and it contributed directly to the WTO Doha Declaration on the TRIPs Agreement and Public Health that was agreed on unanimously by the WTO members that same year.

To put it briefly, the Doha Declaration singled out certain TRIPs provisions related to pharmaceutical patents, parallel importing and compulsory licensing and reinstated governments' right to use certain policy tools to deal with public health crisis, as and when they arise. Although an important achievement, by virtue of simply reinstating and clarifying what was already in TRIPs, the Declaration hardly constricted global pharmaceutical IPRs. Rather, what was more worrisome for PPCs was the WTO process that was set in motion by the Declaration with regard to compulsory licensing. After the Declaration in 2001, the task ahead of the WTO TRIPs Council was to find a solution for countries with insufficient pharmaceutical manufacturing capacities whose right to use compulsory licensing for public health purposes was limited by the mere lack of such capacities, as well as by provisions in TRIPs which did not permit compulsory licences for import/export purposes.[10] As far as PPCs were concerned, if such provisions were relaxed, a large number of countries could claim insufficient manufacturing capacities for individual or a group of medicines; in a worse case scenario, this would have meant, from PPCs' perspective, a *de facto* erosion of global patent protection mandated by TRIPs. For this reason, individual PPCs and their associations, PhRMA, EFPIA and IFPMA, worked relentlessly to limit the number of countries that would be eligible to use compulsory licences for import, as well as the number of diseases for which such licences could be issued. These positions were mirrored in various negotiation proposals put forward by the key advanced countries, particularly the USA.

In the meantime, PPCs' efforts to protect and strengthen their IPRs globally continued at the bilateral and unilateral front. At the behest of PPCs, a few FTAs negotiated by the USA effectively prohibited parallel importation of medicines and set restrictions on compulsory licensing, the very issues on which the negotiations at the WTO TRIPs Council were based during the early 2000s. With regard to compulsory licensing, for instance, the US FTAs with Jordan (2000), Singapore (2003), Australia (2004) and those initiated in 2003 with the South African Custom Union and the Free Trade Area of the Americas (FTAA) (both stalled) limit the grounds upon which a licence can be granted, while those with Singapore, Australia and Morocco (2004) effectively block parallel imports (Abbott 2004; Morin 2006). In addition, all the US FTAs concluded since the early 2000s have included 'TRIPs-plus' provisions for data exclusivity and patent extensions (GAO 2007). Furthermore, the Special 301 procedure continued to be used in order to pressurise other countries to 'improve' their pharmaceutical IPRs; indeed, from 2000 onwards, nearly half of the countries listed in the Special 301 reports were found to have 'inadequate' IP protection for pharmaceuticals, with data exclusivity, a key issue for pharmaceutical companies, emerging as the top concern.

Back at the WTO, a 'solution' was agreed upon during the Cancún Ministerial meeting in 2003 and the relevant TRIPs provisions were amended just before the Hong Kong Ministerial meeting in 2005 to mirror the solution. A series of

administrative barriers were set up for countries that would contemplate issuing compulsory licences for import/export, while the markets of advanced countries (as mentioned above, these constitute over 80 per cent of the global market of PPCs) were effectively fenced off from the amendment through an 'opt-out' artifice.[11] The extent to which this 'solution' will improve access to cheap and affordable medicines in poorer countries remains to be seen. An attempt by MSF to use the mechanism set up by the solution in 2004 was unsuccessful and Rwanda's efforts using the mechanism since mid 2007 have yet to produce results (The National Board of Trade 2008). The WTO mechanism for compulsory licences for import/export aside, a few countries have been able to use the *threat* of issuing a compulsory licence for the domestic market with some success; Brazil is a noteworthy example in that, until recently, it has been able to negotiate with PPCs considerable price reductions for some HIV/AIDS pharmaceuticals under such threats. However, when compulsory licences for medicines have been issued, particularly in markets of interest to PPCs, considerable pressure has been brought to bear by PPCs and their home countries. For instance, considerable pressure was placed on Thailand and Brazil by PPCs, the USTR and the EU Trade Commissioner for issuing compulsory licences on antiretroviral medicines in 2006 and 2007.[12]

Last words

These recent developments are certainly not the last ones on the IP access to medicines front. Nor are they the only developments in the field of pharmaceutical IPRs. This article is necessarily limited and has only sought to introduce PPCs as global political actors in the area of global IPRs. The involvement of PPCs with the latter has been considerable and has grown even further since the 1980s, a period during which, incidentally, PPCs have become less innovative and more unclear about their future direction. Despite these uncertainties, or rather because of them, PPCs continue to be active politically in various levels and fora. This essay has largely dealt with developments within the global trade regime and the WTO, but others have been unfolding and engaging PPCs elsewhere. One such development is the WHO Commission on Intellectual Property Rights, Innovation and Public Health that set in train a serious rethinking of pharmaceutical R&D and potential ways to fund research for diseases disproportionately affecting people in developing countries, which the current R&D model is failing to do. Various proposals have emerged such as one that aims to grant prizes for successful medicines rather than pharmaceutical patents and another that proposes the creation of a health impact fund that would pay PPCs in proportion to the extent to which their products reduce the global burden of disease. Whatever the final outcome, what is clear now is that the pharmaceutical R&D model is under scrutiny, as is the IP system based on it. For their part, as has been highlighted, PPCs have sought to strengthen and enhance their IPRs through various unilateral, bilateral and multilateral channels. On the latter channel, a new development relates to reports circulated at the time of writing (September 2008) concerning an Anti-Counterfeiting Trade Agreement being negotiated behind closed doors between the US, EU, Switzerland, Canada and a few other countries

on behalf on key IP-reliant industries. PPCs are reportedly trying to use this new agreement as a way to prevent parallel trade and thereby reduce access to cheaper medicines (Silverman 2008). Access to medicines aside, other issues related to pharmaceutical IPRs will continue to engage PPCs politically. As we have seen, one such issue relates to pharmaceutical test data protection. Another relates to patents that involve genetic resources, with groups and state actors from genetic resource-rich countries demanding disclosure and benefit sharing with the patent holders. Overall, the issues are many, the stakes are high and the repercussions considerable – PPCs are obviously not the only actors involved, but they are certainly powerful and significant.

Notes

1. Two such studies were widely circulated to state negotiators and civil society groups before and during the WTO Doha Ministerial in 2001 (Bombelles 2001; Attaran and Gillespie 2001); also see the Consumer Project on Technology (2001).
2. According to data from Fortune 500, available at http://money.cnn.com/magazines/fortune/fortune500/2008/industries/21/index.html [Accessed 14 September 2008]; and Med Ad News (2008), http://www.pharmalive.com/magazines/medad/?date=09%2F2005 [Accessed 14 September 2008].
3. That is, apart perhaps from the growth of the US market, which slowed down during the 2000s. See for instance Med Ad News (2008).
4. A 'blockbuster' drug is one that works for the majority of the patients with a certain condition and achieves sales of over US$1 billion per year. The 1980s represented the first time in history of the pharmaceutical industry that some companies derived up to 50 per cent of their profits from one 'blockbuster' drug only.
5. Some of these points are highlighted by various authors: see, for instance, Sell (2003), Matthews (2002) and Watal (2001).
6. Unlike 'pipeline' protection, the 'mailbox' provision intends to freeze the novelty requirement for the granting of pharmaceutical patents for products that were filed after the TRIPs agreement came into force (1995), but which would not benefit from patent protection in countries where this protection is not available until a later date if the mailbox mechanism is not provided. As the GATT secretariat explained to the pharmaceutical companies distressed over the long transition periods granted to developing countries, 'for all practical purposes the economic effect on the grant of product patents for pharmaceuticals will be as if the obligation to grant product patents were effective in *all* countries on the day of entry into force' of the TRIPs agreement (see Gorlin 1999).
7. See USTR Special 301 lists, website www.ustr.org.
8. Parallel importing or parallel trade of patented medicines which consists of the exportation and importation of such medicines through distribution channels other than those authorised by the patent holders. PPCs are particularly concerned about parallel trade given their practice of price discrimination and the high value of pharmaceuticals per unit weight, which makes it worthwhile to parallel trade them in other countries even for minor price differences.
9. For a discussion of these cases and Panel decisions, see Reichman (1998) and Trebilcock and Howse (2005).
10. Article 31(f) of the TRIPs agreement on Other Use without the Consent of the Right Holder stipulates that 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'.
11. The countries that 'agreed' to opt out were: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxemburg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the UK and the USA. Additionally, 10 countries expecting (in 2003) accession to the EU agreed to use the system as importers only in cases of national or other extreme cases of urgency, upon which accession they would opt-out completely. These are: the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia. Finally, 14 other countries agreed to use the system only in cases of national emergency. These include high-income developing countries: Hong Kong, China, Israel, Korea, Kuwait, Macao China, Mexico,

Qatar, Singapore, the Separate Customs Territory of Taiwan Penghu Kinmen and Matsu, Turkey and the United Arab Emirates. The list can be found in WTO (2003).

12. For reactions to these compulsory licences, see http://www.cptech.org/ip/health/ [Accessed 18 September 2008].

References

Abbott, F. (2004), *The Doha Declaration on the TRIPs Agreement and public health and the contradictory trend in bilateral and regional free trade agreements*, Occasional paper 14, Quaker United Nations Office, Geneva.

Attaran, A., and Gillespie-White, L. (2001), 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa', *Journal of the American Medical Association*, 286 (15), pp. 1886–92.

Bale, H.E. (1998), 'The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals', *Journal of International Economic Law*, 1 (4), pp. 637–53.

Ballance, R., Pogany, J., and Forstner, H. (1992), *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy* (Cheltenham: Edward Elgar).

Bombelles, T. (2001), 'Facts and figures on patenting and access in Africa', Presentation of a report of an August 2001 PhRMA survey on patents in Africa, American Society of Law, Medicine and Ethics (ASLME) Conference on Law and Human Rights, Philadelphia, PA, 30 September.

Consumer Project on Technology (2001), *Comment on the Attaran/Gillespie-White and PhRMA surveys of patents on antiretroviral drugs in Africa*, Available from: http://www.cptech.org/ip/health/africa/dopatentsmatterinafrica.html [Accessed 15 September 2008].

Danzon, P., and Keuffel, E. (2005). 'Regulation of the pharmaceutical industry', paper presented at the National Bureau on Economic Research Conference on Regulation, 9–10 September, NBER, Cambridge, MA.

Danzon, P., Epstein, A., and Nicholson, S. (2003). 'Mergers and acquisitions in the pharmaceutical and biotech industries', paper presented at the Organizational Economics of Health Care Conference, http://ssrn.com/abstract=468301, Rochester NY, 24–25 October.

DiMasi, J., Hansen, R., and Grabowski, H. (2003), 'The Price of Innovation: New Estimates of Drug Development Costs', *Journal of Health Economics*, 22, pp. 151–85.

Drahos, P. (2001), 'BITs and BIPs: Bilateralism in Intellectual Property', *Journal of World Intellectual Property*, 4, pp. 791–808.

Drahos, P., and Braithwaite, J. (2002), *Informational Feudalism: Who Owns the Knowledge Economy?* (London: Earthscan).

Dutfield, G. (2003), *Intellectual Property and the Life Sciences Industries: A Twentieth Century History* (Sudbury, MA: Dartmouth Publishing).

EFPIA (2004), 'Annual Report', The European Federation of Pharmaceutical Industries and Associations (2004). Available from: www.efpia.org [Accessed 18 September 2008].

EFPIA (2008), *Industry in figures 2008*. Available from: http://www.efpia.org/content/Default.asp?PageID=358 [Accessed 14 September 2008].

GAO (2007), *Intellectual property: US trade policy guidance on WTO declaration on access to medicines may need clarification*, GAO-07-1198 (Washington, DC: The United States Government Accountability Office).

Gorlin, J. (1999), 'An analysis of the pharmaceutical-related provisions of the WTO TRIPS (Intellectual Property Agreement)', Intellectual Property Institute, London.

IMS Health (2008), '2008 Global pharmaceutical market insights', Available from: http://www1.imshealth.com/web/content/0,3148,64576068_63872702_70260998_82829532,00.html [Accessed 17 September 2008].

Matraves, C. (1999), 'Market Structure, R&D and Advertising in the Pharmaceutical Industry', *The Journal of Industrial Economics*, 47, pp. 169–94.

Matthews, D. (2002), *Globalising Intellectual Property Rights: the TRIPs Agreement* (London: Routledge).

May, C. (2000), *A global political economy of Intellectual Property Rights: the new enclosures?* (London: Routledge).

Med Ad News (2008), '21st Annual Report: Belt Tightens on Big Pharma', Available from: http://www.pharmalive.com/magazines/medad/view.cfm?articleID=5067 [Accessed 17 September 2008].

Morin, J.-F. (2006), 'Tripping Up TRIPs Debates: IP and Health in Bilateral Agreements', *The International Journal of Intellectual Property Management*, 1 (1–2), pp. 37–53.

Reichman, J.H. (1998), 'Securing Compliance with the TRIPs Agreement after US vs India', *Journal of International Economic Law*, 1 (4), pp. 585–601.

Ryan, M.P. (1998), *Knowledge diplomacy: global competition and the politics of intellectual property* (Washington, DC: Brooking Institution Press).

Santa Cruz, M. (2007), *Intellectual property provisions in European Union trade agreements: implications for developing countries*, Issue paper 20, International Centre for Trade and Sustainable Development, Geneva.

Sell, S. (2003), *Private power, public law: the globalization of intellectual property rights* (Cambridge: Cambridge University Press).

Sell, S., and Prakash, A. (2004), 'Using Ideas Strategically: The Contest between Business and NGO Networks in Intellectual Property Rights', *International Studies Quarterly*, 48, pp. 143–75.

Silverman, E. (2008), '*Counterfeit trade deal may hurt generics: activists*', 17 September 2008. Available from: http://www.pharmalot.com/2008/09/counterfeit-trade-deal-may-hurt-generics-activists/ [Accessed 18 September 2008].

Tarabusi, C.C., and Vickery, G. (1998), 'Globalisation in the pharmaceutical industry'', *International Journal of Health Services*, 28, pp. 67–105.

The National Board of Trade (2008), *The WTO decision on compulsory licensing: does it enable import of medicines for developing countries with grave public health problems?* The Government of Sweden. Available from: http://www.kommers.se/templates/Standard_3127.aspx [Accessed 18 September 2008].

Trebilcock, M.J., and Howse, R. eds. (2005), *The regulation of international trade* 3rd ed. (London: Routledge).

Von Braun, J., and Pugatch, M.P. (2005), 'The Changing Face of the Pharmaceutical Industry and Intellectual Property Rights', *The Journal of World Intellectual Property*, 8, pp. 599–623.

Watal, J. (2001), *Intellectual property rights in the WTO and developing countries* (Alphen aan den Rijn: Kluwer Law International).

WTO (2003), Chair's Statement, WTO General Council meeting minutes, WT/GC/M/82, 13 November 2003.