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Received 12 August 2014
Revised 27 November 2014
Accepted 27 November 2014

Abstract

Purpose – This paper aims to explore how established multinational enterprises (MNEs) have responded to the perceived threat from rising power firms by seeking to alter the intellectual property institutional environment in key emerging economies.

Design/methodology/approach – The key place of emerging economies in the efforts of established MNEs to seek patent law change is discussed. Two case studies review developments related to pharmaceutical patents in India and South Africa, highlighting the influence of MNEs in driving policy change and the contested nature of their actions.

Findings – While India and South Africa both present evidence of MNEs seeking to influence pharmaceutical patent laws, distinct differences emerge. In India, most MNE pressure has been in response to the emergence of an active domestic industry and a patent law oriented towards generic entry, while the MNE priority in South African has been geared towards maintaining MNE dominance and a system which leads to generous granting of patents.

Practical implications – Managers and decision-makers seeking to invest in emerging economies must take account of a plethora of institutions present, which may be better suited towards local industrial and consumer interests and may prompt resistance to any established MNE-led attempt at institutional change.

Originality/value – The article offers a comparative perspective on pharmaceutical patent laws in India and South Africa, which have been subject to significant contestation by policymakers, civil society organisations and both rising power and established MNEs. The comparison explores and questions the increasingly widespread "institutional void" thesis in international business.

Keywords Pharmaceutical, India, South Africa, Institution, Patent, Rising power

Paper type Conceptual paper

Introduction: out of, and into, the "institutional void" – firms in emerging economies

The transformation of firms from rising powers into emerging multinational enterprises (MNEs) (UNCTAD, 2006) poses a potential competitive challenge to established

The author would like to sincerely thank the special issue editor, Rudolf Sinkovics, and the anonymous referees for their helpful comments on earlier drafts of this paper. The author would also like to acknowledge the encouragement and support of the "Rising Powers" team at the University of Manchester, led by Khalid Nadvi.

critical perspectives on international business
Vol. 11 No. 3/4, 2015
pp. 285-300

1742-2043
DOI 10.1108/cpoib-08-2014-0039

multinationals – in both emerging economies and in developed country markets. Having familiarity with the emerging market institutional environment, developing country MNEs can possess key strategic advantages over developed country MNEs (Bhattacharya and Michael, 2005; Lall, 1983; Ramamurti, 2012; Williamson *et al.*, 2013; Yeung, 1994). Whereas the latter can face a "liability of outsidership" (Johanson and Vahlne, 2009), emerging MNEs have mostly generated their initial capabilities specifically for their domestic and proximate markets (Sinkovics *et al.*, 2014, p. 677). Their evident advantage is manifest in the significance of developing country MNEs amongst the largest foreign firms in the least developed countries (Cuervo-Cazurra and Genc, 2008) and in the higher failure rate of developing country subsidiaries in developed countries (Garg and Delios, 2007).

Established multinationals must respond to this growing competitive threat and to their institutional disadvantage in emerging markets. Whereas the presence of particular market-supporting institutions can be taken for granted by developed country MNEs in their home markets, the absence can hamper firms entering emerging markets (Cuervo-Cazurra and Genc, 2008). Characterising emerging markets as "falling short to varying degrees in providing the institutions necessary to support basic business operations", Khanna and Palepu (1997, p. 1) argue that for MNEs to "win" in emerging markets, they must overcome relative gaps linking buyers and sellers – which they call "institutional voids" – in product, labour and capital markets (Khanna *et al.*, 2005; Khanna and Palepu, 2010).

This article takes the case of the pharmaceutical industry to explore how established MNEs have responded to the institutional conditions in emerging markets. The "pharmerging" markets, involving the BRIC (Brazil, Russia, China and India) countries as well as Mexico, Turkey and South Korea, are a major focus of growth for the pharmaceutical industry (IMS Health, 2009). Whereas the Global North is characterised by mature markets, patent expirations and increased regulatory hurdles, pharmaceutical growth in the Global South is driven strongly by changing disease patterns, including increases in so-called lifestyle illnesses such as diabetes, cardiovascular and oncological diseases which require prolonged care; it is also driven by such developments as greater economic growth and greater insurance funding (IMS Health, 2013). With double-digit growth predicted until 2017 (IMS Health, 2013), emerging markets have been hailed as the "promised land" of the pharmaceutical industry (Booz&Co, 2012). Yet the largest pharmaceutical companies in the world are still underrepresented in the major "pharmerging markets". In 2009, for example, only 0.9 per cent of the combined sales of the world's top 15 pharmaceutical manufacturers was accounted for by China, while Brazil, India and Russia together represented only 2.9 per cent (IMS Health, 2009).

For established MNEs competing with rising power firms and entering emerging economies, a key challenge is presented by differences, particularly the relatively "weaker" protection available, in the pharmaceutical patent laws. Compared to the Global North, a lack of formal, intellectual property (IP) legal protection, in addition to issues such as infrastructure difficulties (e.g. problems with cold chain distribution), has been called an "institutional void" in the product market facing pharmaceutical firms (Khanna *et al.*, 2005; PM360, 2013). Foreign companies seeking local partners to access markets may worry about the lack of a familiar system of patent enforcement and thus be put off entering emerging economies (Khanna and Palepu, 1997, p. 47). This is

significant in the pharmaceutical industry where, although substantial investment and a long-time investment are required to introduce a new molecule, the drug is then relatively easily copied (Muzaka, 2009). Many pharmaceutical MNEs have cited a lack of patent protection and fears of appropriation of their key research as an investment deterrent, particularly in developing and emerging economies (Mansfield, 1994). The rising power economies are thus a focus of contestation around the setting of IP rules (Abbott *et al.*, 2013), with intense debate being generated by recent revisions (proposed and actual) to patent laws in India, Brazil and South Africa. Such economies may not be characterised by "institutional voids", however, but rather different regulatory regimes that are suited to encouraging the growth of emerging economy firms and serving wider health interests. Less patent protection has greatly benefited rising power pharmaceutical firms (as well as those in other sectors), providing some competitive advantage in generics.

This paper challenges some of the main tenets of the "institutional void" thesis through a review of how MNEs have sought to shape pharmaceutical patent law in India and South Africa in response to potential and actual threats of institutional change. Given that, even when extensive patent protection characteristic of the Global North is absent, many actors are present who have developed various norms and routines to operate in this environment, it is argued that calling such emerging economies "institutional voids" is misleading. Rather than MNEs coming in to fill the alleged voids for societal benefit, it is further suggested that a lack of patent protection may actually be better suited to local firms and even to public health interests. The two country cases considered here point to some of the more contentious and, at times, socially divisive ways in which established MNEs operate in developing countries (Roberts and Dorrenbacher, 2012; Yamin and Sinkovics, 2009).

The article proceeds by first discussing the significance of IP in emerging economies, particularly in the pharmaceutical industry. The two country cases are then taken to chart the trajectory of contestation, including recent controversies. The article concludes by arguing that while MNEs may seek to change institutions in rising powers in response to growing competition, it may be inappropriate to interpret emerging markets as "institutional voids" that MNEs will fill with socially beneficial results.

Emerging economies and IP

One of the trade issues most characterised by North-South difference centres on IP, particularly patents (Shadlen, 2004). Most of the world's IP is owned by firms in the global North, while the Global South largely imports it. However, the majority of countries in the Global North only implemented extensive patent protection, including in pharmaceuticals, once they had achieved a considerable degree of economic development (Chang, 2001; Cimoli *et al.*, 2011). Historical evidence suggests that IP protection is more beneficial to developed countries (WDR, 2002, p. 146), whereas weaker IP can facilitate access to technology in developing countries. If host emerging markets fail to grant or enforce intellectual property rights (IPR) (Hennart, 2012), many established MNEs encounter an institutional environment unsuited to their business model.

Increasing competition, and a perceived threat, from rising power firms to established IP holders has been cited as a key factor behind the significant pressure on emerging and other developing economies to conform to the IP norms of countries in the

Global North. For example, Roemer-Mahler (2013, p. 123) observes that "competition between R&D-based innovator companies in the USA and Europe, and firms in emerging markets helped catapult the [IP] issue onto the global agenda in the 1980s". Abbott *et al.* (2013, p. 28) also refer to actions of industrialised countries designed to limit "penetration of imports from emerging markets".

On a global level, the response of established MNEs, through their business groups, to the perceived competition from emerging economy firms was most notable in the formation of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement of 1994, a global agreement on IP. With the Global North facing declining competitiveness in some manufacturing industries from the 1970s and 1980s onwards, its multinational firms played a key role in presenting, and ultimately securing, a global agreement on IPR (Muzaka, 2009; Sell and Prakash, 2004). The pharmaceuticals industry, along with agro-business and software, lobbied for the inclusion of IPR in the Uruguay Round of trade negotiations starting in 1986. Pfizer's Chief Executive and the Chairman of IBM established the Intellectual Property Committee to coordinate the policy of IP-based corporations, which then lobbied the US Congress and the US Trade Representative (USTR) to promote increased IP protection abroad (Klug, 2008, p. 213).

Large emerging economies in particular were targeted for IP reform during the TRIPs negotiations, being placed under considerable bilateral pressure. Threats were made to remove offenders' benefits under the USA's Generalised System of Preferences (GSPs). For example, South Korea was threatened with loss of benefits in footwear, tires and electronics. In some cases, including for Brazil (1988), Thailand (1989) and India (1992), and all in relation to disputes over pharmaceutical patents (Flynn, 2010, p. 311), these threats were followed through and benefits were removed. India and Brazil had led a coalition of developing countries, mainly expressed in the G77, which had defended their right to have their own patent laws until the Uruguay Round of trade negotiations (Drahos, 2002). Ultimately, after a long period of bilateral pressure, placed particularly by the USA on major emerging economies, the TRIPs Agreement became a condition of membership of the World Trade Organisation (WTO) in 1994. The Agreement, which also involved copyright and trademark protection, required signatories to introduce 20-year patents in all fields. Developing countries were allowed a ten-year adjustment period until 2005, while least developed countries were granted some further extensions. In a demonstration of the political agency of pharmaceutical companies in setting the institutions of the global business environment, the US pharmaceutical industry is credited with having drafted most of the initial text of the TRIPs Agreement, with subsequent negotiations being mainly fine-tuning (Carolan, 2009, p. 378).

The dramatic growth of the BRIC countries is increasingly seen as having the potential to challenge the trade rules around patents, including those in pharmaceuticals, which have been mostly driven by firms and countries from the Global North (Abbott *et al.*, 2013; Dreyfuss, 2009; Sell, 2011). Given the interest in strong IP protection in the Global North, and the relative lack of advanced technological capabilities in much of the Global South, there is a sense that any move for any relaxation in the TRIPs patent rules is likely to come from emerging markets concerned to benefit their domestic firms and consumers (Abbott *et al.*, 2013; Dreyfuss, 2009).

As a result, continued business and diplomatic pressure from the Global North has been placed to secure and maintain extensive and long patent protection, with rising

powers being targeted in particular. In total, 11 countries were assessed in the first report into IP protection by the US Chamber of Commerce Global Intellectual Property Center (GIPC) (2012) in 2012. Whereas the USA was ranked highest, Russia, Brazil, China and India were the bottom four. In 2014, the five BRIC economies, including South Africa, were characterised as facing "serious challenges" (GIPC, 2014, p. 29). A 2013 report on the "theft of USA Intellectual Property" anticipated that as local companies mature in emerging economies, these countries "will develop adequate legal regimes to protect the intellectual property of international companies as well as domestic companies", but also warned that the USA "cannot afford to wait for that process […]. and needs to take action in the near term to protect its own interests" (GIPC, 2014, p. 2). Building on the capacity-increasing efforts of the Office of Policy and External Affairs of the US Patent and Trademark Office (USPTO), the report recommended not just pressure on foreign governments but also more stringent penalties.

Pharmaceutical patents and MNEs in India and South Africa

Here, I document the strategic responses of some multinational firms and their industry associations to the IP institutional environment in emerging economies – specifically taking the cases of India and South Africa. Both countries have significance as large, emerging economies and also have global relevance for their influence on global governance (e.g. negotiations in trade agreements) and for their demonstration effects to other rising powers and developing countries. This discussion features the key place of both states in the global debate over pharmaceutical IP rules in developing countries and focuses on their position at the frontier of relevant contemporary contestation. Although both involve MNEs seeking to influence pharmaceutical patent law, South Africa has been quite prolific in granting patents, whereas India has been less so and has long been a thorn in the side of multinationals as a result.

India: MNEs' struggle for institutional change

Long prominent in the efforts of multinational firms efforts to shape global trade rules regarding pharmaceutical patents, India is nonetheless now the third largest supplier of medicines (in volume terms) in the world. With a home market – estimated at US $11.2 billion in 2010 – dominated (approx. 70 per cent market share) by domestic firms (Department of Pharmaceuticals, 2012), India is also a key supplier of generic medicines, across the world, including through such organisations as UNICEF; the Global Fund for AIDS, TB and Malaria; the Clinton Foundation; and PEPFAR. The Indian industry has emerged from a context of relatively limited regulatory protection for pharmaceutical patents, and, as a result, India has been subject to considerable multinational pressure to change its IP policies.

In the immediate period post-independence in 1947, multinational firms, which dominated the market, were influential in maintaining India's relatively strong patent laws, inherited from the colonial era. However, government inquiries, including the Ministry of Industry and Supply (1950) and Ministry of Commerce and Industry (1954), recommended changes to reduce the length and scope of pharmaceutical patent protection, thus setting the law in line with the national interest and level of development. Such suggestions were guided by both a public health interest, in terms of access to medicines, and a local industrial development interest. A small group of domestic industrial interests, gathered under the banner of the Indian Drug

Manufacturers Association from 1961, also campaigned for patent reform, whereas the multinationals, from 1965 onwards under the aegis of the Organisation of Pharmaceutical Producers of India, lobbied against the proposed change and succeeded until 1970. In his comprehensive review of business and politics in India from independence to the early 1970s, Kochanek (1974, p. 308) has noted the success of the MNE lobbying to be the most significant example of government policy being shaped by foreign business pressure.

The post-1970 change in the institutional environment played a key role in the development of local, generic firms. From the implementation of a new Patent Act in 1972 until the final amendments to become TRIPs-compliant in March 2005, no pharmaceutical product patent protection operated and short process patents (five years) were provided. During this period, a significant domestic pharmaceutical industry emerged, lowering the prices of medicines. Indian firms used their informal access to networks of knowledge to produce imitated versions of products that were elsewhere under patent and which they sold at a fraction of the original price in India. In contrast, the subsidiaries of many foreign MNEs struggled to compete in the Indian domestic market. Their technology could be easily appropriated by local firms, who introduced many drugs within 2-3 years of their first release on world markets. With MNEs following similar patent guidelines to their home countries, and also facing limits on their ownership share, foreign companies gradually saw their share of the domestic market decline from approximately 70 per cent in 1970 to under 40 per cent by 1992 (Horner, 2013, 2014).

In response to these changes and even though the Indian market was relatively small in the context of the global pharmaceutical industry, multinational companies sought patent law change in India. According to a later statement by the Pharmaceutical Research and Manufacturers of America (PhRMA), "the Indian patent system was the most direct motivation for USA efforts in the Uruguay Round negotiations relating to patents" (PhRMA, 1999, cited in Roemer-Mahler, 2013, p. 131). Major pharmaceutical MNEs persistently claimed that their investments in India and elsewhere were restricted by what they argued was a limited degree of patent protection. In one survey of US firms across 6 industries and 16 countries (96 different combinations) in the run up to TRIPs, the Indian chemicals industry (including pharmaceuticals) was ranked as the most significant in terms of IP protection being too weak for their investment (Mansfield, 1994). However, the potential reintroduction of product patents was met with heavy resistance within India. A campaign group of Indian domestic industry and civil society was formed in 1988, under the guise of the National Working Group on Patent Laws, to "create a movement against foreign pressure to change our patent laws and India's general position on intellectual property rights" (Nand, 1988). Civil society campaigners benefited from access to industry data, while the industry groups benefited from a wider interest group base being involved (Ramanna, 2003). However, with declining support elsewhere and facing balance of payments problems, India eventually agreed to patent law changes as part of TRIPs (Patnaik, 1992).

Since the signing of TRIPs, MNE interests have continued to campaign in relation to the amendments to, and interpretation of, India's pharmaceutical patent law. India has constantly featured in the USTR's annual Special 301 Report, introduced in 1989 to identify trade barriers for US companies due to IP laws. Starting with concern over the absence of mailbox provisions[1], which became the first IP case to

go to dispute settlement at the WTO in 1997 (and which the USA won), India has never dipped below "Priority Watch List" level on the Special 301 Report in its 26 editions to 2014. In one study in February 2000, PhRMA claimed that losses in India from 20 commonly copied drugs amounted to $69 million per year. PhRMA was quoted in *The New York Times* in 2000 as stating in relation to the Indian patent law that it is "designed to punish importers of patented technology into India and to coerce local production" (McNeill, 2000). However, as the interests and partnerships of Indian domestic companies have changed, the business pressure for patent law change is no longer just externally imposed. Major industry association groups in India, representing domestic and foreign firms, such as the Confederation of Indian Industry, the Associated Chambers of Commerce and Industry (Assocham) and the Federation of Indian Chambers of Commerce and Industry have argued the case for strong IP protection (Ramanna, 2003).

Civil society campaigns, along with some domestic industrial pressure, helped ensure some public health safeguards were incorporated into India's TRIPs-compliant patent amendments in 2005. Notably, Section 3(d) required meeting strict criteria on novelty and inventive step for a patent to be granted. In spite of this, some have claimed that various non-allowable patents are still being granted in India (Correa, 2011).

Two more recent events have intensified the concerns of foreign multinationals about pharmaceutical patent law in India. A compulsory license, the first in India under TRIPs, was issued in March 2012 to Natco Pharma to produce Nexavar – a liver and cancer drug from Bayer, making it available at just a fraction of the former price and also leading to knock-on reductions on the prices of other cancer drugs. This decision was followed by the rejection or revocation of patents on other anticancer drugs (Harrison, 2013, p. 732). In another high-profile case, the application by Novartis for a patent on Glivec was rejected by the Indian patent office in 2006. Following a long-drawn procedure, Novartis' appeal was dismissed by the Indian Supreme Court in April 2013 on the grounds of not having met the standard of efficacy required by Section 3(d) of the 2005 Patent Act.

Business and diplomatic pressure for further patent protection, driven by multinational concern, has intensified as a result. The issuing of the first compulsory license attracted debate in the US House of Representatives (27 June 2012), a USPTO official stating that "we are consistent in trying to stop those efforts and trying to stop the granting of compulsory licenses". Pfizer's Chief IP Counsel and Senior Vice President, Roy Waldron, linked these developments to promoting the competitiveness of Indian firms: "India's chief reason and rationale for not complying with the full extent of its TRIPs obligations is related to preserving its domestic industry's export markets" (Letter to the Indian Pharmaceutical Alliance, 23 May 2013). Citing the Novartis decision and India's first compulsory license, India was again placed (May 2013) as a "Priority Watch List" country on the 2013 Special 301 Report. In June 2013, 17 US industry associations, including the US Chamber of Commerce, issued a letter raising concerns about policy decisions in India "undermining recognised intellectual property standards", while 170 members of the US Congress also sent a letter in the same month to President Barack Obama criticising India's IP climate. The GIPC (2014) of the US Chamber of Commerce subsequently ranked India lowest in terms of its IP environment.

Of particular concern to multinationals is the possibility for India having a demonstration effect elsewhere. For example, Pfizer's Roy Waldron, in 2013 Testimony before a House Committee (13 March 2013), claimed that:

> India's actions reverberate far beyond its borders. We have seen several countries adopt policies similar to India's, which are leading to a worldwide deteriorating trend on intellectual property.

Citing the Indian case as one to learn from, Brazil has recently started drafting proposals for patent reform (Bill No. H.R 5402/2013), including limiting patent terms at 20 years maximum and clarifying what is eligible to count as an inventive step. For the GIPC (2014, p. 29) of the US Chamber of Commerce, the Brazilian proposal appears "to emulate the negative experiences from India". Meanwhile, in South Africa, a country where pharmaceutical patent laws have been set much more in line with MNE interests, the Indian case has also been invoked as an exemplar.

South Africa: MNEs' efforts to maintain broad patentability

South Africa presents a contrasting case to India in terms of the degree of patent protection, yet there is also a considerable influence from MNEs in shaping an emerging economy's patent laws. The pharmaceutical industry is much smaller than its Indian counterpart, being estimated at $3.7 billion in 2011 (Kudlinski, 2013). Although a South African-owned company, Aspen, is the largest in the domestic market today, pharmaceutical multinationals such as GSK and Pfizer have a significant presence and a long history in the country. South Africa's pharmaceutical patent laws have been less irksome to the big pharmaceutical MNEs than those of India, yet two very high-profile controversies in South Africa demonstrate the continuing role of MNEs in seeking to maintain the relatively broad scope of patentability in South Africa and to head off initiatives driven by public health concerns around access to medicines.

Until the late 1990s, South Africa's pharmaceutical patent laws attracted relatively little global attention. With patent legislation in place as early as 1916 and the current statute since 1978, a later Intellectual Property Laws Amendment Act was passed in 1997 (subsequently amended in 2002 and 2005) to make South Africa TRIPs-compliant. This extended the patent term from 16 to 20 years and provided an institutional environment which suited MNEs. A system was created that gave little encouragement to the emergence of strong, domestic, generic challengers to MNEs. As will be documented below, key reforms have been proposed, yet ultimately rebuffed.

To encourage generic entry, a new Medicines and Related Substances Control Act was introduced in 1997 with provision for parallel importing and compulsory licensing. Although generic equivalents to certain drugs were manufactured and available at lower prices in Thailand, India and Brazil, they were not available in South Africa because of the patent protection (Barnard, 2002, p. 162). This was particularly significant for antiretrovirals, given that South Africa was then (and is now) the country with the largest number of HIV positive people in the world (T'Hoen *et al.*, 2011, p. 3).

Fearing institutional change, MNEs launched a high-profile campaign to challenge this legal reform in South Africa, both at its proposition stage and after it was signed. The pharmaceutical MNEs objected to the proposed reforms in 1997 meetings with the South African Ambassador to the US and South Africa's Minister of Health, as well as in correspondence with the Deputy USTR. The Chairman of the US–South Africa Business

Council wrote (June 1997) to the US Secretary of Commerce arguing that the proposed amendments will have "grave consequences for not only the USA pharmaceutical industry, but all USA direct investment in South Africa". This was not just a US industry campaign as the European Commission also noted (in a letter of 25th November 1997 to the South African Department of Health) that it had received complaints from the European pharmaceutical industry about bill Section 15C.

The Pharmaceutical Manufacturers' Association (PMA) of South Africa, along with many of its mostly multinational (or MNE subsidiary) members, legally challenged the amendments following their signing into law in December 1997. A suit filed in February 1998 (High Court Case Number 4138/98) claimed that the government was in violation of its WTO TRIPs obligations and that the South African constitution was violated by delegating legislative power to the executive without limiting the Minister's power.

Considerable business and diplomatic pressure ensued to prevent the full changes proposed in the Medicines Act. In its submission to the USTR, PhRMA recommended South Africa be listed as a priority foreign country and claimed that:

> South Africa has become a "test case" for those who oppose the USA government's long-standing commitment to improve the terms of protection for all forms of American intellectual property, including pharmaceutical patents.

South Africa was placed on the USTR's 1998 Special 301 Watch List (only its second appearance – its first being over trademark issues in 1995). In June 1998, the White House announced that South Africa's requests for preferential tariff treatment on four items would be temporarily suspended pending changes in South Africa's IP legislation. South Africa was also then placed on the USTR's Special 301 Watch List in 1999, where it was stated that:

> South Africa's Medicines Act appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights (Consumer Project on Technology, 1999, which also provides a detailed timeline of events).

The multinational pharmaceutical industry campaign struggled, however, and met considerable public resistance (Bond, 1999). Civil society organisations, most notably the Treatment Action Campaign (formed in December 1998) and with some international support from organisations such as the AIDS Coalition to Unleash Power (ACT UP), were driven by concerns over access to medicines and publicly challenged the MNE campaign. A few MNEs withdrew their support for the lawsuit and left the PMA to set up Innovative Medicines South Africa (IMSA)[2]. The multinational pharmaceutical companies abandoned the lawsuit against the South African Government in April 2001. Eventually, an out-of-court settlement was reached, with voluntary licenses on major antiretrovirals being granted to at least three generic companies (Klug, 2008).

The case had implications beyond South Africa, raising general awareness of the public health implications of patents and the need to clarify such issues within TRIPs (T'Hoen *et al.*, 2011). Following trade pressure in South Africa and elsewhere, the Africa Group instigated a proposal at the WTO that later turned into the 2001 Doha Declaration on the TRIPs Agreement and Public Health. The declaration upheld the public health provisions in the TRIPS Agreement to allow countries the right to issue compulsory licenses and to engage in parallel importing.

South Africa has continued to maintain relatively strong patent laws, more stringent than international law requires and lacking many of the flexibilities present in the WTO's TRIPs Agreement. More flexibility is potentially available in such areas as compulsory licenses for health, strict rules for patenting, pre- and post-grant opposition, exceptions to patent rights and grounds for revocation (Gray and Vawda, 2013, p. 185). Perhaps because of the nature of its regulations, South Africa is noted for being relatively prolific in granting patents. For example, 2,442 pharmaceutical patents were granted in 2008 (only 10 of those to local companies – Vawda, 2011). In comparison, only 273 were issued in Brazil during 2003-2008 (TAC, 2014), while India, which has a much larger pharmaceutical industry, issued only 2,347 (25 per cent) to local companies, between 2005 and 2008 (Correa, 2011, p. 7). Compared with the USA and EU, a study found that South Africa was granting 40 per cent more pharmaceutical patents on identical applications (Sampat *et al.*, 2012). Recent United Nations Development Programme research has found that a stricter patentability standard would lead to a decline in the number of patents, potentially increasing competition and leading to a reduction in price of medicines (Park *et al.*, 2013).

In recent years, the reform of South Africa's patent laws has again been proposed by the state. The South African Department of Trade and Industry launched a Draft National Policy on Intellectual Property during 2013. With provisions for higher standards regarding patentable subject matter and "inventive" step, the proposals also recommend learning from India's facility for both pre- and post-grant opposition to weaker patents that fail to meet requirements of "newness", "novelty", "obviousness" and "usefulness for trade/agriculture" (DTI, 2013, p. 9). The proposed reform has been particularly supported by activist groups, including the Treatment Action Campaign, which has been running a "Fix the Patent Laws" campaign in South Africa since 2011.

In response to this initiative, major pharmaceutical companies have again expressed their concerns over a potential change to an institutional environment which has been facilitative towards the interests of foreign MNEs. A proposed campaign to derail the reforms called "Forward South Africa", funded by PhRMA and the Innovative Pharmaceutical Association of South Africa (IPASA) and coordinated by a US lobbying firm, Public Affairs Engagement (PAE) (2013, p. 3), has attracted widespread attention and concern. Suggesting that "South Africa is now ground zero for the debate on the value of strong IP protection", the PAE campaign proposal has warned that:

> […] if the principles in the draft are adopted […]., it may also provide the model for other developing nations, inside and outside Africa, including such important aspiring economies as India and Brazil.

The US Chamber of Commerce's (GIPC) submission (7 February 2014, USTR–2013-0040) to USTR's 2014 Special 301 Report expressed further concerns with South Africa's Draft National Policy on Intellectual Property. Noting a resemblance in the pharmaceutical patentability requirements to Section 3(d) of India's Patent Act, it found "troublesome any IP policies which mirror India's due to the rapid deterioration in India's IP environment over the last two years". In the 2014 list, South Africa scores lowly on the "Patents and Related Rights" category – cited as due to the lack of a pharmaceutical products patent term extension and the lack of regulatory data protection for clinical data (GIPC, 2014, p. 4).

The multinational pharmaceutical industry's efforts to prevent institutional change in relation to patent law in South Africa have attracted considerable criticism. The Director General of the World Health Organization commented that "no government should be intimidated by interested parties for doing the right thing in public health" (Saez, 2014). Médicines Sans Frontières described the campaign as a "covert attempt by the multinational pharmaceutical companies to spend extraordinary amounts of money to interfere in South Africa's legislative process" (De Wet, 2014). The South African Health Minister, Aaron Motsoaledi, even went as far as to call the multinational pharmaceutical industry's campaign "genocide". Invoking other emerging economies as well, he suggested that the multinational campaign:

> […] is using South Africa as an entry point, but this is an attack on Brazil, an attack on India […] an attack on China, Russia and the whole developing world (De Wet, 2014).

Conclusion: beyond the IP "Institutional void"

The institutional and regulatory environment in rising powers is the subject of huge focus, debate and contestation by international business managers and scholars alike. Rising power firms can draw advantages, both in their domestic and international activities, from their greater adaptation to their home country and wider emerging economy institutional environment. Historically, imitation has been a characteristic and a strength of emerging economy firms, facilitating their competitive development *vis-à-vis* established MNEs. In contrast, established MNEs, notably pharmaceutical MNEs from the Global North, can encounter an unfamiliar institutional environment in emerging economies and may respond by seeking to change the institutions, including the patent laws. Even though the domestic pharmaceutical industries in India (<2 per cent of the global market value) and South Africa (<1 per cent of the global market value) are relatively small in value terms, a threat is perceived, particularly in relation to the demonstration effect for other countries in terms of price comparisons. Multinational firms respond by acting via direct corporate pressure, and also via the diplomatic efforts of their own governments, to influence the patent law dimension of the "institutions" in emerging markets.

The Indian and South African cases, while both globally prominent and involving MNEs seeking to influence institutional change, display very distinct trajectories. In India, the change of patent law in the 1970s helped give rise to a substantial domestic industry oriented towards generics production. MNEs countered what they claimed was an emerging competitive threat by seeking to reform India's patent law and reintroduce product patents via the Uruguay Round. With significant civil society awareness, India provided considerable resistance, although ultimately succumbed to TRIPs. More recently, however, the patent flexibilities embedded within TRIPs have been made use of within India and are continuing to challenge some MNE interests. In South Africa, on the other hand, the patent policy has been much more favourable for MNEs. Mostly lacking a domestically owned industry which will aggressively challenge the MNE agenda on patent laws, the state has struggled to push through reforms oriented towards generic entry and has faced considerable counter-pressure from MNEs. Table I below summarises some key distinctions in relation to pharmaceutical patenting and MNE's influence in India and South Africa.

Key characteristics of pharmaceutical patenting	India	South Africa
Estimated pharmaceutical market size	$11.2 billion (2010)	$3.7 billion (2011)[a]
Estimated number of pharmaceutical manufacturing firms	10,563[b]	26[a]
Year became TRIPs compliant	2005	1997
Notable aspects of patent law	Medium patent proliferation Pre-grant opposition Section 3(d) aimed at avoiding ever-greening patents with criteria for novelty and inventive step	High patent proliferation No prior examination of patents
Features in US special 301 report 1989-2014[c]	26 – 3 priority foreign country, 23 priority watch list	4 – 3 watch list, 1 other observations
MNEs policy influence	Maintaining wide scope of patenting (until 1970), re-introducing product patents with TRIPs (2005) and discouraging use of TRIPs flexibilities	Preventing any reduction in patent scope and duration (e.g. 1998-1999, 2014)
Domestic firms challenge to MNEs' patent agenda	Strong	Weak

Table I. Pharmaceutical patenting and MNE's influence: India and South Africa

Sources: [a] Kudlinski (2013); [b] Department of Pharmaceuticals (2012); [c] The IIPA has a chart of countries' special 301 placement 1989-2013; available at: www.iipa.com/pdf/2014SPEC301HISTORICALCHART.pdf

The two cases provide considerable grounds for reconsideration of the "institutional void" thesis. Characterising emerging markets as having "institutional voids" misrepresents the associated economies and the type of strategies that may work, at least in the pharmaceutical industry. Even if these markets do not necessarily have the institutions characteristic of the Global North, rather than an institutional vacuum, pharmaceutical MNEs and their industry association groups encounter established institutions with norms and practices shaping knowledge access and appropriation. When given the opportunity, as in the Indian generic pharmaceutical industry, local firms can establish practices and orientations to deal with local conditions, which they may also leverage in their international expansion. Those institutions best suited to the generally smaller-scale firms and consumers in emerging economies are often quite distinct from the strong intellectual property protection that would support markets for large MNEs from the Global North. Indeed, the particularities of the IP system in India, with the absence of extensive patent protection for a long time, have been crucial to giving rise to the increasingly globally competitive Indian pharmaceutical industry. In South Africa, while some domestic firms are present, multinationals have benefited from broader and longer patent protection.

The Indian and South African cases demonstrate that MNEs intent on coming in to change institutions or to fill so-called "institutional voids" may not necessarily be in the

best interests of development. Instead of viewing emerging economies as in some way "deficient" of institutions, including in intellectual property, scholars and policymakers may recognise the value of fitting such regimes in accordance with the level of development and societal interest. With this in mind, rising powers may not be expected to inevitably converge towards or emulate those institutional environments practised in the Global North, but instead are likely to set their own agendas in accordance with their heterogeneous interests.

Notes

1. A facility allowing inventors to file patent applications in developing countries from January 1995 even though a decision on the patent did not need to be made until the end of the TRIPs adjustment period.
2. The PMA was subsequently renamed to the Pharmaceutical Industry Association of South Africa (PIASA). IMSA and PIASA remained separate until 2013 when they merged to form the IPASA.

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