

# **Politics of Innovation and Development: the Role of Industry Associations in Integrating Political, Industrial and Health Systems in India and South Africa**

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**Abstract:** Integrating political, industrial and healthcare systems has been a major challenge for politics of innovation and development policy in low and middle income countries. This challenge has so far been understood in terms of separate industrial and health related innovation policies without paying adequate attention to the institutional roles of biopharmaceutical and other umbrella associations. This paper seeks to examine such roles in the developmental contexts of South Africa and India. The argument put forward is that in both countries biopharmaceutical and umbrella associations have evolved from lobbying organisations to institutional partners who influence the politics of innovation and development, and therefore the degree of integration and fragmentation of political, industrial innovation and health systems.

## **1. Introduction**

Industry associations are often considered to be controversial actors of innovation and development. Several political scientists and economists express distrust in them. It is not an accident that as early as the 18<sup>th</sup> century Adam Smith (2003) accused industry associations of playing a negative role in the economy, raising the prices of goods and conspiring against the public interest. Such a role was against the emerging economic and political liberalism and the market competition. Much later, Mancur Olson (1982) argued that industry associations always seek unproductive rents and pursue their narrow private interests. In the same line of argument, Moore and Hamalai (1993) warned that industry associations can even generate conflict and lead to waste of resources, discouraging competition instead of promoting innovation and development.

However, this criticism is not shared by researchers who examine the impact of state-business relations (SBR) on innovation and economic performance of developing countries. For instance, Amsden (1989) and Evans (1995) stress that industry associations can collaborate with the state, creating growth-enhancing relations. In this context, Maxfield and Schneider (1997), Doner and Schneider (2000), Cali and Sen (2011) and Sen (2013) and te Velde (2013) argue that effective SBR not only matter for economic performance but also for efficient skills development, capital formation and high productivity. Also, from a historical institutionalist perspective, Leftwich (2009; 2006) understands SBR as relations between political and business elites which interact in order to achieve common goals such as innovation and economic growth.

Despite the long-standing interest of political scientists and economists in SBR, the academic literature has so far overlooked the question of their impact on integration and/or fragmentation of political and industrial innovation systems of developing

countries in specific sectors. Although the concept of political systems describes the set of institutions which interact to facilitate political decisions about allocation of resources and achievement of social goals (Easton, 1957, 1953; Almond and Coleman, 1960), the concept of innovation systems describes the set of institutions which facilitate the generation and diffusion of new technologies and which provide the framework within which government and industry and other actors (e.g. civil society organisations) negotiate policies to influence the innovation process (Watkins et al, 2015; Metcalfe, 1997). In fact, these systems are based on the interaction between public and private domains, enhancing productivity and development in key sectors of economy and society (Lundvall, 2007, 1992; Freeman and Soete, 1997; Freeman, 1995). This paper is particularly focused in the sector of healthcare, examining the role of biopharmaceutical industry associations in the integration and/or fragmentation of political and innovation systems of South Africa and India. The argument put forward is that, in both countries, such associations have evolved from being policy reactive and rent-seeking lobby groups to being institutional intermediaries which influence the degree of integration of political, industrial and health innovation systems. Achieving this complex integration has been a major challenge for policy and practice in developing countries. Biopharmaceutical industry associations shape regulatory institutions bringing together key actors of politics, industry and healthcare. However, in doing so, they also consolidate power dynamics which influence whether the direction of innovation will be towards meeting the needs of the poor or excluding them from the process of economic development and thus reproducing the already high levels of unequal access to health and poverty.

The remainder of the paper is organised as follows. Section 2 conceptualises biopharmaceutical industry associations in terms of politics of innovation and development. Section 3 presents the methodology of research. Section 4 discusses the cases of biopharmaceutical associations in South Africa and India. Section 5 concludes by summarising the paper's overall argument about these associations as institutional actors of fragmentation and integration.

## **2. Conceptualising Biopharmaceutical Industry Associations in Terms of Politics of Innovation and Development**

Politics of innovation and development is concerned with the role of politics, governance and institutions in production and diffusion of new technological goods and services for improving the lives of people, especially in developing countries. According to Leftwich (2013: 688) this concern has only become evident very recently due to crisis of neo-liberalism. 'Indeed, the contrast between the 1980s and early 1990s, when neo-liberalism was in its ascendancy could not be more stark. In its *World Development Report* of 1991 entitled 'The Challenge of Development' the World Bank prescribed a very limited role for the state and its institutions. But by 1997, when many structurally adjusted economies had not achieved what had been intended, the *World Development Report* of that year 'The State in a Changing World' began to acknowledge 'a far more sympathetically realistic, but still cautious, role for the state in development'. In the new millennium and especially in the first quarter of 21<sup>st</sup> century, the state is fully back in the academic debate about key institutional actors of technological innovation and economic development.

This historical shift of focus towards political institutions, and not just economic processes, has enabled the conception of relationship between the state and innovative businesses in terms of complex and multi-layered interactions of different groups and interests (Leftwich, 2007). Such interactions are mediated by industry associations and other collective actors who bring together political and industrial innovation systems for the sake of development. This implies the re-birth of political pluralism as a theory that conceives the democratic process in terms of interaction of competing interest groups (Dahl, 1961; 1972; 1983). Power is not necessarily concentrated in the state. Rather it is diffused on pluralist lines among strong associations (Smith, 2006). But political pluralism, as Muniz-Fraticelli (2014) stresses is far from a coherent school of thought. For instance, as he points out, there is ‘...another sense of pluralism – that of the so-called British pluralists – which concerns not the strategies of groups within the sovereign democratic state, but the constitution and legitimisation of the state itself: the very personality of groups, the definition of sovereignty and the justification of liberal democracy’ (*ibid*: 557). Muniz-Fraticelly regards this school of pluralism as ‘normative’ because it does not accept the state as the unlimited source of legitimate authority and the existence of associations as the result of the sovereign’s tolerance. Indeed, normative pluralists such as Harold Laski (1993) criticised state sovereignty and its claim to authority. However, their critique failed to persuade for the legitimate authority of associations which essentially remain dependent on the regulatory authority of political state. The latter, as Nikos Poulantzas argued in the 1970s, is constituted historically as an institutional entity that is both evolving and relatively autonomous from ruling economic elites and in any case it is never a simple instrument of their associations (Poulantzas, 2014). For Poulantzas, classical elite theory (Michels, 1962; Pareto, 1935; Mosca 1939) that emphasises the concentration of power in a small number of controlling elites but also Marxist theory (Miliband, 1969; 1970) that conceives the state as an instrument of the interests of dominant class fail to grasp the causal priority of structures over agents of development. Poulantzas views the form and functions of the state as being largely independent of the interests and aspirations of classes, elites and their associations (Hay, 2006).

The relative autonomy of the capitalist state enables certain level of SBR for achieving overarching goals such as health innovation. Indeed, several case studies (e.g. Bergek et al, 2008; Hekkert and Negro, 2009; de Ven et al, 1999) indicate three things. First, the successful emergence, development and commercialisation of new technologies is the result of interactions and linkages between micro-firm economic processes and macro-level political institutions: interactions that both purposively and recursively link firm level processes to broader industry activities and government policies – demonstrating that innovation systems both shape and are shaped by broader yet highly active political systems. In these case studies, it is government, at national level, that initially stimulates entrepreneurial activity and then responds to the needs of nascent technology producers and the demands of a fragile yet emerging market. More recent work by Mazzucato and Perez (2014) and Block and Keller (2011) demonstrates the importance of government and the political system for providing normative direction to innovation systems through financing of radical innovations and technologies for the common good. Second, it is industry associations that are identified as lobbying government on behalf of entrepreneurs and industrial elites for greater incentives and advantageous market conditions. These associations play the role of institutional intermediaries and perhaps (temporary) government partners which integrate political, industrial and innovation systems in key sectors

such as health. Thus, for example, this integration appears to be evident when industrial systems and health innovation policy-makers succeed to grapple with issues of whether new initiatives for pharmaceutical production should be national, regional or local and whether they should be rooted in practical activities and applications of knowledge (Chataway, et al, 2009). Third, the presence and interplay of both virtuous and vicious cycles demonstrates that conflicts, negotiations and compromises between different institutional actors, as evidenced by the activities of industry associations, are both inevitable and central as processes through which institutions are informed, innovation policy adjustments are made and incentives are gained, industry standards are set and favourable market conditions are created.

The application of systemic approaches to politics of innovation and development in India and South Africa is of particular interest here. These economies emerged rapidly as global powers alongside Brazil and China, following government policies of greater economic and political liberalisation. India's liberalisation policies began in 1990 and South Africa's political transition to liberal democratic state took place in 1994. Although the actual policies employed by these countries were different due to their unique historical and national contexts, the political and innovation strategies for 'catching up' purposes appear to have some similarities. These include: emerging political and economic pluralism, greater openness to foreign trade and foreign direct investment, the opening up of indigenous industries to global competition, and greater support for private enterprise and entrepreneurial activity along with co-current policies towards the technological development, maturation and global orientation of some domestic firms. These catching up strategies might be seen as the result of bargains between industrial and political elites or as political settlements (Khan, 2000) based on a common understanding of how narrow elitist interests can be served through macro-economic policies of development. Such bargains and settlements are often exclusive of non-elites and civil society organisations, facing problems of unequal representation and therefore weak legitimacy. Indeed, recent research indicates that the types of issues that lobbyists bring to the bargain and settlement table are different from the types of issues that are most important to non-elites and civil society organisations. This is, of course, not something that is unique in developing countries. For example, as Kimball et al (2012) points out, the United States is dominated by corporations and industry associations which have lobbying agenda different from political agenda. What is unique in developing countries is that despite problems of representation and legitimacy, exclusive bargains and settlements between political and industrial elites are effective in directing innovation and development towards liberalisation. This is because they generate political order and stability that helps different actors of political, industrial innovation and health systems to interact through associations. Elite bargains and political settlements in developing countries tend to allocate rents to particular industrial elites. However, recent research suggests that the more inclusive a bargain or political settlement the stronger the coalitions for economic growth (Wood, 2000; Acemoglu et al, 2003). The exclusion of non-elites, civil society organisations and unorganised groups such as the poor and the unemployed leads to weak coalitions. Innovation led growth and development in specific sectors such as health presupposes inclusivity i.e. integrating the lobbying agendas and the political agendas as much as possible.

### **3. Methodology of Research**

This paper draws on an empirical study of biopharmaceutical industry associations and umbrella organisations in middle-income developing countries. The overall methodological approach is qualitative cross-national comparison. The focus is on two countries: India and South Africa. India was selected as one of our empirical research sites because of its active involvement in health innovation and its pluralist context that allows strong policy input from innovation actors such as health industry associations (Athreya and Chaturvedi, 2007). India also has a well-established knowledge-driven health industry (Abuduxike and Aljunid, 2012), and has fast become ‘...one of the world’s largest suppliers of vital medicines and vaccines’ (Srinivas, 2012: 10).

India has experienced a high growth rate of GDP. During 2005-2006 the country grew 9% and during 2006-2007 it grew 9.2% with an average 6.9% for the seven-year period from 2000 to 2007 (Krishna, 2013). Much of India’s recent growth is driven by technological innovations in manufacturing of health products e.g. drugs, pharmaceuticals and medical devices. As Srinivas (2015: 183) notes ‘The Indian health industry, with substantial pharmaceuticals and biopharmaceuticals capability, has been called “supplier to the world”’. Indeed, despite the 2008 economic crisis, the health sector witnessed reasonable stability. Also, the global R&D flows to India have been sustained (*ibid*). A number of companies within the Indian health innovation system are represented by biopharmaceutical associations such as the Organisation of Pharmaceutical Producers of India (OPPI), the Association of Biotechnology Led Enterprises (ABLE) and the Indian Pharmaceutical Association (IPA). At the same time umbrella organisations such as the Confederation of Indian Industry (CII) and the Federation of Indian Chambers of Commerce and Industry (FICCI) play crucial role in promoting health innovation at national level. Finally, government agencies such as the Biotechnology Industry Research Assistance Council (BIRAC), private consultancy companies such as Pricewaterhouse Coopers (PWC), research organisations such as SERUM Institute and MNCs such as GlaxoSmithKline (GSK) constitute important stakeholders in the Indian health innovation system.

South Africa was identified as our second empirical research site because of its position as a biopharmaceutical industry fore-runner in Africa and its recent introduction of a systemic approach to innovation that allows interactions between different actors, including government and industry associations. A number of innovative companies and products in this country are in the sector of health (Cloete et al, 2006: 559). This is because Sub-Saharan Africa in general and South Africa in particular are unique in terms of requirements for health products which combat diseases such as HIV/AIDS, Malaria and Tuberculosis. South Africa’s expenditure for healthcare amounts to approximately 8% of gross domestic product (GDP) (IMSA, 2012). Biopharmaceutical companies in this country are members of both industry specific and umbrella organisations. On the one hand, the Pharmaceutical Industry Association of South Africa (PIASA) until recently represented domestic but also foreign MNCs. In 2009 its members supplied about 40% of the total pharmaceutical market in South Africa (PIASA, 2009). However, in April 2013, PIASA merged with Innovative Medicines South Africa (IMSA) to form a new association named Innovative Pharmaceutical Industry Association South Africa (IPASA). Other industry specific associations within the South African health innovation system include the National Association of Pharmaceutical Manufacturers (NAPM), the

South African Medical Device Industry Association (SAMED), Pharmaceuticals Manufactured in South Africa (PHARMISA) and the Self-Medication Manufacturers Association of South Africa (SMASA). These associations, joined by Roche Pharmaceuticals as an independent company, make up the Pharmaceutical Task Group (PTG), a liaison body involved in pharmaceutical matters within the pharmaceutical industry in South Africa and with several relevant stakeholders where appropriate<sup>1</sup>. On a broader level, the South African Chambers of Commerce and Industry (SACCI) is an umbrella organisation that represents multi-sectoral companies, including biopharmaceuticals. Finally, government departments such as the Department of Trade and Industry (DTI) and Department of Science and Technology (DST), pan-African bodies such as the New Partnership for Africa's Development (NEPAD) but also major MNCs such as Pfizer and GSK are some of the many stakeholders in the South Africa health innovation system.

Data for this paper were collected through both desk-based research and fieldwork. The latter took the viewpoints of all three types of innovation actors mentioned above i.e. biopharmaceutical industry associations; umbrella organisations and related stakeholders. From July 2011 to June 2014 relevant documents such as reports and web-based publications of these actors were collected. In addition 45 face-to-face interviews were conducted with key respondents in India and South Africa. The interviews lasted 30 to 90 minutes with a mean duration of 40 minutes. Interview questions focused on the context and historical background of health industry specific associations and umbrella organisations, their main activities and their relation to political and health systems. Empirical data were triangulated with other sources, including government publications, research journal articles, consultancy reports and media releases. These data were analysed in terms of our conceptual framework of politics of innovation and development, to reveal the role of biopharmaceutical industry associations in integrating political, industrial innovation and health systems in India and South Africa.

#### **4. Findings, Analysis and Discussion**

##### ***India***

Over recent decades, the growing economic power of India, one of the so-called BRICS, has attracted substantial attention (Wilson and Purushothman, 2003). However, researchers tend to focus on the drivers of India's economic growth and its implications for global governance and development, without paying so much attention to the importance of India's political system. India is the world's largest democracy and this has implications for SBR. According to Kohli (2001: 1) 'Indian democracy is ...best understood by focusing, not mainly on its socioeconomic determinants but on how power distribution in that society is negotiated and renegotiated'. This argument draws attention to the power dynamics within and between political (i.e. democratic/pluralist), industrial innovation (i.e. pharmaceutical industry) and healthcare (i.e. new health products/services) systems. The role of biopharmaceutical industry associations and umbrella organisations in integrating or

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<sup>1</sup> <http://www.compcop.co.za/wp-content/uploads/2015/05/PTG-Submission-Response-to-Stakeholders1.pdf> accessed 19 August 2015

fragmenting these systems is crucial for the country's economic and social development.

To understand this role, one should start analysis from the early years of independence when India brought together inherited businesses and political communities experienced with liberal procedures of parliamentary democracy. As Yadav (2008: 69) points out 'By 1947, there were more than 1500 businesses and trade groups ... in India'. This marks an important difference from the SBR of other developing countries. Indeed, as Kotchanek (1995-1996: 530) also reminds us, the development of associations and interest groups in India '...has historically drawn upon liberal traditions of free association and pluralism rather than European, collectivist-public-law based corporatism'. Take for example the case of CII, a leading umbrella organisation in India. According to one respondent:

"[CII]... started as just a 5-company association in Calcutta ... at the time British capital in Calcutta formed an association of engineering companies. So that expanded with British capital and a lot of things came under railways ... Now when Indian capital came to fore they had exactly the same structure as the Indian Chamber of Commerce in Calcutta" (interview extract: 1).

This fundamental division between British and Indian capital as well as caste-and-region-based social separations led to the emergence of a multiplicity of associations, representing industrial elites in India (Kotchanek, 1995-1996). In the decades since independence and especially in the 1980s and 1990s, the roles and strategies of these associations have evolved towards becoming less individualistic and more pluralistic. This clearly corresponds to an accelerated process of political, industrial and healthcare change in India. Specifically, at the level of the political system, the electoral loss of the Congress Party in 1989 and the emerging pattern of coalition governments in the successive years led to pluralism that promotes public policy contributions by businesses and industrial sectors. At the level of the industrial system the New Economic Reforms in 1991 towards liberalisation, export promotion, privatisation and foreign direct investment (FDI) encouraged the private industrial sector in areas such as health not only to innovate for achieving global competitiveness but also to collaborate with government for achieving appropriate regulatory frameworks for innovative products. This is what Srinivas (2015: 185) calls '...Third Market Environment (TME) associated with technological shifts in biopharmaceuticals ... The state in the TME was far less visible ...'. This particular change in the Indian political and industrial systems has enabled biopharmaceutical industry associations like OPPI to lobby government for policies in favour of strong IPRs with tremendous impact on healthcare. Given OPPI's representation of research-based pharmaceuticals, especially MNCs, the tightening of IPRs is considered to be a major incentive for industrial manufacturing of innovative drugs and therapies. Thus, one respondent from OPPI confirmed:

"OPPI spearheaded the movement towards strong IPR laws in India. We made presentations to government ministers, provided evidence of its benefits and created awareness among key government decision makers" (interview extract: 2).

The 1990s liberalisation also enabled the emergence of new associations such as ABLE with the objective to lobby for the Indian biopharma. This industry currently includes more than 300 companies with total revenue of more than US \$2,365 million. Innovative products range from biosimilars and vaccines to bio-manufacturing and stem cells.

Certainly it should be stressed that although biopharmaceutical industry associations welcomed the 1990s liberalisation in India, umbrella organisations such as FICCI opposed it fearing that increased competition from overseas companies would affect their members. This led to a split of opinions about the right approach towards the New Economic Reforms. Other pro-liberal umbrella organisations such as CII criticised FICCI:

“I think CII was behind reform process from the early 1990s and that is very much credit to the CII, although it wasn’t true of other industry organisations ... CII represented progressive face of the industry and I regret to say that FICCI ... represented regressive face of the industry” (interview extract: 4).

This statement reflects the conflict of power among umbrella organisations as regards the influencing of politics of industrial innovation and development. It also reflects the fact that Indian industrial and political elites are far from being a unified community. Politically, the close identification of FICCI with the Indian National Congress has been considered by more liberal industrialists to be an unacceptable sign of corporatism (Kochanek, 1995-1996). In fact, the rise of CII is due to conflict between traditional and liberal/pluralist SBR. This conflict has had impact on the Indian healthcare system. FICCI for instance has been preoccupied with keeping the cost of healthcare down. According to one respondent from FICCI:

“The single greatest importance ... for India is to continue to offer the best and the cheapest medical care for the people of India. As you already know India offers the best and the cheapest medical care in the world in terms of the network, the cost of pharmaceutical products, and [the] cost of medical devices” (interview extract: 5).

By contrast, CII has been preoccupied with fostering health innovation regardless of the cost for patients. According to one respondent from CII:

“We now have a healthcare ... team ... what is called the team for knowledge initiatives. [It] focuses squarely on innovation whether it is in biopharma it does not matter ...”(interview extract: 6).

However, despite their differences, both FICCI and CII provide platforms for integration of the healthcare system with industrial innovation and political systems. As one respondent from private consultancy company stressed:

“CII and FICCI usually concentrate on big ticket policy items that are very high profile in nature, they are closely connected with governments, so they tend to hold annual summits with the government policy makers and stakeholders both foreign and domestic and try to move the agenda on the key issues of the day; bureaucracy, regulatory, tax, strategy, basic industry issues” (interview extract:

7).

This statement reveals two things: first the initiative for integration of different systems is usually taken up by umbrella organisations such as CII and FICCI; second, annual summits constitute a particular platform that is used by such organisations to bring together representatives of political, industrial innovation and health systems.

Systemic integration of different stakeholders is not a by-product of rent-seeking activities of umbrella organisations but rather a clear strategy that aims to achieve stronger coalitions for national economic growth and development. According to one respondent from FICCI:

“...we kind of try to bring in various stakeholders of the ecosystem and work with all of them, so we work with the government, we work with industry, private sector, we work with international agencies and we work with start-ups and venture capitalists and angel investors. So we kind of try to link them all and connect the dots” (interview extract: 8)

The main rationale behind the integrating role of umbrella organisations is avoiding institutional fragmentation. As one respondent from MNC pointed out:

“...industrial associations are important because in an industry that is as fragmented as the Indian industry is, obviously you cannot expect the government to speak to each and every stakeholder” (interview extract: 9).

But apart from reducing fragmentation, how important are industry associations for shaping government policy and state institutions in accordance with their interests and aspirations? And are umbrella organisations more effective than biopharmaceutical industry associations in terms of integrating political, industrial innovation and healthcare systems? On the first question, our data confirms the ‘relative autonomy’ of the Indian state towards biopharmaceutical industry associations despite their systemic and integrating role. Thus, as one respondent from a private consultancy company said about these associations in India:

“...all of them are very useful, they all have some roles to play, in fact, if you look at some policies ... I am not saying because of them [associations] they happened but they certainly played some role in moving the conversation forward in New Delhi and that is very important because it only works through constant representations of industry associations. So the input of industry associations is highly valued by the bureaucrats, the secretaries ...of the respective departments, because for them at consensus time democracy works best when pieces of paper are given by industry associations as opposed to a single large company, a single large company is always viewed as distract in Delhi, so definitely when it comes to bureaucracy on issues of IP or tax they may not succeed but that is the principle of all communication with government” (interview extract: 10).

This statement implies that political decisions on issues such as IP or tax which influence both industrial innovation and healthcare systems in India cannot only be explained in terms of the integrating role of industry associations but also in terms of

structural elements of the Indian capitalist state. The latter include the historical establishment of the Indian federation that depends on resources of the central state and its formal institutions (Dasgupta, 2001). Institutional intermediaries such as industry associations ‘...integrate the state and civil society but they also intermingle very substantially with civil society (defined here as “associations of voluntary nature, standing between the household and the state with at least some autonomy from the state”’ (Manor, 2001: 78). However, these intermediaries do not necessarily control the state. Their power is limited to providing information for public policy making and the political outcome of lobbying is always uncertain.

On the second question about the effectiveness of integration of political, industrial and healthcare systems in India, it might be said that biopharmaceutical industry associations are less successful than umbrella organisations in bringing together key systemic actors. This is because their focus is not on systems but on individual actors such as governments which directly benefit the industry. Consider for example the activities of ABLE. This specific association has established a long term partnership with government agency BIRAC. According to one respondent from ABLE:

“BIRAC ... provides funding to ABLE on a need basis [and] we provide some services to them..” (interview extract: 11).

The most important service that ABLE provides to government is advice on issues such as taxation and regulation of biotechnology. These issues have tremendous impact on life sciences innovation in India. Similarly, other biopharmaceutical associations such as OPPI provide data through reports and submissions to government on issues such as IPRs and clinical trials which influence the environment within which biopharmaceutical innovation takes place. According to one respondent from OPPI:

“...we are looking at how to create favourable government policies which will help innovation and IPR and ...[are] not differentiating at all between multinational and domestic [companies]” (interview extract: 12).

Although biopharmaceutical industry associations in India do not directly integrate political, industrial innovation and healthcare systems, they seem do so indirectly through their involvement in several integrating platforms set up by umbrella organisations and/or government. As another respondent form OPPI revealed:

“... [we] play an active role in all national chambers, so India has three national chambers: CII, FICCI, ASSOCHAM, I am also co-chair at ASSOCHAM, I am co-chair on one of the sub committees on IPRs at FICCI” (interview extract 13).

Indirect involvement of biopharmaceutical industry associations in integrating platforms has impact on innovation and healthcare systems. In fact, through this involvement, various systemic actors come together to change the direction of innovation and healthcare. What forces different institutional actors to integrate is the need to reach agreement on specific regulatory issues such as for example, international non-proprietary names (INN). These are internationally recognised names for pharmaceutical substances recommended by the World Health

Organisation (WHO). INNs are universally applicable names for drugs and thus help to provide a standardised system and to reduce confusion. Given that they are non-proprietary in nature, the same INN can be used by all manufacturers regardless of the brand name under which a specific drug is marketed by each pharmaceutical company (Gopakumar and Syam, 2007). However, until recently, there was no clear policy for regulating the use of INNs in India. Biopharmaceutical industry associations such as OPPI were forced to participate in consultations in order to reach agreement about how to regulate INNs. According to one respondent from OPPI:

“... the Patent Office wanted INN to be mandatory when patent applications are filed. [But OPPI's position was] ... no it's ridiculous because INNs come afterwards, first we file the patent application ...then we have to think whether to commercialise or not” (interview extract: 14).

Given the different positions, a consultation meeting took place in Mumbai that brought together actors from political, industrial and healthcare systems. As the same respondent from OPPI observed:

“...generic companies were there, Indian and multinationals and NGOs were there, patent agents were there, law firms were there, and I was there” (interview extract: 15).

This meeting agreed that INN should not be mandatory when patent applications were filed in order to enable industrial innovation in pharmaceutical products. Thus, OPPI clearly succeeded in influencing the regulatory process in accordance with the interests of biopharmaceutical industry.

Importantly, it is worth reiterating that the relative success of OPPI in influencing the regulatory process in this way must be seen within the historical context of Indian SBRs. In the case of India, successive governments, following independence, have effectively supported the growth of the domestic Indian pharmaceutical industry, this as part of a sustained state directed development approach as described by Kohli (2004) that aimed to both develop domestic industrial and innovation capacities and, to some extent alleviate poverty. In this regard, the Indian Patent Act of 1970 was instrumental in allowing the successful development of India's generic medicines industry. This was coupled with further protections against foreign imports, the promotion of exports, and perhaps most importantly, sustained and considerable investment by the Indian government in India's S&T infrastructure, particularly the building of research institutes and the training of scientists and engineers capable of filling the needs of a rapidly growing industry. It could be argued that the Indian government's early and strong support for the Indian pharmaceutical industry, and domestic industry more generally, allowed industry associations to build their capacities for negotiation and knowledge exchange, i.e. the Indian government, over time, has relied increasingly on industry associations to advise it on how best to grow the industry and to later implement gradually the flexibilities under TRIPS. It could also be argued that this strong government support for the development of the Indian pharmaceutical industry allowed industry associations such as OPPI, often at odds with the position of government, to have a voice at the negotiating table, particularly as the Indian pharmaceutical industry has grown more research intensive over the past two decades.

### ***South Africa***

South Africa is another BRICS country that made the transition from an apartheid state to a constitutional democratic state back in 1994. Since then South Africa has experienced high economic growth but also increased inequality and extreme poverty in certain sections of the population. One important aspect of the South African politics of development is the relationship between the state and civil society. This relationship is characterised by vocal interest groups and industry associations putting pressure on the state about issues of capability expansion through co-production of goods and services and increased share of resource revenues for investment in innovation and development (Evans, 2011; Heller, 2011; Arrighi et al, 2010).

Like in the case of India, to understand the role of industry associations in South Africa a historical approach is necessary. Specifically, one should go back to the early years of transition to democracy when the country moved towards a more pluralist approach to politics than a corporatist one. According to Lehman (2008: 116), ‘Evidence strongly suggests that democratisation … in South Africa since 1994, has weakened the corporatist hold of the state and has strengthened and expanded civil society’. Corporatism is associated with authoritarianism such as was the case during the apartheid era. It describes a system of interest representation based on non-competing associations supervised and controlled by the state (Nyang’oro, 1986). By contrast, neo-liberal pluralism describes a competitive market system of associations which form part of civil society i.e. the realm in which members of society voluntarily create autonomous groups to advance their values and interests (Fioramonti, 2005). As Lehman (2008: 118) points out ‘…the evolution of interest groups in South Africa has been interlined with neo-liberal economic policies, expansion of civil society and uneasy relationship with the state’.

Indeed, this is reflected in the case of two biopharmaceutical industry associations: PIASA and IMSA. In April 2013 these associations merged to form IPASA, currently representing MNCs which conduct their own R&D and excluding domestic pharmaceutical companies which have no IP. Although the vision of IPASA appears to be that of better access to healthcare, the association is in conflict with government over the latter’s policy plan to change the rules for medicine patents. That plan incorporates patent flexibilities after the Doha Declaration (WTO, 2001) and recommends elimination of weak patents, promoting the production of generic drugs (DTI, 2013). In response, IPASA appears to have embarked on an international campaign against full implementation of the government plan, lobbying for stronger IPR regime on innovative medicines. Its main objection is that, by using TRIPS flexibilities and by promoting generics, the South African government’s plan on IP policy will reduce industrial innovation and fail to attract FDI into knowledge-based firms such as biopharmaceuticals (IPASA, 2013). As one respondent from IPASA put it:

“We currently have an environment where there is … adequate respect for intellectual property rights. There is a policy on the table that proposes to change that. The policy itself is not clear enough to our minds, on where it’s

going or how it's going to be implemented ... There is a lot of misinformation going out there ..." (interview extract: 16).

In response to IPASA, the South African government insists that its policy plan is not about weakening the TRIPS regime and the country's health innovation system but about implementing TRIPS with all the necessary flexibilities for the sake of public good (The Economist, 2014). According to one policy maker from DTI:

"... the research industry overreacted ...[and] ... created unnecessary tension ..." (interview extract: 17).

But this conflict is political and mainly takes place between the South African department of health (DoH) and IPASA. It is important to stress that other government departments such as the DTI appear to be more sympathetic towards IPASA, trying to play the role of mediator between government and biopharmaceutical industry. For example, as another policy maker from the DTI made clear:

"... the battle between government and big pharma is led by the health minister, not the DTI, so we try to mediate in one way, DTI is caught in the middle" (interview extract: 18).

Although the conflict between IPASA and government has not been completely resolved, it is crucial to point out that the lack of integration of political, industrial innovation and healthcare systems in South Africa is historical and goes back to the so called 'Big Pharma v Nelson Mandela' case in 1998. That is when the then Pharmaceutical Manufacturers Association (PMA) and 39 MNCs filed a legal challenge against the Mandela government over a law that would allow the country to import generic and cheap drugs to deal with health emergencies such as the HIV/AIDS crisis. Although in 2001 PMA agreed to drop their lawsuit after facing substantial international and domestic opposition, the trust between government and industry and healthcare had been already damaged. As one respondent from an MNC pointed out:

"... pre-1994 I think the industry was more in an advisory role, although perhaps not with lobbying focus, access to government ministries was quite possible. What changed it completely for the industry was the court case of 1998 to 2004 which was all about weakening intellectual property and so created a sense that we [the industry] were against the government. So from that time onward, whenever you went into the halls of government, they [the government] would see you as 'you are that industry that took us to court'; so that created such animosity between the department of health, the relationship has never really been constructive" (interview extract: 19).

This statement confirms that, in South Africa, SBR in the area of biopharmaceutical innovation are fragmented and therefore lack essential characteristics of effectiveness such as transparency, reciprocity, credibility and mutual trust (Cali and Sen, 2011). This ineffective SBR seems to deeply concern several MNCs in South Africa. The reason is their increasing inability to integrate industrial goals with political and healthcare goals. Instead, other civil society organisations and activist groups have

entered the pluralist arena, becoming more successful in integrating their goals with the South African political and healthcare systems. One of these goals is shifting the focus of policy and practice away from innovative drug patents and towards expanding the import of cheap generic drugs from other markets e.g. India. According to one respondent:

“The big drive now which is happening, which is actually very concerning, you can see now our [industry] lobbying efforts have been very ineffectual and the winners in lobbying have been the activists” (interview extract: 20).

This statement reveals the strong competition for power between biopharmaceutical industry associations and other civil society actors for influencing the values and normative direction of biopharmaceutical innovation through integrating or fragmenting political, industrial and healthcare systems in South Africa. It also confirms the emerging neo-liberal pluralism in the country that is highly competitive and eventually leads to winners and losers of power over influencing regulation and governance of health innovation.

Given the limited success of biopharmaceutical industry associations to integrate political, industrial and healthcare systems, the question that arises is whether umbrella organisations provide better platforms for systemic integration. Based on our empirical research findings, we might suggest that the answer is in the positive. According to these findings, umbrella organisations such as SACCI actively seek to bring together actors from politics, industry and healthcare. As one respondent from SACCI said:

“...we do have a very good relationship with government, all things considered. We regularly house cabinet members at our breakfast events and this provides an opportunity for our members to first-hand meet the minister and I think its also a good thing to be able to see and hear the person because seeing someone in person gives a different vibe and they are able to put their case to membership” (interview extract: 21).

Other platforms of integration include high profile events which go beyond narrow industrial innovation issues and towards issues of the wider economy and development. According to another respondent from SACCI:

“...earlier this year we had an election debate so we had representatives from the biggest parties in the national convention all to share thoughts on what is happening in the economy...we have an upcoming event we are going to host for the ruling party specifically about their views” (interview extract: 22).

Indeed, in South Africa, the possibility of integration of political, industrial innovation and healthcare systems appears to be more realistic on overarching public policy goals. The role of the PTG is pertinent in this regard, and their recent submission to the health sector inquiry sums this up in their call to reflect on the fact that ‘[T]he right to access does not only extend to medicines currently available but also to new and/or improved medicines and technology, central to which is R&D and innovator pharmaceutical manufacturers and those domestic companies that license these

products' (PTG Health Sector Inquiry Submission, 2015<sup>2</sup>). Elevation of issues beyond narrow sub-sector interests is also attempted through umbrella associations such as SACCI who act as gatekeepers of broader South African SBRs. As another respondent pointed out:

"[Biopharmaceutical industry associations] also need to take into account there is recognition of how the policies affect the economy. We seldom have to tell a member that what you're saying now might be good for you but it's actually going to hurt the economy moving forward" (interview extract: 23).

The fact that umbrella organisations do not just represent one industry but rather different ones, leads to a more balanced approach towards systemic integration of key institutional actors on issues such as, for example, IP policy. According to the same respondent:

"...one of the principle critiques against IP policy is that it's going to affect the economy but it seems to be that drafters of the policy are only looking at pharmaceuticals. So if you are a small engineering company it's going to affect you even more or just as much" (interview extract: 24).

The problem of closing the gap of integration of political, industrial innovation and healthcare systems in South Africa is not only addressed by umbrella organisations such as SACCI but also by supranational initiatives such as the New Partnership for South Africa (NEPAD). Although not an industry association, NEPAD has been trying to bring together key actors from politics, industry and healthcare in order to promote innovation and facilitate economic development across South Africa. According to one respondent from NEPAD:

"...we facilitate integration and discussion with stakeholders and we can also be partners with multinationals, they really need to align with an aspect which is not well understood on the continent because we might have new things because innovation is anything related to novelty on the market compared to what was happening before...NEPAD is about partnership; we can work with all these associations in a way that everything they need to do can benefit Africa" (interview extract: 25).

Certainly, the focus of NEPAD is not just South Africa, but the African continent as a whole. However, NEPAD promotes harmonisation of regulatory frameworks for pharmaceutical innovation across African countries and for this reason it also integrates information provided by different national associations. According to one respondent from NEPAD:

"...different members of these pharmaceutical associations are contributing because they send questionnaires to firms...associations are directly involved in the process of drug harmonisation (interview extract: 26)

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<sup>2</sup> <http://www.compcop.co.za/wp-content/uploads/2015/05/PTG-Submission-Response-to-Stakeholders1.pdf> accessed 19 August, 2015

For South Africa, though, this ongoing process of harmonization holds particular pertinence: the competition among various industrial associations and civil society groups for power to influence regulatory and pharmaceutical innovation frameworks in South Africa is very much based on the long held notion, among these competing actors, that South Africa stands as the regulatory template for other African countries. In other words, in terms of pharmaceutical regulation and standards, it is believed that as South Africa goes so will the rest of the African continent.

Finally, it is apparent that the historical relationship, much as in the case of India, between the South African government and the pharmaceutical industry has heavily influenced the activities and effectiveness of these industry associations over time. For South Africa, the Apartheid era government, although heavily directing industry through a rather coercive state driven corporatist approach, did very little to support the development of science and technology intensive industries, including a domestic pharmaceutical industry. At this time, the relatively small South African pharmaceutical industry, represented by the PMA and later NAPM, worked with government in support of government aims, but these aims were very narrow and were certainly not aimed at either expanding access to medicines to the wider population nor were they about developing a domestic pharmaceutical industry. By the end of the apartheid era, therefore, the South African pharmaceutical industry lacked sufficient capabilities for both innovation and access, and was still reliant on medicines from abroad. In turn, this has contributed to a lack of constructive policy dialogue and reinforced industry-government distrust, particularly regarding the pervasive assumption that the growth of an innovation-led biopharmaceutical industry in South Africa is incompatible with widespread access to effective and affordable medicines. Furthermore, it could be argued that upon the end of apartheid and the ushering of a more pluralistic state, the South African pharmaceutical industry and the respective industry associations also lacked the experiential based capacity to negotiate with government and to build the necessary coalitions to do so.

## **5. Conclusions: Biopharmaceutical Industry Associations as Actors of Fragmentation and Integration**

The cases of India and South Africa suggest two things. First, the transition of both countries from non-liberal and/or authoritarian political systems to liberal democracies has enabled a level of pluralism that encourages bargains and political settlements through industry associations. Second, these associations in such developmental contexts are not necessarily instruments of ruling elites which control the state. This, in some respects, confirms the neo-structuralist approach to the state defended by Poulantzas (2014). Indeed, political, industrial and healthcare elites are not homogeneous and the state is a relatively autonomous institution that constantly evolves (Jessop, 1982). Under these circumstances, industry associations can be better analysed as actors within innovation systems, representing various and sometimes competing industrial and political interests. In both India and South Africa, the liberalisation processes shaped the state in a way that allowed associations to either integrate political, industrial innovation and healthcare systems (India) or fragment them (South Africa). The table below sums up the sources of integration and fragmentation in the two countries' pharmaceutical innovation arenas.

Table 1: Drivers of integration and fragmentation in the Indian and South African health innovation sectors

	<b>India</b>	<b>South Africa</b>
<b>Drivers of integration</b>	Both umbrella (CII & FICCI) and sector specific associations (OPPI & ABLE); broader innovation and development objectives for the country	Pharmaceutical Task Group (PTG), Umbrella associations (e.g. SACCI), Civil Society Organisations & Supranational bodies (e.g. NEPAD) and DTI; broader innovation and development objectives
<b>Drivers of fragmentation</b>	Sectoral industrial interests; political interests; Policy incoherence; Information asymmetries; Intellectual property (IPR) conflicts;	Intellectual property (IPR); Policy incoherence and tensions among government departments (DOH v DST & DTI); lack of innovation and health policy co-ordination; MNC v domestic company tensions (via the biopharma industry associations); Information asymmetries

*Source: Table developed by authors from research findings*

However, integration and fragmentation are not straightforward processes. Our data shows the degree of integration and/or fragmentation varies from country to country. Clearly, biopharmaceutical industry associations in India integrate less politically as healthcare actors than do umbrella organisations. This is because the latter have historically broader innovation and development objectives than the former. In addition, umbrella associations provide more effective platforms for institutional integration than biopharmaceutical industry associations.

By contrast, biopharmaceutical industry associations in South Africa have been actors of fragmentation in the sense that they have reproduced the historical conflict between politics, industrial innovation and healthcare. For this reason, South Africa is still struggling to develop a biopharmaceutical innovation system that is in line with the country's political and economic goals. At the same time, it cannot deliver innovative products to meet the healthcare needs of all South Africans. Although umbrella organisations, the PTG and NEPAD play more important role in integrating politics, industry and healthcare than biopharmaceutical industry associations, this is not enough yet for facilitating equitable health innovation and economic development in the country. There is a need for better integration and less fragmentation of the key public and private actors involved in the South African innovation system.

Certainly, integration depends on both power dynamics and collaboration between these actors. In both India and South Africa it seems that umbrella associations are closer to governments' innovation and development goals than biopharmaceutical

industry-specific associations. This does not necessarily imply that the direction of health innovation will be pushed towards meeting the needs of BOP through collaborative activities. Rather it implies that health innovation will have to adopt clear development dimensions, including the combating of HIV/AIDS, malaria and other diseases of the poor. For biopharmaceutical industry associations such dimensions cannot be embodied in every drug and therapy production. Rather economic development is an unintended consequence or a by-product of an innovative activity that primarily aims to make profit.

In conclusion, it might be said that although biopharmaceutical industry associations and umbrella organisations have evolved from being rent-seeking lobby groups to institutional intermediaries, they play different (and occasionally competing) roles in the integration of key systemic actors of industry, politics and healthcare. Based on our data, a development policy suggestion might be that empowering umbrella associations might have more advantages in this respect than strengthening biopharmaceutical industry specific associations. In any case, both types of associations increasingly appear to be indispensable for health innovation and economic development in India and South Africa.

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