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When access to drugs meets catch-up: Insights from the use of CL threats to improve access to ARV drugs in Brazil

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ABSTRACT

Access to affordable lifesaving medicines is considered a human right. This leads to a question largely understudied in the catch-up literature on accumulation of industrial capabilities. Can the need to improve access to an essential commodity impact the sectoral catch-up trajectory of the corresponding industry? In 1996, Brazil initiated a policy of universal and free access to highly-active ARV therapy, which put an enormous pressure on the Brazilian Ministry of Health (MoH). In order to ensure an adequate supply of ARVs in the public healthcare system with a limited budget, MoH started negotiating price reductions for high-cost patented drugs, often deploying the threat of using compulsory licensing. Through a scoping review of the literature and construction of the Brazilian case study, the paper explores how the need to access is impacted by prior catch-up in the pharmaceutical sector and triggers in turn future sectoral catch-up. It shows that price negotiations may or may not impact both catch-up and access positively. Catch-up can provide bargaining strength in price negotiations and have a positive inter-temporal impact on both future catch-up and access. However, results suggest that only successful catch-up can lead to long term access, as the capabilities accumulated in aborted catch-up are not sufficient for large scale production of low cost essential medicines. Thus, industrial policy and health policy can impact one another and twining between catch-up and access can be helpful.

1. Introduction

Catch-up theories of industrial capability build-up, like macro-economic theories of growth, focus on the supply side. Sectoral catch-up studies describe pathways by which local firms accumulate capabilities within their sectoral and national innovation systems, expand their markets, and contribute to economic growth (Abramovitz, 1986; Malerba and Nelson, 2011). Catch-up is important for policy makers, because of the underlying implicit assumption that if production is increased, then its trickle-down benefits would improve access to commodities, in terms of their availability and affordability. For most products, these trickle-down benefits are left to be determined by markets, with the state being held accountable for catch-up in terms of the technological, innovative and industrial capabilities upstream, and the quality and safety of goods reaching final consumers downstream. However, for some essential commodities and services, access is also deemed to be the responsibility of the government, and not to be left to markets alone. For example, access to food, water, sanitation, medicines, education etc. as embodied in the 17 Sustainable Development Goals (SDGs), are considered as human rights, and hence, important policy goals. This leads to a question largely understudied in the catch-up literature. Can the need to improve access to an essential commodity impact the sectoral catch-up trajectory of the corresponding industry? In order to throw light on this issue, the present paper takes a bottom-up perspective instead of a top-down view and enquires if access goals of the state can impact catch-up.

Drugs for life threatening diseases are essential commodities, whose universal accessibility is important for inclusive growth. For middle and low-income countries, which have to catch-up in pharmaceuticals, this challenge is most daunting. The manufacturing of small molecule drugs involves two main operations in decreasing levels of complexity and knowledge intensity: production of 'active pharmaceutical ingredients' (API)[1] and drug formulation[2]. The wider the scope of technological capabilities over the production process, the higher the catch-up in

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[1] These are the core therapeutic components of drugs. Industrial production of APIs involves development and optimization of the chemical synthesis.

[2] It is the preparation of final pharmaceutical products (e.g. tablets, capsules, injections, parenteral solutions). It is a relatively simple manufacturing activity wherein inputs go through a physical transformation process.

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pharmaceutical manufacturing. The World Health Organization reports that there are at least 126 developing countries without API production capabilities and 42 in this set have limited, or no competence in drug formulation, relying exclusively on imports to satisfy their demand (WHO, 2011).

When a country is faced with a high disease burden and has to improve access to the corresponding drug, its response is affected by its level of catch-up and whether or not the drug is patented. For emerging countries with limited API production capabilities, the problem may become untenable, if drug manufacturers are unwilling to supply adequate quantities at acceptable prices and/or the corresponding technology cannot be licensed from the supplier and developed independently by other firms. In such cases, Target 3b of Goal 3 of SDG affirms that governments have the right to use, to the full, the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) regarding flexibilities to protect public health, and, in particular, provide access to medicines for all in accordance with the 2001 Doha Declaration on the TRIPS Agreement and Public Health. This includes the possibility of issuing a compulsory license.

Compulsory license or CL is a flexibility contained in TRIPS, whereby a government can permit third parties to produce the patented product without the consent of the patentee. This is a measure that has been purposefully introduced to minimize the potential negative impact of patents on access to medicines. Scholars have confirmed that the CL option empowers developing countries to negotiate prices with pharmaceutical companies more aggressively (Beall et al., 2015; Beall and Kuhn, 2012; Ramani and Urias, 2015).

Under this context, the central questions of our paper can be redefined as follows. For an emerging country with limited manufacturing and innovation capabilities, what are the possible inter-temporal impacts of sectoral catch-up in pharmaceuticals on access to life saving drugs and vice versa? Furthermore, what insights can be gained from the interrelationships between price negotiations of essential patented drugs, access and catch-up?

For our research queries, the Brazilian catch-up experience in the production of antiretroviral (ARV) drugs required by HIV/AIDS patients presents itself as an ideal trajectory to study. In 1996, Brazil initiated a policy of universal and free access to highly-active ARV therapy (HAART) (or simply Universal Access Policy), which put an enormous pressure on the Brazilian Ministry of Health (MoH). In order to ensure an adequate supply of ARVs in the public healthcare system with a limited budget, MoH started negotiating price reductions for high-cost patented drugs, often deploying the threat of using CL. In this context, the paper explores how the need to improve access in Brazil was impacted by prior catch-up in the pharmaceutical sector and in turn triggered future sectoral catch-up.

A mixed methodology is applied to answer our central questions. The literature is first examined and its main findings on catch-up and access are summarized as theoretical constructs through figures. Then the Brazilian case study is built using multiple sources of data. Its implications for the interrelationships between catch-up and access are validated through expert interviews. At each stage, results are inferred, and then in the final section, they are combined together to provide a broader analytical insight. The case study method is applied, because it is suitable for studying complex contemporary social phenomena, when boundaries between a phenomenon and its context are not clearly evident (Yin, 1994). Moreover, since the number of observations of CL threats in Brazil is not sufficiently high to justify a statistical analysis, the case study method is more appropriate.

The rest of the paper is organized as follows. Section 2 presents a scoping review of the literature and summarizes its main findings through theoretical constructs (Figs. 1 and 2). Section 3 starts by tracing the Brazilian catch-up trajectory and then presents a detailed study of the use of CL in price negotiation episodes for ARVs in Brazil. Section 4 discusses the main results obtained, and the refinement they provide of the earlier frameworks (Fig. 3). Finally, Section 5 concludes the paper.

2. A brief review of the literature

The term catch-up has been used broadly to study the comparative or individual experiences of communities (countries, regions or firms) in terms of the evolution of their income, productivity, capabilities or other economic variables (Hartnett and Russell, 2002; Nayyar, 2013). The focus is either on patterns of (lack of) convergence of economic variables in a set of regions or over time (Verspagen, 1991) or on the tracing of the strategy-outcome paths of economic actors (Lee and Malerba, 2017; Odagiri et al., 2010). In the latter, a sub-stream centres on the dynamics of knowledge and capability accumulation within an innovation system applying qualitative inductive research methods such as case studies (Malerba and Nelson, 2011; Ramani, 2014). The present paper situates itself in this niche of evolutionary economics. However, even a comprehensive survey of this sub-stream is beyond the scope of this article. Hence, we briefly discuss the influential theoretical constructs on technological catch-up and then look into the role of access in this literature.

Technological catch-up in production of a commodity can be defined as the acquisition of knowledge, savoir faire, equipment, personnel, infrastructure etc. i.e. all the capabilities, required to manufacture the product in terms of a targeted quantity and quality. Empirical studies demonstrate that even technological catch-up is not technologically deterministic, either in terms of the drivers, the processes or the final state, for the evolutionary trajectory is formed of a series of systemic outcomes, crucially marked by initial conditions and path dependencies (Kline and Rosenberg, 1986; Rosenberg, 1994). Besides being catalysed by science push or demand pull, innovation is induced by systemic changes such as resource scarcities, changing relative prices and productivity challenges (Binswanger et al., 1978; Ruttan and Hayami, 1984). State investment, policy initiatives and the functioning of public agencies play a pivotal role in the performance of national innovation systems. For instance, public investment in developing an educated work force with social capabilities (Abramovitz, 1986) and a dynamic public research network (Nelson, 1993) are crucial. Entrepreneurial firms can thrive only if there are financial institutions that can support the costs of risky investment (Gerschenkron, 1962). Finally, all of the above must be steered by a benevolent and rational government policy to create an enabling environment for industrial capacity building (Freeman, 1995; Lundvall, 1992). Indeed, inadequate institutional capabilities such as rule of law and contract enforcement alongside widespread corruption are cited as the main obstacles to catch-up of developing countries (Keefer and Knack, 1997). Thus, technological catching-up cannot be taken for granted; a variety of necessary and complementary capabilities are required under an enabling environment for effective absorption of available technological knowledge and its transformation into industrial capabilities (Ramani and Szirmai, 2014).

Following Abramovitz (1986), technological catch-up goes through four phases: entry, catching-up, forging ahead, and falling behind. Triggers for thrust into any of the stages may emanate in the innovation system in the form of new problems, actors, knowledge, discovery, technology or innovation, and finally, new policy initiatives (Lee, 2005; Perez and Soete, 1988). Some important triggers for catch-up in the pharmaceutical sector in emerging countries have been changes in the intellectual property rights (IPR) system (Guennif and Ramani, 2012), bandwagon effects of inter-organizational learning (Athreye et al., 2009), reverse brain drain of engineers trained in the USA and Europe (Kale et al., 2008), access to foreign know-how via joint-ventures and alliances (Lee and Kim, 2010) and import of technology and materials (Ren and Su, 2015).

Catch-up by a firm starts with entry through investment in the build-up of absorptive capabilities necessary to learn about existing and superior technologies. Then it continues through learning and