



Qualitative Market Research: An International Journal

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Article information:

To cite this document:

Shyama V. Ramani, Ajay Thutupalli, Eduardo Urias, (2017) "High-value hi-tech product introduction in emerging countries: The role and construction of legitimacy", *Qualitative Market Research: An International Journal*, Vol. 20 Issue: 2, pp.208-225, doi: 10.1108/QMR-01-2017-0034

Permanent link to this document:

<http://dx.doi.org/10.1108/QMR-01-2017-0034>

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High-value hi-tech product introduction in emerging countries

The role and construction of legitimacy

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Abstract

Purpose – This paper aims to study how multinational enterprises (MNEs) can best integrate legitimacy concerns into their new product-launching strategy to successfully introduce high-value hi-tech innovations in emerging countries.

Design/methodology/approach – Theoretical constructs on the role and process of legitimacy construction for the introduction of a new product are built upon the existing literature. Then they are validated and refined through the formulation and analysis of case studies of the launch of genetically modified cotton seeds by Monsanto in India and a HIV/AIDS drug cocktail by Merck in Brazil.

Findings – Legitimacy construction can serve MNEs to face challenges successfully while launching high-value hi-tech products in emerging countries. Challenges to MNEs are likely to be founded on a combination of four types of uncertainties: technological, commercial, organizational and societal. Expected challengers are public agencies and actors representing civil society. An MNE can prepare itself through legitimacy construction along three dimensions: redesign of technology, revision of marketing strategy and non-market investments. To implement the aforesaid, MNEs can engage in outreach in the form of strategic patience, market transaction, business collaboration, compromise and/or confrontation with diverse carefully chosen stakeholders.

Research limitations/implications – The authors limited ourselves to tracing only the formal interactions of MNEs, while it is well-known that many informal and backdoor activities can also accompany their growth in emerging economies.

Practical implications – Legitimacy construction can help MNEs face challenges successfully while launching high-value hi-tech products in emerging countries. This calls for an evaluation of the systemic uncertainties followed by the formulation of a strategy for legitimacy construction and implementation through outreach to diverse systemic actors. Strategic patience can yield positive returns. Market transactions can serve as economic anchors. Collaboration can be pursued with parties who can share the costs of legitimization construction and/or reduce technological and marketing uncertainties. Confrontation should be

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The authors thank the Special Issue editor Prof. Suraksha Gupta and Profs. Arijita Dutta and Michael Czinkota, for useful comments. Eduardo Urias is grateful for support from the CAPES Foundation under the aegis of the Ministry of Education of Brazil (Grant No. 1,020-12-9), and all authors gratefully acknowledge support under the European Union's Seventh Framework Programme project MNEmerge (Grant Agreement No. 612889).



the last choice. Compromise is the most probable but not the only outreach strategy possible after a confrontation.

Social implications – Legitimacy implies product acceptance not only from the targeted consumer but also other societal stakeholders concerned with the safety and equity of the consumption in the emerging country, especially when regulations are not well-defined and/or implemented. The two kinds of societal stakeholders which are likely to monitor MNEs are public agencies and civil society groups. Public agencies will be concerned about the quantity, quality, technology or price of the innovation to be introduced. Civil society and NGOs may help the MNE act as citizen watchdogs for the environment and vulnerable communities.

Originality/value – Theoretical constructs have been developed in this paper on the sources of challenges in new product introduction, the types of challengers and the components of the firm's legitimacy construction strategy and its implementation through an outreach strategy.

Keywords Innovation, Legitimacy, MNE, Bt cotton, ARV drugs, Monsanto, Merck

Paper type Research paper

Introduction

New product introduction in emerging countries poses special challenges for foreign multinational enterprises (MNEs). On one hand, emerging countries offer new and growing markets, cheap sources of qualified labour and manufacturing sites with lower regulatory costs. On the other hand, their very state of underdevelopment and lower per capita income poses commercial risk. This challenge is further increased if the product is a high-value hi-tech one that can benefit not only the rich but also the not-so-rich and even the poor. A variety of regulatory hurdles may need to be crossed if the product is an innovation *vis-à-vis* the emerging countries. It would thus seem that prior to and during the process of introducing any high-value hi-tech product in an emerging country, MNEs should invest in establishing business and social legitimacy, barring which its new product introduction may fail. While there is a growing literature on the returns to legitimacy investment, in terms of long-term growth prospects (Ahlstrom *et al.*, 2008) if and when the systemic conditions are propitious (Bucheli and Sommer, 2014), its role in new product introduction remains understudied. This could be because of the implicit assumption that any new product and associated technology to be introduced in a target region has already earned its legitimacy, if it serves unsatisfied needs or demand. Thus, to contribute to closing this gap, the focus of this paper is the role and construction of legitimacy in MNE strategies for launching high-value hi-tech innovations in emerging countries.

By high-value products, we refer to those that significantly improve living conditions (e.g. low cost air or water filters to improve access to clean air and water), human health (e.g. cancer drugs) or the environment (e.g. high-yielding seeds that require less fertilizer). High-value products are important for inclusive development, i.e. a growth process that benefits all sections of society without excluding any specific group and renders economic opportunities generated by the growth process, accessible to all.

In addition, if the product is also hi-tech, it is challenging for MNEs to maximize profit and rent through introduction in new markets, especially in emerging countries, where capacity to pay may be low. On one hand, MNEs need to recuperate the high R&D costs sunk into its creation, which drew upon the expertise of highly qualified and skilled personnel working with costly and sophisticated equipment over lengthy periods. On the other hand, they need to make the product, especially if it is an innovation *vis-à-vis* the emerging country, accessible to the maximum, while also managing their intellectual property rights (or IPR) to protect their innovation from imitation.

To address these multiple challenges presented by emerging country markets, MNEs have to formulate localization strategies that look beyond adaptation through language and

culture to local consumers. Legitimacy may be essential for the embedding and success of the MNE's product in the emerging country innovation system (Deegan *et al.*, 2002). Legitimacy implies product acceptance not only from the targeted consumer but also other societal stakeholders concerned with the safety and equity of the consumption in the emerging country, especially when regulations are not well-defined and/or implemented. Under this context, our central research question is:

RQ1. How can MNEs best integrate legitimacy concerns in their business strategy to maximize returns from the introduction of high-value hi-tech innovations in emerging countries?

The answers to the above query proposed in the present work form our original contribution to the existing literature on legitimization of innovations for market success. They are of two main kinds. First, the paper proposes theoretical constructs on the role and process of legitimacy construction in new product introduction. Second, it validates these frameworks with real experiences of MNEs seeking to commercialize high-value hi-tech products in emerging countries yields. Two emerging countries, India and Brazil, and two sectors, seeds (Bt cotton) and drugs (HIV/AIDS drug cocktails), form the background, against which the localization strategies of Monsanto and Merck & Co. are examined. The products chosen, namely, genetically modified seeds and antiretroviral (ARV) drugs for HIV/AIDS, are hi-tech, essential commodities with high developmental impact. High-quality seeds ensure better yields and returns to farmers, thereby improving their livelihoods. Similarly, ARV therapies dramatically reduce the mortality and improve the quality of life of people living with HIV/AIDS. Furthermore, both Brazil and India have democratically elected governments and strong civil societies. Taken together, this means that though they offer large and lucrative markets, MNEs cannot take legitimacy for granted in new product introduction. The successes and failures of the MNEs yield insight for managers and also suggestions for the optimal implementation of localization strategies for high impact product innovations.

The remainder of the paper is structured as follows. The next section explains our approach and methodology. Thereafter, the conceptual frameworks based on an examination of the relevant literature are presented. This is followed by two sections with the case studies and the discussion of their main findings. Finally, the conclusion summarizes our arguments and spells out future research directions.

Research approach and methodology

The conceptual frameworks developed in this paper draw upon the extant literature on localization and legitimacy in the context of new product introduction, from two streams of literature: innovation system studies in economics and stakeholder theories of management.

Localization strategies have to be context based. Following the "National System of Innovation" approach spearheaded by the seminal works of Lundvall (1992), Nelson (1993) and Freeman (1995), a context can be considered as a system comprising a set of actors, their endowments and their forms of interaction via networks, markets, alliances, regulation, implicit and explicit norms, etc. The individual actions of the diverse actors jointly determine the economic performance of each and the collective performance of the system. Thus, legitimacy construction can be considered as the outcome of interactions between an MNE and other stakeholders in the emerging country's innovation system.

Though focused on the innovation setting, the systems approach developed in economics has clear overlaps with the stakeholder theory literature in management studies (Freeman, 2010). According to Jones (1995), an organization is characterized by its relationships with

many groups and individuals, each with the power to affect the organization's performance (e.g. profitability, growth) and/or a stake in the firm's performance. Then, a stakeholder can be defined as any group or individual, who can affect or be affected by, the achievement of a corporation's objective. From this perspective, the core ideas of stakeholder theory are consistent with the innovation systems viewpoint, where production and diffusion of innovations are viewed as processes within a system of actors interconnected in diverse ways, playing games according to a set of self-organized rules. As will be detailed, in our paper, the focal actor is the MNE striving to introduce an innovation in an emerging market, while identifying the influence of systemic parameters on its own and other actor strategies and their interactions.

In a second step, the theoretical constructs developed are applied to build case studies of new product introduction by Monsanto and Merck & Co. The issue of legitimacy construction does not lend itself to be answered through examination of secondary data. Indeed, the case study method was the natural choice, as the purpose of our scientific query was to understand the "how" rather than the "why" of legitimacy construction. This form of empirical inquiry is particularly suitable for studying contemporary, complex, social phenomena when boundaries between a phenomenon and its context are not clearly evident (Yin, 1994). Academic literature was supplemented by government reports, newspaper articles and internet sources to build the case studies. The last source was particularly useful to access national and international reports and ministry websites.

Once the cases were developed through reconstruction of historical events, we presented the principal results and their managerial implications to key informants in the seeds sector in India and the stakeholder system of ARV drugs in Brazil. In India, the key informants included marketing managers of seed MNEs, distributors and retailers, public and private sector scientists, economists and subject matter experts on Indian seed sector, representatives of farmer groups and managers of NGOs. In Brazil, the key informants included academics, politicians, lawyers, activists and business persons. In total, 27 interviews in India and 26 interviews in Brazil were conducted. The interviews were exploratory in nature. We introduced our results to the interviewee, questioned them about their validity and noted down their answers in writing without recording them. This procedure allowed us to locate new information, opinions and common knowledge from new angles on the topic to refine the results (Kvale and Brinkmann, 2009).

Finally, we analysed our findings to refine our conceptual model and infer strategy recommendations. Our methodology thus involved a triangulation approach (Denzin, 1978), wherein diverse methods for gathering data from several sources were used to identify the salient features of the process of legitimacy construction for effective new product introduction.

Conceptual framework

Following the extensive literature on national and sectoral systems of innovation, the business eco-system of an MNE in an emerging one can be represented as in Figure 1 (Malerba and Nelson, 2011). There are many studies adopting a systemic stakeholder approach that have examined how MNEs strive to maximize profit through new product introduction in emerging countries. As in mainstream markets, the MNE must take into consideration the activities of other local firms, which may be producing either "substitutes" or "complements/complementary services" (Guennif and Ramani, 2012). Universities and public research institutions in the emerging country may be able to provide valuable sources of qualified personnel and technical and scientific knowledge (Notten and Ramani, 2014). An MNE may have to deal with the state and public agencies through negotiations about the

quantity, quality, technology or price of the innovation to be introduced (Ramani and Urias, 2015). Civil society and NGOs may help the MNE or strive to disrupt its market depending on the perceived impact of the innovation (Ramani and Mukherjee, 2014).

When an MNE enters the emerging country and introduces the innovation, if no other economic actor in the ecosystem contests its presence in the market or sector, then it can be considered to have business legitimacy. This intangible asset of legitimacy is necessary for firms to mobilize resources for production, and at the same time, it is an outcome of firm strategy (Dowling and Pfeffer, 1975; Zimmerman and Zietz, 2002; Hall *et al.*, 2014a; Rao *et al.*, 2008). But it does not exist always, and it cannot be assumed to remain stable once acquired (Bergek *et al.*, 2008). Legitimacy fails to exist or is threatened whenever there is a lack of fit between the values associated with or implied by the MNEs' activities and those of the stakeholders in its innovation system. These threats may take the form of legal, economic and other social sanctions triggered by contestations from other economic actors (Dowling and Pfeffer, 1975). They may even involve actors who are not involved in the innovation value chain.

Contestations from one or more actors in the emerging country are usually founded on one or more of the four types of *systemic uncertainties* which act as triggers to issue a challenge to the MNE.

Technological uncertainty concerns the scientific, technical and engineering hurdles to be tackled to create a targeted new process or product to address a problem/need/unmet demand (Christopher, 1982). The MNE's innovation may not have a good fit with local needs, local demand, local resources, local skills and/or local knowledge. Legitimacy effort by the MNE by way of response may involve redesign of the product or technology, so as to be functional *vis-à-vis* the demand in the target country, while making use of local sources for manufacturing or distribution. Rogers (1995) in his seminal work on the diffusion of innovations proposes that relative advantage, compatibility, complexity, observability and trialability are important attributes of innovation for its wider acceptance. Technology design that is in conformity with social norms and practices increases an innovation's demonstrability in the society (Michael and Palandjian, 2004). Demonstrability of an innovation in turn depends on its compatibility with the existing social norms and trialability within a context of existing practices.

Commercial or market uncertainty is about whether the new technology can compete successfully in the marketplace. This is determined by the nature of the innovation, the nature of the supply and demand sides of the market and especially market competition, entry barriers and consumer acceptance (Christopher, 1982). Such factors influence market

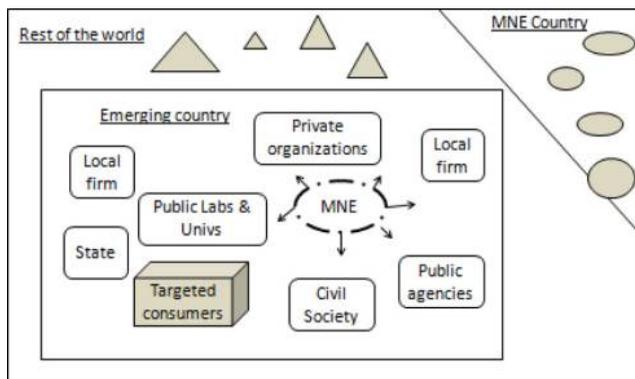


Figure 1. Innovation system of an MNE with a high-tech, high-value innovation in an emerging country

share, brand loyalty and brand equity of the MNE concerned. By way of response, the MNE may revise its pricing, distribution and communication strategies to make the product attractive, accessible and affordable; comply with local regulation, norms and customs; and access local complementary assets (Schmid and Kotulla, 2011). Legitimacy construction can also be incorporated within the marketing strategy to help firms gain confidence of early customers for their innovations which will go a long way in the firms' reputation in the market (Wang *et al.*, 2014). Especially with regard to breakthrough innovations, O'Connor and Rice (2013) have shown firms must spend as much time and investment in marketing as in technology/product design for successful commercialization.

Organizational uncertainty defines the degree to which an organization can appropriate potential economic or reputational gains. There is an extensive literature on how policy, regulation and a host of other systemic regulations such as IPR govern appropriation (Teece, 1986; Freeman and Soete, 1997; Markusen, 2001).

Societal uncertainty issues from societal stakeholders outside of the firm, who decide or influence whether to accept or approve the MNE innovation, based on their beliefs about the innovation's potential socio-economic and/or environmental impact. It could be a representation of the discord of societal members about the socio-economic or environmental impact of the product or activities of the MNE, and/or availability, physical access, quality or affordability of the MNE product/service. It could be the response of stakeholders who may or may not be part of the innovation supply or distribution chain. With respect to the commercialization of major innovations in emerging countries, societal uncertainties play an important role (Hall and Martin, 2005; Hall *et al.*, 2011, 2014a and Pillania, 2011). However, implications of these outside challenges have received least attention from scholars. Most articles studying how firms can reduce the technological and commercial uncertainties of innovations, assume societal acceptance or the absence of societal uncertainty (Jalonen, 2011).

MNEs respond to organizational and societal challenges through non-market investments including engaging in non-market interactions with local actors, which may or may not necessarily relate to their innovation. MNEs' interactions with non-traditional partners and local firms in developing custom innovations and building local capacity is found to increase their social embeddedness in emerging markets (London and Hart, 2004). Non-market investments serve to gain legitimacy in the eyes of stakeholders and promote the success of product innovations (Rao *et al.*, 2008). These interactions include corporate social responsibility activities and other philanthropic endeavours to create reputational value and trust (Ramani and Mukherjee, 2014) as well as bribery and other forms of corruption (Wu, 2006; Martin *et al.*, 2007).

To sum up, prior to entering an emerging country with an innovation, an MNE has to evaluate the nature of the systemic uncertainties – technological, commercial, organizational and societal and estimate the possibility of challenges being issued by any of the actors in the eco-system on account of any of these. Then, it must formulate its response, i.e. its strategy for legitimacy construction through revising its technology design or marketing strategy and/or non-market investments, either proactively to avoid a challenge or once a challenge is issued. Thereafter, the legitimacy construction strategy must be implemented through an outreach strategy to some or all systemic stakeholders.

We propose four types of outreach actions to tackle challengers: strategic patience, market transactions, business collaboration, compromise and confrontation. Under strategic patience, the MNE exerts a zero or minimal response of any kind, it continues to simply co-exist. Market transactions can involve exchange of assets, technologies, products, materials and services at existing market prices. Agreements can vary from price

negotiations to collaborations when two or more organizations work together for mutual benefit. Compromise refers to actions that involve a real cost to the MNE with a positive gain for the other party in the ecosystem – at least in the short run. Confrontations are disputes that are taken to third party, say a court, for settlement. Our theoretical construct is summarized in Figure 2.

Case studies

The case of Monsanto and Bt cotton in India

The product innovation. In 1982, scientists at Monsanto isolated the genes of the Cry family in *Bacillus Thuringiensis*, a soil-dwelling bacterium, which were capable of producing a toxin for bollworms, a major pest in cotton plants. Further, they successfully transferred the genes into cotton plant cells that could be fully regenerated, marking a radical technological breakthrough in plant production technologies. Cotton variety into which Bt genes are successfully transferred is popularly called Bt cotton. The speciality of Bt cotton is that it contains its own pesticide for bollworms. When the pest ingests any part of the plant, it is killed by the toxin. By 1996, Monsanto had commercialized Bt cotton varieties in the USA with great success. At this point, it turned to emerging countries to expand its market. However, a feature of genetically modified plant varieties is their fragility. Thus, to diffuse it in an emerging country, Monsanto had to cross its own variety with a robust local variety to create the Bt cotton seed most suitable for the local agro-ecology.

Entry motives. India was a natural lucrative target for Monsanto because despite having the largest cotton growing area in the world (about 12 million hectares in 2013), at the time, Indian cotton yields were among the lowest in world. Further, severe pest problems required high pesticide usage. For instance, in 2000, cotton accounted for about 54 per cent of the total pesticide consumption in India (Raghuram, 2002). Small farmers were in distress with debt and environmental damage.

Challenge from government. Monsanto first approached the Indian government to get approval to integrate its technology into local plant varieties via public agencies. But this was refused on the grounds that the technology fees Monsanto planned to charge were too high (Newell, 2003). To counter this challenge, Monsanto initiated collaboration with Maharashtra Hybrid Seeds Corporation (Mahyco), the leader in the conventional cotton hybrids market. Mahyco got approval from the *Department of Biotechnology* (DBT) to import Bt cotton seeds developed by Monsanto to backcross into Indian cotton varieties in

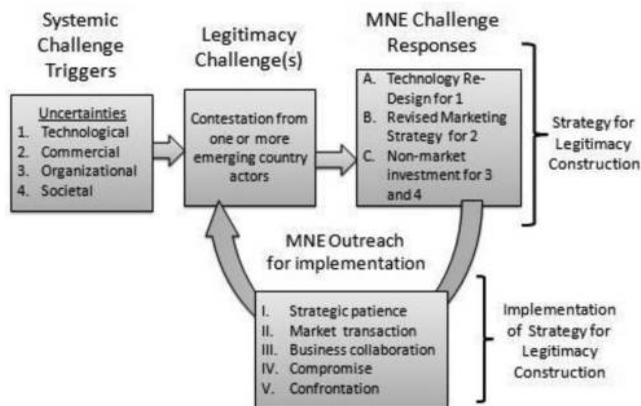


Figure 2.
Legitimacy efforts
integrated into
localization strategy of
MNE

March 1995. To strengthen this alliance further, in 1998, Monsanto obtained a 26 per cent stake in Mahyco and created a 50:50 joint venture, called *Mahyco Monsanto Biotech* (MMB) for the diffusion of Bt technology in India.

Challenge from non-governmental organizations. A second challenge came in April 1998, after the DBT approved small-scale field trials of Bt cotton by Mahyco. However, when the sites of the field trials were publicly announced, they caught the attention of activists against genetically modified organisms (GMO) and farmer groups. In November 1998, Karnataka Rajya Raitha Sangha, a farmers' association from the state of Karnataka, destroyed the cotton fields in which the field trials were being carried out. In January 1999, a case challenging the legality of even the field trials authorized by the DBT was filed by a well-known activist Vandana Shiva in the Supreme Court.

This challenge was partially mitigated by the regulatory authorities themselves because while the case was still pending with the Supreme Court in July 2000, the Genetic Engineering Approval Committee (GEAC) gave a green signal to Mahyco to carry out large-scale field trials in several states and to produce Bt cotton seeds. However, a year later in June 2001, under pressure from activists' and NGOs' protests, the GEAC insisted that field trials of Bt cotton be extended by another year and that large-scale field trials on 100 hectares be carried out with close monitoring by the Indian Council of Agricultural Research.

Challenge from local firms. Then, while MMB was carrying out additional field trials in several states, news broke out in October 2001 that in the state of Gujarat, 30 per cent of the cotton fields, planted with seeds distributed by a local company called Navbharath Seeds, were unaffected by the severe bollworm infestation that was causing havoc in the state. In 2002, MMB filed a complaint to GEAC that its technology had been illegally copied by Navbharath Seeds. Navbharath, which was founded by a US trained former employee of Mahyco (Kulkarni, 2003), defended itself claiming that the hybrids were developed from insect resistant plants identified by natural selection followed by a series of back-crossings. However, in later legal hearings, it was confirmed that Navbharath 151 was indeed genetically modified and was sold in other states as well though it was not the same as the MMB Bt cotton, as a different parental line with the same Cry1A(c) gene had been used to produce this hybrid (Venkateswarlu, 2001).

The commercialization of illegal Bt insect resistant varieties (illegal because it had not been approved by the Ministry of Environment and Forests) in the different Indian states by Navbharath in turn helped Monsanto gain publicity for its new Bt insect resistance technology, as the farmers were extremely satisfied with the seed performance. Indeed, the challenge was now turned against the regulatory authorities by some protesting farmers. Thus, within six months, in March 2002, the GEAC approved the commercialization of three varieties of insect-resistant Bt cotton hybrids (Mech-12 Bt, Mech-162 Bt and Mech-184 Bt) for the central and southern states. Since then, the diffusion of Bt cotton in India has been phenomenal, with the area under Bt increasing from around 10 per cent of the total cotton area in 2004, to more than 95 per cent in 2013 (Choudhary and Gaur, 2010; James, 2014).

Challenge from state governments. Another type of challenge emerged in 2006 after the success of MMB Bt cotton became evident. NGOs and farmer organizations complained that the cost of Bt cotton cultivation was fuelling farmer indebtedness due to the higher seed price (Sahai and Rehman, 2003, 2004). Eventually, the Government of Andhra Pradesh brought it to the deliberation of the Monopolies and Restrictive Trade Practices (MRTP) Commission (Sadashivappa and Qaim, 2009), and it was identified that the higher seed price was due to the higher technology fees paid by the seed firms to MMB for the Bt trait. The technology fee paid to MMB for the trait value accounted for almost 78 per cent of the cost of a packet of cotton seeds (Arora and Bansal, 2012). The MRTP commission therefore questioned MMB, to

which MMB responded that the returns were being used to develop other products that would be helpful for farmers. The MRTTP commission then asked MMB to reduce the loyalty for the trait to a reasonable level, and, in response, MMB offered to reduce it to INR 900. However, the Government of Andhra Pradesh demanded that it be reduced further, which MMB refused to do. As the issue did not move towards any resolution, the central government intervened, with the Ministry for agriculture backing the MRTTP commission's recommendation (Sadashivappa and Qaim, 2009). Here, MMB took the issue to Supreme Court, but the Supreme Court upheld the directive of MRTTP commission. Meanwhile, the State Government of Andhra Pradesh set a price ceiling of INR 750 for a packet of Bt cotton seeds and other states followed suit.

Challenge from non-governmental organizations. During the years thereafter, a variety of other legitimacy challenges were also hurled at Monsanto, but none managed to damage Monsanto's profits in India. There were regular reports in the media about NGOs, farmer groups, scientists and corporate representatives arguing for and against Bt cotton in terms of impact on farmer profits, farmer indebtedness, farmer suicides and damage to health of farmers, cattle and the environment. Socio-economic studies finding positive as well as negative outcomes of Bt cotton appeared in academic journals as well as in NGO reports (Ramani and Thutupalli, 2015).

Due to this controversy, a moratorium on the introduction of any other transgenic plant varieties, and their field trials in India was initiated in 2010 [Ministry_of_Environment_and_Forests, M. (MoEF), 2010]. However, the resounding success of Bt cotton with farmers combined with the strategic patience of Monsanto seems to have paved the way for the lifting of this ban. In July 2014, GEAC cleared the approval of field trials of a range of food crops including rice, mustard, cotton, chickpea and brinjal (Menon, 2014). In November 2014, the Minister of Environment asserted in Parliament that there is no official ban on GM crops research, and any such ban would be against national interests (PTI, 2014). This shows that the legitimization efforts of Monsanto have paved the way for other MNEs and Indian firms as well to exploit the lucrative Indian seed market.

The legitimacy challenges and the outreach efforts of Monsanto to construct legitimacy with other actors in the Bt cotton innovation system are summarized in Table I.

Uncertainty trigger	Challenger	Challenge	MNE Response	MNE outreach
Commercial	Central Government	High-technology fee	Change of partner	Collaboration with leading local firm
Societal	NGO	Illegal functioning of MNE	Responding to complaint by extending field trials	Compromise strategic patience
Organizational	Local firm	Illegal Functioning of local firm	Filing complaint to government	Contestation
Commercial	State government	High price	Accepting government set price ceiling	Compromise
Societal	NGO	Ecological externalities	Increasing sales to farmers and getting their support	Market transactions strategic patience

Table I. Legitimacy construction by Monsanto within the Indian innovation system

The case of Merck and antiretrovirals in Brazil

The product innovation. Efavirenz was originally developed by the joint-venture between Du Pont and Merck in 1998. Efavirenz is an ARV drug used in the treatment of HIV that belongs to the class of drugs termed non-nucleoside reverse transcriptase inhibitors. Until 1999, preferred initial drug regimens to treat HIV/AIDS included a combination of two nucleoside reverse transcriptase inhibitors and, in case of patients at higher progression risk, one protease inhibitor. However, following the findings of Staszewski *et al.* (1999), a combination of efavirenz with two nucleoside reverse transcriptase inhibitors became a standard recommendation for initial HIV/AIDS treatment worldwide.

Entry motives. The US-based pharmaceutical company Merck & Co. had been operating in Brazil through its fully owned subsidiary Merck Sharpe & Dohme since 1952. Its business opportunities further expanded in 1996, when Brazil initiated an official and well-structured policy of universal and free access to highly active antiretroviral therapy (HAART) through the public-sector health system. In 1997, Merck started supplying its protease inhibitor Indinavir (brand name Crixivan®) to the Brazilian anti-HIV/AIDS program. In 1999, Merck introduced the drug Efavirenz, which rapidly became a central component of the HAART offered by the Ministry of Health (MoH) of Brazil.

In the case of ARV drugs marketed in Brazil, MNEs sell standard products (i.e. same formulation and concentration), commonly, under a global trademark. These companies, however, do discriminate prices for their ARV drugs across markets. Nevertheless, Brazil and other upper-middle income countries are excluded from MNEs' preferential pricing lists. This price discrimination often generates social uncertainties, as local public agencies such as MoH strive to maximize access to lifesaving drugs.

Challenges from government and local firms. Societal uncertainty due to price discrimination was indeed the issue of contention with HAART. As the price of the patented ARV drugs mounted, the sustainability of the universal free access program was put at risk for MoH. In response, the Brazilian Government's strategy to reduce prices of ARVs was based on two main pillars:

- (1) the local productions of off-patented ARVs – mainly in state-owned laboratories; and
- (2) the use of a threat to issue a compulsory license^[1] to leverage price discounts (Galvão, 2002).

When commercial and societal challenges issue from public agencies, MNEs have three options:

- (1) compromise by agreeing to the demand of the public agency immediately;
- (2) engage in prolonged price negotiations with the public agency to gain time and negotiate a more favourable outcome; and
- (3) do not give in to the demand at all and instead continue the confrontation, building alliances with other actors to force the public agency to accept the status quo.

Let us now turn to what happened in reality.

In early 2001, MoH threatened to issue a compulsory license for Merck Sharp & Dome's drug Efavirenz to the state-owned laboratory Far-Manguinhos, unless its price was substantially reduced. At that time, Efavirenz represented about 11 per cent of MoH's total expenditure on ARVs (Galvão, 2002). Farmanguinhos was already importing a small amount of Efavirenz from Indian generic drug suppliers to develop its production technology. This strategy invoked a strong reaction from the US Government, which threatened to impose trade sanctions against Brazilian exports to the USA (Pinheiro, 2006). Finally, in March 2001,

Merck agreed on a 59 per cent discount for Efavirenz, as long as the Brazilian Government did not issue compulsory licenses for generic production.

In July 2003, the Brazilian MoH started another round of negotiation for patented ARV drugs. At that time, Efavirenz was responsible for more than 16 per cent of all MoH's yearly expenditure with ARVs. In the first meeting with MoH, Merck requested 60 days to submit a proposal for a voluntary license for Efavirenz. In this case, the patentee was to set up collaboration with Far-Manguinhos to transfer the technology (Bacoccina, 2003). On November 18, 2003, it was announced that Merck's 25 per cent price drop offer for the drug Efavirenz had been accepted (STD/AIDS Department, 2003).

By 2005, Merck was still negotiating the terms of the voluntary license for Efavirenz to Farmanguinhos. Merck's strategy was to further delay the voluntary license of Efavirenz and, at the same time, obtain support from the Ministry of Development, Industry and Trade (MoDIT). With MoDIT, it was pushing for a proposal to manufacture certain AIDS drugs locally but have them packaged and distributed by the state-owned lab (Danilovich, 2005). But this also never happened.

The company's decision not to cooperate with MoH was successful at that stage. To avoid a shortfall in the supply, in March 2006, MoH and Merck signed a contract without changing the price of Efavirenz. Eloan Pinheiro, who was Director of Farmanguinhos at that time and actively engaged in the price negotiations of ARV drugs, affirmed that Brazil did not issue a compulsory license due to the political and economic pressures (Pinheiro, 2006). For instance, the US Embassy in Brazil recommended that Brazil should stay on the USTR Priority Watch List, but be downgraded to the Watch List if negotiations with Merck reached a mutually satisfactory conclusion prior to the Special 301 announcement (Linehan, 2006).

In November 2006, MoH re-opened a price negotiation with Merck & Co. for Efavirenz. About 68,000 patients (40 per cent of the total) were under Efavirenz treatment, an increase of 12 per cent as compared to 2004, when its price was reduced for the last time. After seven meetings with Merck, the company's best offer was a reduction of 3 per cent (from US\$1.59 to US\$1.54 per tablet) while MoH demanded a 60 per cent discount. Given Merck's non-cooperation, MoH took the first step towards a compulsory license and declared Efavirenz to be a drug of public interest. Then, Merck offered a price reduction of 30 per cent and a technology transfer agreement to start local production in Farmanguinhos by 2010 (two years before the patent expiration). However, MoH did not accept its offer, as there were generic versions available for US\$0.44. Moreover, according to MoH, the technology transfer agreement would not benefit the country (Simão, 2007).

Finally, on May 4, 2007, MoH issued a compulsory license for the drug Efavirenz. The drug was initially imported from Indian suppliers until local production was prepared. Three local private enterprises were responsible for the development and production of the active pharmaceutical ingredient, while two state-owned laboratories were in charge of the drug formulation and distribution.

Merck was thus able to successfully achieve legitimization of its drugs in three of the four challenges issued by the public agency MoH. During confrontations, both MoH and MNE had started interacting with other strategic actors in the innovation system to create the necessary conditions for the best possible outcome. The legitimacy challenges and the outreach efforts of Merck to construct legitimacy with other actors in the Brazilian innovation system for ARV drugs are summarized in Table II.

Discussion and managerial implications

The case studies shed light on how managers of MNEs can tackle the uncertainties of new product introduction while validating our theoretical construct through five main results.

Table II.
Legitimacy
construction by Merck
within the Brazilian
innovation system

Year	MNE response	MNE outreach	Outcome
2001	Price discount if no compulsory license	Compromise	59% discount
2003	Offer of voluntary license and price discount	Collaboration and compromise	25% discount
2005	Offer of voluntary license and discussions with MoDIT	Collaboration	No voluntary license and no discount
2006-2007	Lobby with home government	Collaboration and compromise	Issue of compulsory license in 2007
	Offer of voluntary license and price discount after announcement of compulsory licence		

First and foremost, our case studies confirm that it is possible for MNEs to construct legitimacy in the face of challenges to launch high-value hi-tech products successfully in emerging countries. Monsanto faced direct challenges in India with public agencies (MoE, GEAC, state governments) and NGOs due to concerns about the long-term impact of the innovation on human health and the ecology. To this, the technological uncertainty and marketing uncertainty were added, given the radical nature of the innovation, which nevertheless required extreme localization in terms of technology design and marketing for commercial success. Monsanto handled all these challenges successfully through an astute mix of strategic patience and compromise with public agencies and NGOs and fruitful collaborations and agreements with local firms.

Merck was also subjected to repeated challenges in Brazil with public agencies (MOH, MoDIT) concerned about the socio-political implications of limited access to an essential commodity due to its high price. Merck had no option but to engage each time in prolonged bargaining to reduce the socio-political uncertainty for the public agencies and its own organizational uncertainty (i.e. rent appropriation). Its legitimacy efforts were focused on strengthening its bargaining power by seeking help from its home government, outreach with other local actors and continuing the dialogue with the challenger. This brought into play actors such as the US Government, other local public agencies, local public labs and international generic producers, i.e. the systemic stakeholders who were not directly linked to the challenges. In three of four confrontations, Merck was successful in its legitimacy construction.

Second, the three important aspects of the outreach strategy – what type of outreach, with which actor and when – are key to the success of legitimacy construction. When challenges are issued by the state, regulatory agencies and civil society groups, legitimization efforts by the way of strategic patience, collaboration or compromise should be explored before confrontation is launched. For instance, Monsanto was forced to compromise on technology fees to attain legitimacy, wherein an initial negotiation or compromise may have paid more. Timing is also important, and on this score, the last episode of Merck's failed legitimization efforts is particularly revealing. First, it seemed to have been too sure of the backing of the US Government which failed to materialize. Second, it made a mistake in terms of timing its compromise offer. After the Brazilian government decided to issue a compulsory license for Efavirenz, Merck offered a last minute 30 per cent price reduction tied to a technology transfer agreement. However, it was already too late, and the Brazilian Government issued a compulsory license in May 2007. MoH imported the drug from India for about 18 months until local production started at Farmanguinhos in 2009. Therefore, Merck failed to attain

legitimacy and lost the market for its product – something that it could have avoided had it offered a bigger price reduction at an earlier stage.

Third, collaboration with local firms can be pursued if they can share the costs of legitimization construction and reduce technological and marketing uncertainties. At the outset, the degree of technological uncertainty and marketing uncertainty associated with the innovation determines the need for collaboration. For instance, if the innovation is a novel input that must be integrated into a final product, for which the market is dominated by local firms, then it makes sense to collaborate. If the innovation is a new final product, then collaboration with local firms helps to share the technological and marketing risk of redesigning the product to fit local demand. Collaboration is also useful if the marketing platform is complex and heavily localized.

This was aptly illustrated by the case of GM seeds. Gene constructs or gene events are like intermediate inputs that must be incorporated into an agronomically superior variety that is robust for a particular agro-ecology. Clearly if the targeted country exhibits high heterogeneity in terms of agro-ecological zones, it is more profitable to share the cost of “adapting technology design” with local firms. The tacitness of the *in situ* knowledge base, i.e. the know-how on local agro-ecology, makes it all the more costly and time-consuming for a MNE to set up its own subsidiary and carry out the adaptation process. This is indeed the case of seeds, which requires well-established channels of seed dealers, distributors and retailers carrying out their work in local dialects and often with social ties to local farmers. Hence, Monsanto could not localize its Bt technology without collaboration with local firms.

In the case of Merck, in the second bargaining episode, it proposed collaboration with the state-owned laboratory Far-Manguinhos to transfer the production technology of Efavirenz. This reduced its marketing uncertainty, as it was then able to successfully terminate negotiations with MoH with a lesser price reduction than proposed initially. Moreover, this kind of collaboration offered additional benefits to the country, as local actors could then master the technology to manufacture the drug locally. Thus, a technology transfer agreement could lower both marketing and technological uncertainty for the innovator.

Fourth, confrontation is essentially a dynamic bargaining game, wherein an MNE has to re-evaluate its bargaining power at the beginning of every confrontation and not take past victories as an indicator of probable success in the present. Bargaining power of an MNE is determined by the contextual specificities of the time, and it is usually conducted under incomplete information, without either the local challenger or the MNE being fully aware of the bargaining power of the other.

Merck confronted the Brazilian Ministry in 2001, 2003, 2005 and 2007 over a family of drugs for the same disease, and yet each time the outcome of the negotiations was different. The first two negotiations ended with compromise from both parties. Merck reduced the price by 59 and 24 per cent, respectively, while MoH accepted a price drop inferior to the initial request. In the third episode, status quo was maintained, but during the fourth set of negotiations, the Brazilian Government issued a compulsory license, indicating a failure of Merck’s legitimization drive. This is because the bargaining powers were different in each round. In the first two episodes, Merck’s bargaining power was lowered through lack of support from the US Government. Whereas, MOH’s bargaining power was strengthened by support from the state-owned laboratories which had developed expertise in Efavirenz production, a critical factor, as it would enable local production in case of compulsory license granting.

Then tables were turned in 2005. From the outset, Merck engaged in much strong efforts to persuade MoDIT that a compulsory license was not in the best interest of the Brazilian economy. For instance, the company presented investment plans that would be carried out

only if a compulsory license was avoided. Only after obtaining support from MoDIT did Merck start conversations directly with MoH. Besides that, the US Government was much more involved in this episode, especially because two other US-based MNE were also facing compulsory license threat for their ARV drugs. Therefore, in this episode, the actors that were against compulsory license played an important role in persuading MoH to accept Merck's localization strategy. Thus, Merck was able to confront MoH and stall the negotiation until MoH succumbed.

But there was another reversal of fortunes in 2007, when Merck adopted the same confrontation strategy as in the previous one. However, this time, Merck's bargaining power was much weaker, especially because the support from the US Government was not strong, and the company's efforts towards MoDIT did not affect MoH decision to call for price reduction. In addition, on the Brazilian side, an alliance sprang up between NGOs and local companies. While NGOs were mobilizing the media to support a compulsory license, local companies organized a supply network to assist state-owned labs in the local production of Efavirez. With its bargaining power at its peak, the Brazilian Government issued a compulsory license.

Fifth, compromise is the most probable but not the only outreach strategy possible after a confrontation. Astute practice of strategic patience may be necessary. For instance, when Monsanto was confronted in the Supreme Court for its high-technology fees (i.e. royalties) for GM traits, it made sense to compromise by bringing down the price of a packet of cotton seed (500 gm) from INR 1,600 to INR 750, which reduced its innovation rent, but was an expected outcome as the bargaining power of Monsanto *vis-à-vis* the Supreme Court of India is negligible. However, with the NGOs, civil society and farmer groups, Monsanto chose not to confront them directly and instead opted for strategic patience. This was possible because the societal challengers were protesting against GM technology, in general, rather than Monsanto, in particular. This was also fortuitous for Monsanto, as it could then deal with this challenge through acquiescing to the requests of Ministry of Environment for more trials, etc., as its bargaining power *vis-à-vis* these protestors was unclear. This again illustrates that not only does the choice of action within local players matter but also its timing is very important. A small compromise in the beginning may save the MNE from a bigger one later on.

Conclusion

How can MNEs prepare to satisfy the diverse values and aspirations of different stakeholders when commercializing high-value hi-tech products in emerging countries? By way of an answer, the present paper explored the premise that to ensure maximal returns from launching such products in emerging countries, MNEs should invest in legitimacy construction.

Adopting a systemic approach, it started with the premise that new product introduction is a process within a system wherein the relevant actors are the MNE and emerging country stakeholders who could support or challenge the MNE's product launch. Theoretical constructs on the role and process of legitimacy construction for the introduction of a new product were built upon the existing literature. Then they were validated and refined through the formulation and analysis of case studies of the launch of genetically modified cotton seeds by Monsanto in India and a HIV/AIDS drug cocktail by Merck in Brazil.

The case studies confirmed that legitimacy construction can help MNEs face challenges successfully while launching high-value hi-tech products in emerging countries. Challenges to MNEs are likely to be founded on a combination of four types of uncertainties: technological, commercial, organizational and societal. Expected challengers are public

agencies and actors representing civil society. An MNE can prepare itself through legitimacy construction along three dimensions: redesign of technology, revision of marketing strategy and non-market investments. To implement the aforesaid, MNEs can engage in outreach in the form of strategic patience, market transaction, business collaboration, compromise and/or confrontation with diverse carefully chosen stakeholders. Strategic patience can yield positive returns. Market transactions can serve as economic anchors. Collaboration can be pursued with parties that can share the costs of legitimization construction and/or reduce technological and marketing uncertainties. Confrontation should be the last choice. Compromise is the most probable but not the only outreach strategy possible after a confrontation. Finally, legitimacy construction is not a linear input-output process but a non-linear one whose dimensions and nature may change over time. Even then, it is not certain to be successful.

Avenues for further theoretical and empirical research can also be inferred. At the outset, theoretical constructs have been developed in this paper on the sources of challenges in new product introduction, the types of challengers and the components of the firm's legitimacy construction strategy and its implementation through an outreach strategy. These constructs can be tested in other contexts and also extended and refined.

We limited ourselves to formal interactions in this paper, while it is well-known that many informal and backdoor activities can also accompany the growth of organizations, including MNEs. Some mysteries still remain with Monsanto such as how Navbharat Seeds produced cotton containing the Bt gene event developed by Monsanto. Similarly, Merck's interactions with both MoDIT and US Government cannot be seen as a form of collaboration, but rather as lobbying to dissuade MoH from the idea of issuing a compulsory license. In the same vein, MoH's interactions with NGOs and civil society in Brazil were subtle and sometimes informal, as their main role was to influence public opinion (media, citizens) and create public pressure in favour of compulsory licensing. Thus, a greater spectrum of outreach initiatives going beyond that proposed in the conceptual model can be envisaged. Finally, it would be useful to identify and understand the systemic loopholes that can let unethical actions, threats, false promises and lobbying push or detract innovations from markets.

To conclude, MNEs attempting to introduce high-value hi-tech innovations in emerging countries will do well in terms of legitimacy construction. This calls for an evaluation of the systemic uncertainties followed by the formulation of a strategy for legitimacy construction and implementation through outreach to diverse systemic actors. Then, MNEs can transform the classic zero-sum game with potential challengers in an emerging country, into a positive-sum game involving many actors other than the challengers.

Note

1. Compulsory license (i.e. the right to license one's technology to a third without his/her permission) is one of the flexibilities provided by the TRIPS Agreement to cope with the negative impact of patents on access to medicines.

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