

Emerging Market Economies and Intellectual Property Protection:
A *TRIPLe* Balance between Access to Health, Individual Rent-Seeking, and Economic Growth
(Summary)

A. Introduction

With the developed world enmeshed in a series of currency crises (the EU), mired in an epochal natural disaster (Japan), and deeply divided over how to tackle a gargantuan budget deficit (United States), the emerging market economies commonly referred to by the acronym *BRICs* (comprising Brazil, Russia, India, and China) seem poised to set the international agenda for almost all matters commercial throughout the coming decade.

If the fact that the Copenhagen Climate Agreement was eventually hashed out largely by the BRIC countries, which almost side-lined the EU and the United States, holds any lessons for the future of Intellectual Property (IP) Law, it is that emerging market countries are likely to seize the opportunity to (re-)shape the current international legal environment *if and when they see fit*. Predicting (1) *if* these changes will occur and (3) *what* they will affect calls for a profound understanding of the (2) *factors* that *determine* these countries' *perceptions* of the current legal instruments.

B. Methodology

In order to answer the questions set out above this paper applies a two-step methodology:

The *first step* is premised on the notion that countries evaluate international treaties based on their assessment of how such treaties impact upon their domestic domain. While they might not have been able to substantially influence the outcome of the treaty negotiations they will all the more carefully assess the impact of national implementation and, in case of non-compatibility with their policy goals, look for ways of re-launching negotiations with a view to changing the existing legal environment. Any outcome produced by these negotiations will, in turn, be re-examined, thus giving the impression of a *circuit*.

The *second step* is directed at discerning the determinants of perception. Drawing on the analysis of constitutional norms and development theories, it is possible to mould the indispensable balance between the three basic socio-economic vectors of *economic growth*, *individual rent-seeking*, and *access to health* into a triangular structure with each vector at one vertex. Each vector being anchored both in constitutional law, international law (*v. Arts. 7 and 8 TRIPS*) and economic theory, they can be defined as *ends* if assessed comparatively. Yet, when analysing their interrelations from a macro-perspective, their functionality *vis-à-vis societal development* becomes patent. As the furtherance of this superordinate goal requires an act of conscientious balancing, both the constitutional enshrinement of societal development and the inchoateness of 'emerging' markets call for the State to intervene. Besides the asynchronous development of 'emerging' market sectors (contrast, e.g., Brazil's aeronautic sector, which boasts a world market leader like *Embraer*, with its still fledgling infrastructure), the fact that developed countries, both of the welfare and the 'free market' embracing kind, do not entrust private and public health care entirely to the market's 'invisible hand' (think of the United States' health care reform or Britain's NHS reform plans) reaffirms the State's responsibility to act as a balancer. A brief analysis of the cost structure of health care systems and the composition of devices employed by medical staff highlights the paramount importance of medicaments within the ambit of the health care sector. The pharmaceutical industry, in turn, is among the industries with the highest return-on-investment ratios and innovation rates, and employs highly trained and well-salaried staff. Its profitability being substantially dependent on the patenting of its products and processes, it

relies on a temporary monopoly granted by the State (cf. Barton 2004). Hence, given the fact that the means facilitating the individual firm's rent-seeking also lies in the State's hands, the State can avail itself of the IP system as a tool for achieving the aforesaid overall balance.

According to the structure just outlined there are three axes on which the State can achieve balance in order to promote overall balance. The axis linking individual rent-seeking and access to health can be termed *participatory* axis because of the character of social rights intended to enable people of all social strata to fully participate in social life. This designation is coherent with developmental approaches which emphasise the importance of participatory freedom in assessing development (Sen 2001). Furthermore, the firm's stakeholders and shareholders also have a participatory right in the profits derived from the company's commercial activities as a return for their investment. The second axis linking individual rent-seeking and economic growth can be conceived of as a *competition* axis because the competing pharmaceutical companies, in spite of a recurrent political bias towards regulation, are not shielded by their government-awarded monopolies from being subject to competition law. The third axis connecting economic growth and access to health can be called *developmental* axis. This designation is derived from the role public health plays as so-called social overhead capital in the development process of a given country (Jhingan 2007: 190), and is reflected in the inclusion of life expectancy as a proxy for measuring health in the UNDP's Human Development Index (HDI).

C. Application

The application of the two-step analysis will proceed as follows: firstly, the circular analysis will shed light on whether emerging market economies are in a position to challenge the existing international IP system (v. (1)). Answering question (2) must necessarily precede answering question (3).

(1) A brief enquiry into the current and future international political economy both from a neo-realist and neo-liberal perspective lays bare the tectonic shifts in power underway since the late 1980s. The new relative strength of the emerging market countries owes itself more to their own newly acquired economic sinews than to the present state of weakness or self-absorption of the traditional power-brokers in the 'West'.

The assertion that the BRIC countries are likely to take the initiative in international IP negotiations (cf. Yu 2008) can be undergirded by analysing the United States' course during the Uruguay Round and its underpinnings. The fact that the United States was the key *demandeur* country arose mainly from its economic strength and the relative importance it attributed to the protection of IPRs from its own long-term growth perspective. While the second strategic element relates essentially to its domestic constituency, the first element can be utilized to predict the BRIC countries' course of action. Using OECD projections (OECD 2010), the BRICs' transformation from rims to pivots becomes apparent: Whereas the collective share of global GDP (PPP) of the 'Western core' countries, viz. the United States, the EU, and Japan, will have shrunk from nearly 50 per cent in 1994 (the year the WTO Agreement was concluded) to roughly 36 per cent by 2030, the BRICs' collective share will have risen to more or less the same value by that time. China alone will account for 23 per cent of global GDP, thus outperforming the United States at its 'unipolar moment' during the 1990s and 2000s.

(2) An informed analysis of the impact of the implementation of the TRIPS Agreement by means of the triangular scheme will yield the factors determining the BRIC countries' perception of the current IP regime in the ambit of the health care sector.

Having espoused comprehensive market-oriented development strategies at different points in time (China starting in 1979, Russia and India from 1991 onwards, and Brazil following suit in 1994), all countries had to devise new IP regimes or change their existing ones in order to bring them in line with the exigencies of a liberalised market and, apart from Russia, the requirements of the TRIPS Agreement (Bird et al. 2007). Although strategic deliberations to lay the foundations for self-sufficiency in the supply of generic pharmaceuticals had motivated Brazil, China and India either to abandon or not to institute patent protection for pharmaceutical *products*, only India and China had arguably succeeded in establishing generics industries capable of supplying the entire domestic market and vying with MNCs for global market shares (namely Indian companies like *Dr. Reddy's*, *Ranbaxy*, and *Cipla*, cf. CCI 2004; Chaturvedi et al. 2006). While Brazil achieved limited self-sufficiency, Russia's market is largely import-dependent (Kuhrt 2008).

Measuring the overall impact of the TRIPS implementation using the triangular scheme starts with a condensed assessment of the impact on each of the vectors.

Access to Health:

Studies on access to medicines in the BRIC countries have produced multi-faceted findings: Whereas, according to numbers collected in 1997, the situation was dismal in both India and Brazil (50-65% and 50-60% of the population, respectively, did not have regular access to essential medicines), it was better in China (11-19%) and Russia (20-50%) (WHO 2004). Recent studies pointed to the fact that, despite price regulation schemes, low income strata of society in all BRICs still lack access (Akin et al. 2005; Bertoldi et al. 2010; Cameron et al. 2009; Guerra Jr. et al. 2004; Kotwani et al. 2007; Kotwani 2009; Pinto et al. 2010; Mendis et al. 2007; Tripathi et al. 2004; van Mourik et al. 2010; Yang et al. 2009). Interestingly, the downward pressure on prices by public procurement did not feed into higher access rates because public health schemes (e.g., Brazil's *Sistema Único de Saúde*) are limited both in the scope of diseases and in the coverage of medication types (usually only generics are covered) and the private procurement of supplementary medication is subject to mark-ups which elevate prices above international reference price levels (Caliari et al. 2010; Nóbrega et al. 2007; Vieira 2006; Zasimova 2010).

In fine, although overall *access* has apparently been positively affected by the implementation of TRIPS, distributive disparities between social strata seem to persist.

Individual Rent-Seeking

Departing from the notion that corporate profits are allocated to shareholders, stakeholders, and the taxing State, the profitability of pharmaceutical companies is of great interest to each of these ultimate beneficiaries. What is more, intra-company allocation of financial assets for innovation depends on profit margins.

High levels of supply-side fragmentation in all BRICs (with market leaders cornering only 7% of the market) have led to intense competition on price (Hasenclever et al 2009). Yet, incipient consolidation, low wages, cheap supply of APIs (with China and India producing large quantities), and, in the case of India, entries into regulated 'Western' markets, have kept profitability comparatively high for dominant market participants. Apart from India, however, expansion of domestic suppliers has, by and large, occurred only in the generics sector. Interestingly, this expansion can be attributed rather to governmental procurement or reimbursement schemes of generics like the Brazilian *Lei dos Genéricos* of 1999 than to the TRIPS implementation (Urias et al. 2009). Because of the interrelation between ingrained self-curing habits in all BRICs (particularly accentuated among low income strata in India or China which rely heavily on traditional medicine), prevalence of OTC drugs, low

reimbursement rates of outpatient therapies due to low health insurance coverage (e.g., 20% in Brazil) and narrow bases of beneficiaries of public schemes (e.g., the Russian *ДЛО*-programme) profits were accrued largely in the generics sector in all BRICs (Brueckner et al. 2005; Grubert 2010; Kumra 2010; Kuhrt 2008; Valente 2006; Zasimova 2010).

In fine, profits in all BRIC countries but India have been derived overwhelmingly from the domestic market. Furthermore, commercial activities of domestic companies have concentrated on the generics market. The exception to this rule is India where R&D productivity results from both domestic and overseas sales, and from both generics and innovative (e.g. *Ranbaxy's Ciprofloxacin*) medicines.

Economic Growth

Because the growth trajectories of the BRIC countries differ as to the underlying fundamentals, an informed assessment can allow only for limited generalisations: Whereas Brazil, China and Russia can be said to have focussed on export-led growth, India straddled both the domestic and the foreign market. With regard to the pharmaceutical market, however, only India actively pursued an export-oriented strategy. China and India achieved self-sufficiency in the supply of both finished-dose pharmaceuticals and APIs (Brazil only in the finished-dose segment) by impeding foreign market access via import levies and by encouraging reverse-engineering in the absence of patent protection. Yet, while China's and India's industrial complexes were resilient enough to cope successfully with the advent of TRIPS so that the market structure did not change to the detriment of national companies, Brazilian companies lost ground. This is illustrated by positive sectoral trade balances in the case of China and India and a negative one in the Brazilian case (the negative balance of Russia is due to the fact that the country did not manage to build a sectoral industrial base after 1991) (Lima de Magalhães 2008; Mani 2006; Brueckner et al. 2005; Yusuf et al. 2007; Rogachev 2008).

In fine, negative sectoral trade balances and low innovation levels because of low profit margins in generics sectors dominated by price-competition prevented the Brazilian and Russian pharmaceutical sectors from contributing to overall economic growth. Benefitting from a both resilient and innovative manufacturing base, the Indian pharmaceutical sector has been a source of overall growth. The Chinese sector, albeit to a lesser extent, has also contributed to growth.

Informed Synthesis of Vector-Analysis

Evaluating the relation between pharmaceutical self-sufficiency and access to health rates (*developmental and participatory axes*), the BRIC countries can be subcategorised as follows: only China combines high self-sufficiency with high access to health rates; both India and Brazil score high on self-sufficiency, but low on access to health; Russia scores low on self-sufficiency, but high on access to health.

Taking sectoral trade balances as a measure of the level of development of the industry segment, this parameter can be weighted in light of USPTO patent grants as a proxy for innovation (the latter being a precondition for future economic growth) in order to evaluate how the BRICs have benefitted from the much-acclaimed spill-over effects the introduction of patented products was supposed to have on backward economies (*competition axis*): here, India outperforms China because of the higher number of pharmaceutical patents. Brazil and Russia lag behind the two countries with regard to both parameters.

A synthesis of the findings reveals a complex picture:

- Brazil's purported pharmaceutical self-sufficiency turns out to be neither complete nor access-enhancing. Lacking internal API production capacities, the domestic industry focuses on unbranded finished-dose generics. With regulatory price-ceilings inducing price-competition in this segment, the majority of domestic producers still lack the wherewithal to engage in R&D in order to move up the value chain.
- Russia's MNC-dominated pharmaceutical sector operates in a largely unregulated environment. Most private drug purchases being out-of-pocket, the generics market dominates. Patented drugs account only for a small fraction of the market. Because competition by domestic companies (whether foreign subsidiaries or wholly domestically funded) occurs mainly on price, there are no considerable R&D investments.
- India's pharmaceutical industry has reached a level of development enabling it to cater to the domestic market and to the markets of both developed and developing countries (Dahlman 2007). Some of its companies have successfully ventured into innovative analogue research. The country's Achilles heel is its low access to health care which is due to deficient health infrastructures, almost inexistent reimbursement schemes, and low income levels.
- China has achieved self-sufficiency both in the finished-dose and the API production segment. While copy-cat medicines still account for a large share of the market due to lax IP enforcement, branded generics corner almost 20% of the market. Although research is still concentrated in public entities like universities, a growing number of companies is engaging in R&D. Increasing access rates is hampered by inefficient outpatient delivery structures.
- All countries still have a highly fragmented pharmaceutical sector.

(3) Taking into consideration that, in order to level pervasive economic disparities across regions and strata, BRIC countries will have to move beyond mere catching-up strategies and shift their attention towards high value-added commercial activities based on innovation, the pharmaceutical industry could become a focal point of their future developmental policies. Demographic forecasts foreshadowing growing (except for Russia) and aging populations underline this socio-economic growth imperative. Additionally, asynchronous regional and/or societal development will confront BRIC countries with the twin epidemiological challenges of 'neglected' and 'affluent' diseases (Sreeharan 2009; Vidotti 2008).

Having all adopted 'unbalanced growth' strategies during the last three decades, the BRICs' approaches have varied in the prioritisation of the formation of social overhead capital. Growing awareness of access to health both in terms of human development and sustainable economic growth (cf. Viana et al. 2007) has spawned government initiatives in Brazil (the *Profarma* plan and the *PITCE* policy, among others), Russia (the 2020 strategy), India (e.g., the Indian Industrial Policy of 2003 and the Rural Health Mission of 2005) and China (a comprehensive health care reform).

Aiming at expanding the coverage of public and private health care systems, they have opted for imposing stringent price control via extended Essential Medicines Lists. This suggests that they will continue to view the generics sector as instrumental in achieving this goal, all the more because (with the exception of Russia) it is dominated by domestic companies. Even with accelerated generics market consolidation, government investments will be instrumental in providing the financial wherewithal for private companies to engage in R&D. Maybe the State will have to subsidize innovative drugs in order to adjust the prices to income levels. All this applies particularly to Brazil and Russia where the domestic industries still lack the economies of scale necessary for widening profit margins. Because the income elasticity of demand is larger in the long run (Pindyck et al. 2007: 39-40), it will take some time for rising median household incomes to feed into demand for higher priced patented medicines. Therefore the BRICs can be expected to opt against stringent IP

enforcement and for a narrow interpretation of the patentability requirements, and for a wide interpretation of exceptions.

This assessment is borne out by recent developments on the IP plane, which include the issuing of a compulsory license by Brazil (*Efavirenz*) and two court decisions concerning the narrow interpretation of patentability standards (*Gleevec*) and of the requirements for the granting of freezing injunctions (*Tarceva*) from India.

Summary:

The aforesaid perceptive determinants can be linked with corresponding patent law issues in order to obtain a 'policy directory':

- *price (access to health) – parallel trade (exhaustion regime) and exceptions to patent rights*
Although the (positive) correlation between unfettered corporate pricing strategies and the availability of medicines is borne out empirically (*cf.* opinion of Advocate General Jacobs in the *Syfait* case [ECJ, Case C-53/03]), BRIC governments can be expected to opt against free pharmaceutical pricing. They can be expected to favour parallel trade regimes conducive to low-priced imports. Further, the time they will need to level regional and/or social inequalities will make them subordinate patent rights to developmental policies *stricto sensu*, i.e. health infrastructure programmes, all the more because patent rights continue to be overwhelmingly held by MNCs. The strategies adopted will therefore be in the mould of the Doha Declaration on TRIPS and on Public Health (focus on TRIPS flexibilities).
- *profitability (individual rent-seeking) – patentability standards*
Because of stringent price controls market consolidation will be the only avenue for domestic companies to acquire the market share necessary in order to benefit from economies-of-scale effects. In the absence of substantial government incentives they will continue to focus on the generics sector because of low R&D productivity. Thus, they will continue to lobby for a restrictive interpretation of patentability requirements which leaves active ingredients unprotected, to wit, they can be expected to opt against Swiss-type patent claims.
- *sectoral trade-balances (economic growth) – patent enforcement*
In order to lessen dependency on API imports, Brazil and Russia will continue to view patent enforcement as subordinate to the overriding developmental goal of achieving complete self-sufficiency. Even in spite of their fledgling innovative sectors, China and India might not substantially differ on this account because the bulk of their innovative drug production will continue to be destined to high price markets in developed countries for the coming decades.

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