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In The Rush To Emerging Markets, Could Public Health Be The Winner?

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What is the crashing noise so many pharmaceutical companies are hearing these days? Some say it is the sound of key products going over the "patent cliff."

The press has focused recently on the number of blockbuster drugs that are coming off or have come off patent. The news has been big as the list is an impressive one – Plavix®, Lipitor®, Seroquel®, Actos®, Enbrel®, Singulair®, Levaquin®, Zyprexa®, Concerta® and Protonix®, just to name a few.[1] With billions of dollars of revenue at stake, pharmaceutical companies have been considering for years how best to protect and build their businesses in light of this monumental change in the pharma landscape. It has become clear that looking abroad may be one of the best answers.

For many decades, companies have approached emerging markets with suspicion and fear. It is common to hear attorneys enumerate the many patent pitfalls that lie in wait for companies that want to sell pharmaceutical products into developing economies. Many important innovators have gone into emerging markets while attempting to carefully protect their patent rights – with mixed results. Several companies have fought legal fights in far-away places like South Africa, Thailand and India and have lost or, having won, lost the public relations battle that ensued.[2]

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After long legal and public relations battles that were, in some cases, of limited or no success, many pharmaceutical companies have carefully reconsidered and appear to have concluded that resorting to patent right enforcement actions and withdrawal of key products is not a sustainable long-term business strategy. The limited success of such actions has led to a reconsideration of the potential value of emerging markets, resulting in a paradigm shift. No longer are emerging markets viewed only as low-return, high-risk propositions for large pharma. In many cases, pharmaceutical giants are turning to partnerships and innovation to gain access to world markets – with special attention placed on emerging markets.[3] Emerging markets are now part of every company's strategic plan, and one benefit of the quest to access new and growing markets is that it has helped address one of the longtime and lingering criticisms of big pharma – that it only cares about rich countries and the maladies that afflict wealthy populations. The loss of patent protection on key products has led to an infusion of new products into emerging markets, permitting heretofore unaddressed public health needs to be addressed. While not erasing big pharma's image that it cares only for profits, it certainly has eased that perception and changed the game in dramatic ways.

"Copycat" has been a label that many U.S. and European companies pinned on companies in several emerging economies over the past decades.[4] But that label was only sometimes deserved. While some companies were busily copying products, many companies were innovators in their own right. And sometimes several copycats were copying for a good reason – an attempt to address serious unmet health needs. In the past, some might conclude that too often attention was paid to the methods used by such countries in their attempt to supply effective treatments for their needy populations, and very little attention appeared to be paid to the question of how best to provide medicines to all the world's needy at reasonable cost. Much has been written about GSK's battle to protect its HIV medication patents in South Africa, Novartis's battle in India to protect Gleevec®, and Abbott's battle with Thailand's decision to invoke compulsory licensing rights.[5] There is no need to review these cases here. Many of these efforts reflect an old way of thinking about emerging markets, a view that may still be espoused by the U.S. government for its trade purposes.[6]

Innovation in emerging markets has been spurred by many sources. The efforts of many nonprofit organizations and agencies are changing the way companies think about these markets. For example, the Clinton Foundation negotiates improved pricing for the provision of HIV medication and testing; the Gates Foundation invests heavily in efforts to eradicate major diseases in developing countries through innovation in treatments and delivery; and UNICEF has recently added transparency to its product

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procurement process leading to innovation in pricing. At the same time, product and manufacturing innovation in key developing markets is finally being noticed by large pharma. Cipla is one company that grabbed the attention of U.S. and European innovators when the company announced it would sell its cocktail of antiretrovirals for $350 per patient per year, eventually bringing the price to below $100. The Serum Institute of India has for decades developed and manufactured innovative vaccine and other products and sold them into markets at very low prices.[7] Efforts of companies like these have changed worldwide markets by increasing scale, reducing price and ensuring quality, all while permeating markets that Western companies have long neglected. During this period, the growing middle class in many countries and its related medicines market has become more lucrative and, therefore, attractive to Western investment. Large pharma has taken notice.

When many of us think of Indian manufacturing capabilities, we conjure visions of competition based on volume – mass production of key medicines and vaccines. Of course, volume is one of the key engines that drives profitability in emerging markets. The Serum Institute of India sells products into more than 140 countries. One of every two children immunized in the world receives a Serum Institute vaccine. Cipla supplies more than 40 percent of the world's antiretroviral drugs. But volume is only part of the story. Manufacturing innovations have paved the way to such success. As many readers will know, increasing scale requires much more expertise than simply doubling the recipe. It requires substantial work and talent and no small amount of infrastructure and risk taking. Rapid response to changes in market needs and a willingness to innovate have served companies in developing countries well and have saved millions of lives. When a meningitis outbreak was predicted in Africa, the WHO sent out a call for vaccines, and Indian companies were among those that responded. Serum's meningitis vaccines are sold for less than fifty cents a dose.[8] So, while many Western companies were fumbling to get prices down to a few dollars a dose, emerging market leaders were changing the face of business and public health by pricing vaccines at a price that permitted the purchase of many doses for the cost of a single dose from a Western competitor. Such innovation and pricing changes vaccine markets, while preserving generations of children yet to come.

While working hard in the emerging markets, Indian manufacturers have seen the rapid growth of middle classes in many countries, leading to development of products suitable for sale into both public and private markets. Changing markets are leading to innovations in pricing and marketing.[9] Until recently, pricing was frequently set on a jurisdiction-wide basis, with some discounting for group purchasing organizations and Medicare and Medicaid-type programs. But emerging markets often require more complex pricing structures dependant upon the ability of the user to pay. Changes in pricing vary not just by public versus private pricing, but can vary based on income and geographic area. Products for various markets are differentiated by appearance, packaging and sales process. This sort of close attention to the micro-markets within a particular geographic can be a game changer when manufacturers are competing in emerging markets.

Many U.S. companies have fallen behind the curve, and it is time for them to do some catching up. Emerging markets have too long been neglected, and in order to stay in the game, U.S. companies need to invest time and money in products and partnerships. Large pharma figured this out some time ago and has been working on strategic relationships. In 2011, Merck & Co. entered into agreements with Sun Pharma for the speedy development of branded generics and with the Serum Institute for the development of a pneumococcal vaccine. In a 2010 news release, Novartis touted its "… plans to strengthen its commercial position in fast-growing emerging markets and develop significant businesses in China, Russia, Brazil and India" and its "… plans to continue investments to scale up its businesses for long-term growth, especially in emerging markets." Novartis later that year affirmed its commitment to invest $500 million in product development in Russia. In 2011, Pfizer's third quarter U.S. sales dropped by 3 percent, and its foreign sales rose 15 percent. Foreign sales now constitutes over 60 percent of Pfizer's sales.[10]

So the race to capture emerging markets is in full swing, and public health may be the victor. U.S.-style drug pricing may one day fade into history as it is replaced by market saturation and competition for all potential customers.

But some fear that lowering the price of key medications will result in a slowing of innovation. Many of us labor under the notion that incredibly high U.S. drug pricing is required to sustain the research engine that provides new product opportunities, and there is no denying that product development is a costly endeavor. But most in our industry will acknowledge that marketing is the largest part of a budget for a company. Some sources claim it can be twice as large as a research budget for a given product.[11] As markets change, companies will need to reexamine their commitments to traditional marketing techniques and find ways to become more innovative and efficient when disseminating product information.

As we all head out into the unknown of pharmaceutical partnerships in emerging economies, there are several legal and practical issues that counsel will need to re-think. Logistics, insurance, currency risk, indemnification, FCPA risk, IP development and enforcement, marketing practices, pricing and anticompetitive concerns will need examination in a new light. Those issues can be explored in future articles. For now, suffice it to say that the adventure into new markets will be well worth the effort as we help our clients find growth, partnership and shared values with emerging markets leaders and innovators, and new markets receive the treatments they so desperately need and have gone without for decades.

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1 *ABC News*, April 25, 2011.

2 "Quagmire to Goldmine," *The Economist*, May 15, 2008; "Bill Daley's Big Pharma History," *Huffington Post,* September 28, 2011; "Big Pharma vs. The Developing World," *Healthbeatblog,* March 25, 2008.

3 "Merck & Co. has teamed up with Indian generics firm Sun Pharma," *Economist Intelligence Unit,* April 13, 2011; "Lonza and Teva link to top biosimilars market," *Reuters,* June 20, 2009.

4 "China and India Making Inroads in Biotech Drugs," *New York Times,* September 18, 2011.

5 "Quagmire to Goldmine," *supra* note 2.

6 *Supra,* note 4.

7 Both Cipla and Serum are clients of this writer's firm.

8 "Bill Gates' Vaccine Heroes," *Forbes,* November 2, 2011.

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10 "Pfizer's US Sales Drop, Emerging Markets Grow," *Fierce Biotech*, November 1, 2011.

11 "Big Pharma Spends More on Marketing Than on Research, Study Finds," *Science Daily,* January 5, 2008.