

Disruptive Forces in the Global Life Sciences Sector

An Interview with Benjamin Shobert

By Claire Topal
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The global life sciences industry (including pharmaceuticals, medical devices, diagnostics, and biotech) generated total revenues of over \$1.1 trillion in 2011.¹ Even in an era of shrinking budgets, this industry is being recognized for its economic value and growth potential, and Asia's engagement and investment in the sector has been rapidly increasing. NBR asked Benjamin Shobert (NBR Senior Associate) to explain the life sciences' relationship with economic development and address the political and economic implications of evolving global leadership in this sector. Mr. Shobert shares his perspective on China's and India's roles and offers recommendations for U.S. and international policy toward Asia.

Q. What role can the life sciences sector play in a country's economic development?

Economically, the life sciences are coveted areas for nation-states. The jobs created in these sectors tend to be high wage and knowledge-intensive. Countries with vibrant domestic life-sciences players often have analog industries in agricultural sciences, engineered materials, and food production that are equally important. For Asian countries, in particular, the



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development models that have proved effective in lower-wage and less knowledge-intensive areas, such as manufacturing, are now being tested in the life sciences arena. Thus far the results are mixed.

But the life sciences evoke more than just economic rationales. Success in the life sciences is often understood to represent a country's success in moving forward into higher-technology markets overall. In addition, the application of the sector's respective technologies and procedures represents foundational advances in quality of life, disease management, and longevity. The combination of economic impact, the repositioning of a country's technology aptitudes further up the high-tech continuum, and benefits to quality of life make for a compelling argument for why countries pour resources into the life sciences sector.

¹ Deloitte, "2013 Global Life Sciences Outlook: Optimism Tempered by Reality in a 'New Normal,'" 2012, <http://www.deloitte.com/assets/Dcom-Ireland/Local%20Assets/Documents/Life%20sciences/2013%20Global%20Life%20Sciences%20Sector%20Report.pdf>.

Q. Is global leadership in the sector shifting?

The United States and European Union still have clear dominant positions in terms of development and deployment of new technologies and therapies found to create positive outcomes, as well as delivery to individuals. Well-publicized R&D deals such as Merck's \$1.5 billion investment in China obscure the reality that while R&D investments are being globally rebalanced, they are still being driven largely by U.S. and EU companies.² Nevertheless, U.S. and EU firms shifting R&D resources away from traditional domestic sites, toward China in particular, does herald a change. It remains to be seen whether from the Chinese government's point of view this shift has the desired impact of creating a domestic life-sciences sector that has its own domestic champions competing at both the local and global levels.

Q. How has China's role in the life sciences sector evolved to the position it holds today, and how do you envision this role continuing to evolve?

The dominant driver to date has been China's role as a consumer of products and therapies, regardless of their country of origin. China's approach to the companies within these realms has historically been almost conciliatory. As one example of this, China granted price protections to a list of foreign-manufactured drugs for years after patents had elapsed, simply as a way of attracting the foreign companies to sell these drugs inside the country. Those days are long gone! China now not only wants access to drugs, devices, and diagnostics but is also explicit in its desire to develop a domestic life-sciences industry. Between 2008 and 2010, the country invested close to \$1 billion into the pharma sector and put in place new corporate incubation facilities across the country tied to two major investments in government-subsidized R&D centers with Beijing Pharma and Tongrentang. To its credit, China also worked to bring its domestic producers more in line with international good-practice standards, although a lot of work remains to be done in this area.

² "Merck & Co to Invest \$1.5 Billion for R&D in China," Reuters, December 6, 2011, <http://www.reuters.com/article/2011/12/06/merck-idUSL3E7N64HA20111206>.

Q. What are the next steps China will need to take to build up its domestic life-sciences sector?

The next phase is particularly tricky. China needs to drive down prices while getting more technology from foreign companies. The model here is not new to China, or to foreign companies: market access will be traded for technology transfer. This is a particularly nuanced swap at any moment in time but is especially delicate given the regulatory issues foreign pharmaceutical companies are encountering, best evidenced (or worst as the case may be) by the recent troubles of GlaxoSmithKline (GSK).³ The allegations over GSK's bribery of Chinese hospital administrators and doctors in exchange for scripts reflect unwelcome realities about how China's healthcare economy works. Setting aside questions about how foreign companies can most effectively interact with China's Ministry of Health on getting a drug onto the country's essential drug list, now pharmaceutical and device companies in particular are not sure how to tactically access the local healthcare economy.

What GSK is accused of stems from habits and practices that have evolved over several years and reflect simple uncomfortable realities about China's healthcare sector. The fact that domestic players get away with much worse behavior further confuses multinational life sciences companies that are assessing the headwinds of working in China. Technology-transfer expectations are becoming more problematic for foreign companies, which are now wondering whether their traditional strategies for gaining market access are robust enough to survive this next step in the evolution of China's life sciences sector.

Q. India, another major Asian economy, also has a fast-growing life sciences sector. How does India's investment in this sector compare to China's, and what are the implications for multinational companies?

India may hold some painful lessons for multinationals that historically have found China easier to access, simply because the direction China now appears to be taking looks to be reflective of what India has found to work, given its national interests. The most recent example of this is China following India's lead by modifying its national patent-law

³ Andrew Jack, Patrick Jenkins, and David Oakley, "GlaxoSmithKline China Sales Face Growing Pressure," *Financial Times*, September 23, 2013, <http://www.ft.com/cms/s/0/20e5fe62-2462-11e3-8905-00144feab7de.html#axzz2fvh2AojS>.

system to allow for compulsory licenses.⁴ The bigger and longer storyline is what India has done to develop a domestic pharmaceutical sector, even if these objectives at times worked at cross purposes with the designs of foreign industry.

Multinationals in India enjoyed a privileged position until India's 1970 Patent Act changed what protections foreign manufacturers could enjoy—and for how long—within the Indian market.⁵ India became quite sophisticated at process engineering, which has allowed its domestic pharmaceutical sector to become very dominant in the global generic market. This holds a couple of lessons for those watching China's attempt to create a life sciences sector of its own, not least of which is that new entrants who do not respect the traditional boundaries that govern a highly regulated and rule-bound industry can be extremely disruptive. China certainly holds the potential and has a track record of being similarly disruptive, as anyone who has watched the country's involvement with clean technology can attest.⁶

Q. What are the economic implications of shifting leadership in the life sciences sector?

The economic implications—in terms of where technologies are developed—provide insight into how countries understand one another. If we think about the arguments that have been used to support globalization, one of the most common has been that perceived economic dislocation resulting from industries moving from the United States or EU toward parts of the world with low-cost labor would be short term and addressed as workers were retrained and began

⁴ According to the World Health Organization, a compulsory license is a government authorization granted without the permission of the patent holder. Most countries have provisions for compulsory licenses, either under their patent law or, as in the United States, through antitrust legislation. Under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, countries have the right to issue such licenses. While the agreement does not limit the grounds, or reasons, for granting compulsory licenses, countries can only use those grounds that are allowed by their national legislation. ...Countries have specified many different grounds for issuing compulsory licenses, such as public health reasons. Other grounds are for emergency situations, epidemics, public noncommercial use, remedies for anticompetitive practices, or protection of the environment. It is entirely up to the national law to decide which are the grounds, so there is a lot of flexibility. See World Health Organization, "The Trips Agreement and Pharmaceuticals," May 2000, <http://apps.who.int/medicinedocs/en/d/Jh1459e/6.3.html>.

⁵ "Changes in India's Patent Law and Its Repercussions on the Global Drug Industry," Lorandos Joshi Trial Lawyers, <http://www.lorandoslaw.com/Publications/Changes-in-Indias-Patent-Law.shtml>. See also "The Patents Act, 1970," available from the World Intellectual Property Organization, <http://www.wipo.int/wipolex/en/details.jsp?id=2393>.

⁶ Clean technology includes recycling, renewable energy, information technology, green transportation, green construction, electric motors, green chemistry, lighting, greywater, and many other appliances that are now more energy efficient. It is a means to create electricity and fuels, with a smaller environmental footprint and minimize pollution.

to participate in higher-wage, more knowledge-intensive opportunities. In other words, the economic dislocation that globalization set in motion in the American Midwest would be counter-balanced by new opportunities in higher-technology sectors such as clean-tech and life sciences. As China has moved further up the value continuum, it has become harder to make this argument, which has in turn further strained how developed economies should respond to China.

Q. What can experiences resulting from similar shifts in other sectors teach us?

Questions about how China approached clean-tech and whether developed countries misplayed their hand early in that industry's development need to be asked now, specific to China and life sciences. One scenario that should give policymakers pause is if China proves to be as successful in the life sciences arena as it has been in clean-tech. In clean-tech, policies developed by the central government have resulted in China becoming the most attractive geography globally for clean-tech research and commercialization. Good questions about whether China's approach is economically sustainable or not can be asked specific to their clean-tech strategy, but over the last several years there is no question that China's clean-tech policies have served to reallocate where global R&D and production take place, where the most modern installed clean-tech capacity can be found, and where the largest public- and private-sector investments are being made. I am not sure that the policies traditional life sciences leaders (i.e., the United States and EU) have in place to encourage the continued success of their domestic players in R&D, intellectual property protection, and market access are adequate in today's shifting life sciences landscape.

China's efforts to move up the value curve and develop high-technology sectors such as life sciences come at a vulnerable moment in globalization's most recent era. In the aftermath of the 2008 financial crisis, U.S. and EU economies remain uncertain about where they can create new jobs. The idea that will they face competition from China not only in low-wage industries but also in high-wage areas such as life sciences adds a new and complex wrinkle to these regions' relations and trade policies with China.

Q. What does China's approach to fostering its own domestic life-sciences sector mean for life sciences in the United States and how Washington engages with Beijing?

Strategically, the United States needs to bring the concerns of the life sciences sector into existing structured bilateral discussions between the two countries, specifically the U.S.-

China Strategic Economic Dialogue (S&ED).⁷ This needs to happen now, before the life sciences sector faces the sort of headwinds from China that clean-tech did, specific to concerns over market access and technology transfers, to name only two issues that have been constant points of contention in U.S.-China trade discussions. Key concerns that should be included in the S&ED include compulsory licensing, uneven application of regulations between domestic and foreign life-sciences companies, pricing practices, and technology-transfer expectations in relation to market access.

Also at the strategic level, U.S. and EU policymakers need to be working through how to further incentivize domestic players to make ongoing investments in their home markets. Issues specific to patent law and subsidies for expensive drug development endeavors should be high on the list of priorities for the United States and European governments.

Q. What are the implications of China's approach on a tactical level?

The United States needs to engage China in an ongoing effort to protect the intellectual property of U.S. life sciences companies. The companies themselves will need to become a lot more local to be successful in China. A case in point on this tactical necessity is what has been called the “Anhui model.”⁸ This was one Chinese province’s organic response to the combined pressure from central government ministries that new drugs be offered to the people, but that costs not go up. The province set in motion a blind bid-and-tender process that cut the pharmaceutical industry off at the knees—prices dropped by double digits in very short order. The model was so successful that other provinces adopted it, even though it went against the pricing model the central government wanted to see.

The Anhui model was never an actual promulgated policy, but it proved two things. First, it showed how far local governments in China will go to try and broaden coverage while they control costs. Second, the Anhui model reinforced the simple truth that the central government many times does not have the ability to oversee or control local governments to the extent many Western firms anticipate. Blocking this

sort of damaging policy at the central government level is unlikely to work, especially in the short term; in the mid to long term the damage is done. To prevent this, foreign governments and businesses have to be working at the local level. Engaging in strategic policymaking in Beijing alone is insufficient.

Q. Are recent scandals involving multinational pharmaceutical companies in Beijing linked to the broader issues above? If so, in what ways?

The recent GSK scandal should be seen as involving a different, but no less troubling, aspect of how the landscape for the life sciences sector in China is changing. Three narratives have been put forward that best explain what the Chinese government is doing with GSK. The first is that this is part of President Xi Jinping’s overall anticorruption drive. The second is that this scandal is intended to drive down healthcare costs, and that rooting out corrupt practices will play a big role in making healthcare more efficient and affordable. The third and most troubling explanation is that the prosecution of GSK is indicative of the Chinese government’s overall willingness to be more aggressive with foreign players.

Over the last several years, surveys of U.S. and European companies operating in China have found an overall impression that doing business in the country is getting progressively harder. The Chinese government is seen as a competitor through its many state-owned enterprises. Issues like “indigenous innovation”—a policy that established guidelines intended to reduce dependence on foreign technology through the government’s investment in key strategic industries—have played out very badly and been interpreted (rightly or wrongly) as a near mandate for China to prioritize technologies and goods from domestic manufacturers.

The GSK scandal may ultimately prove to be nothing more than an effort to drive corrupt practices out of the country’s healthcare economy. If that is the case, it will be proven only when similar crackdowns occur on domestic Chinese companies. Additionally, the practices highlighted by the GSK scandal will only work to create efficiencies in China’s healthcare system when the central government massively increases its funding of public hospitals and the doctors who work within them. The corrupt practices GSK has been accused of reflect economic realities faced everyday by underfunded Chinese hospitals. If funding levels do not change, the crackdown will have served no purpose other than to frighten foreign players.

⁷ The U.S.-China Strategic and Economic Dialogue was established by the presidents of both countries in April 2009 as a high-level bilateral forum to discuss a broad range of issues between the two nations.

⁸ For more background on the Anhui model, see Dai Lian, “Anhui Model A Bitter Pill for Many,” *Caixin*, January 5, 2012, <http://english.caixin.com/2012-01-05/100346069.html>.

Q. Do the World Trade Organization (WTO) and U.S. Trade Representative (USTR) protocols, along with the S&ED, need to evolve to reflect the unique needs of the life sciences community? If so, in what ways?

Yes, existing bilateral trade discussions such as the USTR's efforts and the S&ED need to evolve further, as do the WTO protocols. Right now, the mediating document that guides these discussions is the WTO's TRIPS. This agreement works to find a balance between a country's public-health needs, its ability to pay industry for technology, and industry's need to make a profit. TRIPS is where we see the idea of compulsory licensing take on more form and substance; namely, the idea that a national government can license a pharmaceutical product to address a national emergency. China only recently (in spring 2012) changed its domestic patent law to accommodate compulsory licenses.

The worst-case scenario for industry—which is not unique to China—is that emerging economies would grant compulsory licenses on classes of drugs and then not establish the sort of boundaries that are supposed to govern compulsory licenses—for example, that they cannot be used for commercial use by the government and cannot be distributed outside the country issuing the compulsory license. A more realistic fear for foreign industry is that compulsory licenses will be used as threats or sticks in discussions between non-Chinese life sciences companies and the Chinese government. Faced with the threat of a compulsory license, does industry move more aggressively either with technology transfer or downward pricing?

Various people in the industry are discussing these fears, but it is equally important to point out that while the life sciences sector is facing new pressures, remedies and dispute-resolution processes do already exist that can be used should such a situation occur. The questions that need to be asked are whether the existing protocols go far enough and whether they take into account the unique needs of the life sciences sector. Part of the answer to these questions has to be independent of such bilateral discussions. While highly valuable in many respects, these mechanisms were nevertheless poorly suited to the ways China developed its domestic clean-tech sector. Would more robust bilateral discussions have

helped prevent China's disruption of U.S. and EU clean-tech endeavors? Certainly. But the bigger question is whether the United States and European governments had the political will, national conviction, and economic capacity to make the sort of investments into their own clean-tech sectors. China had all three.

The USTR, WTO, and S&ED can work to ensure as level a playing field as is possible for U.S. companies, but they cannot be the only tools in the toolbox when it comes to questions over how to productively channel R&D capacity and commercial capabilities for the domestic life-sciences sector. ∞



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