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India needs more tie-ups to boost pharma sector

By: [Nilanjan Banik](#) and [Philip Stevens](#) | Published: May 4, 2016 5:27 AM



Under the leadership of Prime Minister [Narendra Modi](#), the government has shown it understands the need to develop the country's innovative life sciences sector. The government is due to announce a major reform of intellectual property laws, which it sees as crucial for developing modern, high-technology industries. Meanwhile, the Make-in-India campaign and the previous government Budget created a number of tax incentives and research & development (R&D) initiatives aimed at increasing private and public sector research investment.

Such reforms are overdue. India's generic drug manufacturing industry constitutes a healthy 10% of the volume of the global pharmaceutical industry, but only 1.4% of the value. In fact, recent data from the World Intellectual Property Organisation (WIPO) showcase a fall in the number of patents granted to resident Indians, particularly after 2007 (see chart). This is while the Indian pharmaceutical industry flourished under a trade restrictive market access regime, requiring foreign multinationals to abide by a strict Section 3(d) clause of the IPR Act, for them to get IPR protection in India.

If the pharmaceutical sector is to help propel the country towards the next stage of economic development, it needs to be generating much more value, and that means creating medicines instead of just manufacturing copies of those invented elsewhere.

The US pharmaceutical industry, which is largely comprised of innovative, R&D-focused companies, generates a direct output of \$461,000 per employee, compared to \$149,000 on an average for other sectors. In Europe, the pharmaceutical industry contributed an international trade surplus of \$54 billion. It is no wonder that western governments view these industries as major economic assets.

There is no reason why India cannot grow its own biopharmaceutical sector. It has a well-developed scientific base, with a large number of highly-skilled researchers and scientists. India is one of the six most biodiverse countries, and its 8,000-km coastline has a wealth of marine organisms that could provide fertile territory for drug research.

The country's relatively liberal regulatory regime makes it a promising location for stem cell research, cell engineering and cell-based therapeutic R&D. Meanwhile, its proven strengths in information technology means it is emerging as a leader in the use of computer science, statistics and mathematics to analyse and interpret

biological data—crucial for modern biotech research.

While the Indian pharmaceutical industry is still dominated by manufacturing of drugs invented by (mainly foreign) companies, things are starting to change.

The country is now becoming a serious player in vaccine innovation, for instance, with Hyderabad's Bharat Biotech's innovative H1N1 influenza and rotavirus vaccine, and the two anti-malaria vaccines under joint development between Ranbaxy and Bharat Biotech.

Domestic companies also promise much in active therapeutic proteins, protein and antibody production, and fabrication of diagnostic protein chips. In addition, patients are benefiting from changes in the Indian industry. Bangalore's Biocon is close to releasing an insulin product that can be consumed orally. If successful, it could spell the end of the daily injection regime for around 387 million people with diabetes worldwide, including 67 million in India.

While these are early signs of success, the industry has a long way to go. While its "R&D intensity" (the amount it invests in R&D as a percentage of sales) has been rising for several years and now stands at 6%, it is well short of the 20% typical of western pharmaceutical companies.

India spends just 1% of its GDP on R&D, with up to 80% of that money coming from the government. By contrast, about 75% of research funds in wealthy countries come from the private sector.

In addition to the reforms proposed by the Modi government, the country's overall innovation ecosystem needs a lot of work. Last year, India filed a total of 1,394 patent applications, compared to 25,539 in China.

In highly-innovative countries, the academic and private sectors collaborate constantly in their research, each leveraging the advantages of the other. While there is some collaboration in India, the two worlds remain largely isolated from each other. Simple rule changes in this area could bring the two closer.

Another challenge is to provide a domestic market for local innovations. For instance, other innovative countries tend to cover new drugs and technologies in their healthcare systems, which also improves the quality of care and health outcomes. Health insurance in India—where it exists—generally only covers older, less effective medicines, making it difficult for R&D companies to get a foothold in the market. On an average, Indians spend \$160 on healthcare (annualised per-capita figure), of which only 25% is contributed by the government—a figure which is lower than many sub-Saharan countries.

These failings aside, one way to accelerate the transformation of Indian pharmaceutical manufacturers into R&D companies is for them to enter into global alliances with multinational companies. Such cross-border tie-ups import skills, finance and knowledge, which are not always locally available, giving Indian companies a short-cut to upgrading their ability to conduct R&D.

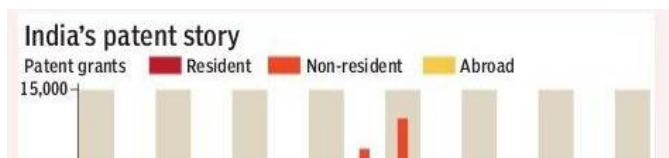
This is already happening on a modest scale. Most recently, in February this year, Sun Pharmaceutical tied-up with AstraZeneca to promote and distribute its new

anti-diabetes drug in emerging markets. However, more tie-ups are needed to give the Indian pharmaceutical sector a skills boost and bring new technologies into the country.

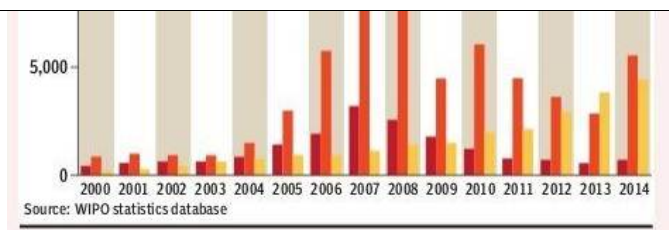
One thing foreign investors need in this sector is certainty over their intellectual property rights, which need to be clearly defined and readily enforceable. Despite the government's focus on this area, the recent decisions by Indian courts around patentability and compulsory licences make potential investors nervous, and could put a brake on the sector's development.

The opportunity is there, it is up to the Indian policy-makers to grab it.

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Source: WIPO statistics database

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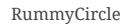
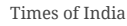
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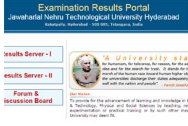


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