

**Keynote Address by Mr. Ranga Iyer, President, OPPI
on ‘Globalization – Leveraging Opportunities In Pharmaceuticals’
at Pharma World Expo 2009, February 13, 2009, Mumbai**

Talking about globalization of the Indian pharmaceutical industry is like carrying coal to Newcastle, as the English saying goes. I'd say it is like carrying sandalwood to Mysore!

The pharmaceutical industry is among the most globalized industries in India. Statistics show that globalization is accelerating with each passing year. Indian companies have filed more than 240 DMFs with the US FDA – more than any other country. India has more than 100 FDA-certified manufacturing plants – the largest number of FDA approved plants outside North America. US FDA now has its office in India.

There was a time when globalization meant exports out of India. That was only the baby step in globalization. India's ambitious entrepreneurs have invested more than \$ 2 billion in recent years in outbound mergers and acquisitions, creating Indian-owned multinationals. Chances are that some of the generic medicines you may purchase anywhere in the world today may have an Indian connection. Exports of pharmaceuticals today are equivalent to the total domestic sales.

One of the original drivers of globalization was the limitations of the Indian market. That picture has changed with India emerging as one of the world's fastest growing markets. You are all familiar with McKinsey's prediction about the Indian market growing to \$20 billion by 2015. It said India will rank among the top 10 pharma markets by 2015, overtaking Brazil, Mexico, South Korea and Turkey. The incremental market growth of \$ 14 billion is likely to be the third largest among all markets, the report said.

McKinsey projections are based on several assumptions. It assumes an industry CAGR of 12.3 percent and a real GDP growth of 7.3 percent. Per capita disposable income will rise from \$ 463 in 2005 to \$ 765 in 2015. 27 million households will move up from the low income category. 59 million households will join the middle income category. India will have 2 million hospital beds. Health insurance will double to cover 220 million people. Patent infrastructure will scale up to enable up to 30 approvals a year.

Many of these assumptions may not hold good any more. I don't think anyone anticipated the financial meltdown and recession. No one talks about the Indian economy being decoupled from the global economy these days. India is feeling the impact. We still prefer to call it slowdown rather than recession. But the writing is on the wall and the pharmaceutical industry is not immune from the global meltdown.

The Indian economy is slated to grow by 7.1 percent during the current fiscal as against 9 percent 2007-08, according to estimates released by the Central Statistical Organization earlier this week.

The pharmaceutical industry growth rate has decelerated from 13.69 percent in January 2008 to 9.83 percent in December 2008 as per ORG. The slowdown will take its toll on other assumptions like growth of middle income class, increase in hospital beds and expansion of health insurance.

Recessionary times put tremendous pressure on everyone to spend less – consumers, companies and governments. Even the seemingly recession-proof pharmaceutical industry cannot escape from the universal urge to cut spending.

Does the recession open up new opportunities for the Indian industry? Can we profit from the compulsion of governments, companies and consumers to spend less on medicines? I think we in India can profit from the situation if we are more proactive. As someone said, “Even when opportunity knocks, one has still to get up from the seat and open the door.” Are we ready to get up and open the doors?

Bill Gates said that success is a lousy teacher. It seduces smart people into thinking they can't lose. India may lose out on opportunities as we bask in our success. We hear at every seminar about the Indian advantage: our chemists are brightest, they speak English, we have the largest patient pool, we are a democracy, we have rule of law and we now have product patents. What more could you ask for?

We talk as though these advantages will bring all the goodies for all time to come. Let us pause for a moment and ask why our neighbour China is overtaking us in research and investment? We are late starters in new drug discovery. The Big Pharma is facing new product draught, declining R&D productivity and looking out for good, low-cost options to pursue R&D.

Most of the multinationals increasingly prefer China over India. GSK is making big ticket investment in China, betting that the future of drug development will be led by China. In his keynote address titled “From Made in China to Discovered in China” at the China Trials 2008 Global Clinical Development Summit in Shanghai, Perry Nisen, senior vice president, cancer research at GSK, emphasized the importance of China with regard to GSK's global strategy. He said that if GSK's China initiative is not successful, it is going to hurt the company because it has invested so much there.

GSK is not the only Big Pharma to set up R&D centre in China. It is followed by Roche, Pfizer, AstraZeneca and Novartis and Ely Lilly.

The Big Pharma is increasingly more comfortable in China than in India. Much of that comfort comes from an increasing trust in China's patent laws which have been getting stronger. China moved late in 2006 to protect the intellectual property of Pfizer's Viagra, while Novartis lost a patent case in India over a cancer drug on the ground that it was only an incremental innovation.

We have to remember that most of the medicines available today are a result of incremental innovation. Look at antibiotics. The original indication was only for parenteral usage. From parenteral, we have progressed to antibiotic tablets, capsules, topicals and inhalers. You will agree that all these are innovations that have added

great value to the patient. Our Section 3 (d) discourages incremental innovation. Why do we need patent protection for incremental innovation? It is required to recoup investment in research and clinical trials to prove the efficacy and safety of the innovation and also to ensure that the product satisfies the patient's need. This is not ever greening as some people argue. Ever greening refers to a company's attempt to pre-empt patent expiration.

Incremental innovations are like low hanging fruits. It will cost a fraction of the investment required for taking a new chemical entity from discovery to market. It will benefit Indian companies more, with their lower R&D costs.

China provides for six years of data protection. Unfortunately, data protection has been misrepresented as backdoor patent protection and TRIPS-plus in India. It is nothing of the kind. Let me quote a KPMG study that compares India with China:

'India needs to look to the achievements of China, where the government's strong commitment and pro-industry policies have produced a positive environment that not only offer drug manufacturers a product patent regime but also, and crucially, data protection.' It adds that India's continuing failure to do so needed to be urgently rectified.

Data protection is essential for the patient's welfare. It will encourage companies to conduct clinical trials in India that will help our doctors take care of adverse events.

The global meltdown and the drive to cut costs will mean more opportunities in the CRAMS – custom research and manufacturing services – sector. Intellectual property plays an important role in CRAMS offshoring decisions. It is no coincidence that the large CRAMS players in India are fully committed to the global patent regime.

Another door to the emerging opportunities is to enhance Indian industry's quality standards and take on the menace of counterfeits. We have several seminars on the subject but there seems to be little concerted action against this organized industry.

Henry Kissinger said that a nation has no permanent friends or enemies -- it has permanent interests. It is in India's interests, and in the interest of the patient, that we seize global opportunities in pharmaceuticals to emerge as the choice destination for the world's leading companies – Indian as well as foreign – to conduct research and manufacture in India for the world at large. Let us capitalize on the opportunities thrown up by the global recession.