

FTA's better IP protection will attract FDI
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Malaysia is currently in negotiations with the US for a Free Trade Agreement (FTA) which is expected to ease the way for attracting more foreign direct investment to Malaysia. Amongst the issues being negotiated is the strengthening of Intellectual Property Rights (IPR) in Malaysia.

Even though Malaysia already has high standards of IPR in the form of patents, trademarks and copyright, there is still a need to enhance the intellectual property (IP) environment in order to recognise and reward research.

In order to attract foreign investment in the R&D sector, it is important to understand that foreign corporations invest not to make simple products but to produce those with high elements of innovation, creativity and design. This will help to promote foreign direct investment as it makes Malaysia more attractive for foreign investors that have invested heavily in research. This is especially so in the pharmaceutical industry which has been identified as a key growth sector under the Third Industrial Master Plan (IMP3).

US pharmaceutical companies spent US\$55.2 billion on R&D in 2006 and there is a great possibility of a fraction of that amount that can be diverted to Malaysia with the FTA. (PhRMA news Feb 12, 2007)

Unwarranted fears

However, there are some unwarranted fears in the industry about the FTA provisions on IPR that will cause difficulties to local drug manufacturers who are mainly producing generic drugs. Such fears and apprehensions are largely misconceived because stronger IP protection does not hurt local generic drug manufacturers or make them lose out. Instead the opportunities for them become better as it will attract investments from large pharmaceutical companies with resulting spin-offs to the local generic drugs manufacturers in terms of joint ventures, contract manufacturing and R&D.

Even China, a nation hardly well-known for its IP laws, has actually passed regulations as early as 2002 to provide for six years of data exclusivity as from the date of marketing approval. In the "Regulations for Implementation of the Drug Administration Law," effective September 2002, the definition of a new drug was modified in accordance with the Trade-Related Aspects of Intellectual Property Rights (Trips).

The new Patent Law further harmonised China's patent system with the rest of WTO member countries. In fact, China's IP protection for pharmaceuticals has gradually been coming into conformity with international standards over the past several years.

The result of China's IPR strategy is clear with the who's who of global pharmaceutical companies moving into China in a big way. Today, multinationals have over 600 joint ventures with local companies in China.

AstraZeneca invested US\$134 million in a manufacturing plant in Wuxi and is set to invest another US\$100 million to open the AstraZeneca Innovation Centre China in 2009. It has a

marketing arm that employs 2,500 people and has also created a division to support local clinical trials.

Novartis is collaborating with the Shanghai Institute of Material Medical Research, a leading Chinese R&D institute and it is constructing a US\$83 million site for drug production and development in Changshu.

World leading pharmaceutical company Eli Lilly set up a research laboratory in cooperation with its Chinese partner Shanghai ChemExplorer in the Zhangjiang New and Hi-Tech Technological Park in Shanghai's Pudong New District. World first-class research equipment has been installed in the lab and it has 230 scientists working in China. The China-based R&D team is the US-based firm's largest R&D group overseas.

Eli Lilly has also agreed to transfer its antibiotics manufacturing technology to leading Chinese company Hisun Pharmaceutical Co Ltd. The move is part of Eli Lilly's US\$70 million global initiative to address multi-drug resistant tuberculosis, in partnership with the World Health Organisation. It also has a factory in adjacent Suzhou city, east China's Jiangsu province.

Golden opportunity

Meanwhile, Pfizer, has invested over US\$500 million in China and will also set up a new R&D centre in Shanghai with initial spending of US\$25 million over the next few years.

In 2002, GlaxoSmithKline (China) Investment Co. Ltd (GSK) was officially established and became one of the largest multinational pharmaceutical companies in China. GSK has established five legal entities encompassing four manufacturing facilities (three are joint ventures) with a total registered capital of over US\$230 million in China. It has offices in 29 major cities (including Hong Kong) with 2,800 employees nationwide. The various companies continue to create jobs and provide training for business managers and professional staff in the pharmaceutical industry, as well as provide business opportunities to local partners and medical professionals.

GSK signed an agreement with China's Sincere Pharmaceutical Group to manufacture and sell a cheaper version of its bird flu drug Relenza for use in poorer countries. The terms of the licensing deal allows Sincere to manufacture and sell zanamivir, the active ingredient in Relenza, in China, Indonesia, Thailand, Vietnam and other less developed countries.

Relenza, together with Roche's antiviral Tamiflu, are the only drugs considered effective against the human form of H5N1 influenza, and would be the first line of defense in the event of a worldwide H5N1 influenza pandemic.

Roche has two manufacturing plants in China, one of which is a high tech manufacturing facility in Shanghai producing the cancer medicine Xeloda and the transplantation medicine CellCept. Both Xeloda and CellCept are major medicines in the Roche portfolio. Xeloda is a tumour-activated oral chemotherapeutic agent used to treat breast and colorectal cancer. CellCept, used as a foundation for immunosuppression, helps transplant patients to live a longer and healthier life.

Roche also opened its new R&D center in Shanghai which is its fifth Pharma research site globally. The center will work with JiangJiang High Tech Park to promote the district to become a leading biomedical research based epicenter of drug research and discovery in

China. In addition, it is working in collaboration with the two Chinese National Human Genome Centers to conduct genetic epidemiology studies to identify genetic predispositions to diseases such as diabetes or Alzheimer's.

Further more, like GSK, Roche is the maker of Tamiflu, an important bird flu vaccine and the company has granted a first sub-license to Shanghai Pharmaceutical Group for the production of Tamiflu for pandemic use in China.

If China can see tremendous benefit of stronger IP protection, certainly Malaysia should be able to recognise the advantages of it as well and not miss the golden opportunity that the MUFTA presents in attracting new FDI and helping us move up the value chain in innovation and R&D.

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