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ASIAN HEALTH NEWSLETTER

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A bimonthly newsletter of developments in the pharmaceutical, hospital and medical device markets

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INTRODUCTION

We hope that you find the *Asian Health Newsletter* informative. In this issue we look at pharmaceutical patenting in India and China.

BDA is a corporate finance advisory firm which helps multinational clients to identify and to execute acquisitions and JVs in Asia. We are well placed to help Western companies structure mutually beneficial transactions with local partners.

If you think that BDA's services may be useful to you, please email me: erellie@bdallc.com.

Euan Rellie
Managing Director

AUSTRALIA

FH Faulding & Co Ltd of Australia has received approval from the US FDA to manufacture and market flvoxamine maleate tablets. The tablets will be used to treat obsessive compulsive disorders (OCDs). They are the equivalent of *Luvox* brand tablets marketed by **Solvay SA** of Belgium with revenues of US\$160m in 2000. This is Faulding's eighth US FDA approval in FY 2000, with another 19 products pending. (December 29, 2000)

MicroMedical Industries Ltd of Sydney received a European patent for developing its wireless medical monitoring technology. The technology aims to monitor cardiac patients through a sensor patch that is connected to a monitoring device and remote-monitoring center using a wireless link. (January 23, 2001)

CHINA/HK

Anke Biological High-tech Co has commenced construction of a Genetic Engineering Drug Industrialization Base in Anhui Province. With a total investment of US\$12m, the plant will have production lines for genetically engineered glucokinase, human growth hormone (annual capacity of 5 million vials) and frozen dried powder injections of interferon a 2b (annual capacity of 5 million vials). The annual output value of the plant is expected to reach US\$120m once operations begin. (January 31, 2001)

China Development Industrial Bank will invest US\$5m to purchase a 6.4% stake in **Optimer Pharmaceuticals Inc**, a US-based pharmaceutical manufacturer in San Diego. The American company has a subsidiary in Singapore which will be listed there in 2001. (January 28, 2001)

GeneMedix Plc of the UK, pending approval, will acquire a 75% stake in Shanghai-based pharmaceuticals manufacturer **Shanghai Dongxin**. The current holding company, **Shanghai Shenlongda Biotech Group Ltd**, will retain 25% of the equity. The total investment in the Chinese plant is US\$17.5m. GeneMedix manufactures generic versions of drugs with patents close to expiration. GeneMedix aims to continue to grow its manufacturing and sales in Asia and India. (January 8, 2001)

LifeTec Group Ltd, a Chinese health food distributor, will soon begin the production and retail of its new drug, *Wei Jia*, through **Weihai Sinogen Pharmaceutical Co Ltd**, in which it holds a 57.12% stake. The drug will be used to treat Hepatitis B and will be priced at about RMB20 (US\$2.40) per dose. The company expects the drug to strengthen its long-term earnings base. (January 17, 2001)

Sanofi-Synthelabo Minsheng Pharmaceutical Co Ltd reported sales growth of over 100% to US\$22m in 2000. The company expects to record sales of US\$36m in 2001. Established in 1996, it is a JV between **Minsheng Pharmaceutical** and **Sanofi-Synthelabo** of France. The JV aims to become one of the top 10 players in China's pharmaceutical industry by 2003. (January 31, 2001)

Shanghai KaiKai Co plans to issue up to 50 million domestic A shares at a tentative price range of RMB5.6 (US\$0.68) to RMB8.6 (US\$1) each so that it may expand into the pharmaceutical industry. (January 10, 2001)

SmithKline Beecham ("SKB") has successfully patented rosiglitazone maleate in China. SKB has one patent for the compound and another for the preparation method. Rosiglitazone maleate belongs to a new class of insulin sensitizers, troglitazones, that may have uses in the treatment of diabetes. The drugs

reduce tissue resistance to insulin and also inhibit breakdown of glycogen in the liver. The product will be marketed in China as *Avandia* and is expected to have good market potential. The drug may be manufactured through one of SmithKline Beecham's JVs in China: **Tianjin SmithKline & French Labs Co**, **SmithKline Beecham (Tianjin) Co**, and **SmithKline Beecham Biologicals (Shanghai) Co**. (January 31, 2001)

Southwest Pharmaceutical Co Ltd has increased its stake in **Chongqing Innovation Bioengineering Co Ltd ("CIBC")** to 65%. CIBC was previously a JV between **Chongqing Yugao S&T Co** and a private investor from Singapore. The company is engaged in R&D, production and marketing of pharmaceuticals and traditional Chinese medicines. (January 8, 2001)

Vincent Medical Manufacturing Co of Hong Kong has signed an agreement with **Medrad Inc**, a US-based subsidiary of **Schering AG** of Germany to manufacture disposable syringes in China. The companies anticipate lower costs for both production and transportation with no reduction in quality. Once the Guangdong facility is up and running, Medrad is likely to cease manufacturing similar products in the US. (January 31, 2001)

INDIA

Alembic Ltd of India has applied to introduce its own version of *Viagra* into India. The company will also seek approval of the US FDA, in order to comply with the WTO's standards that will take effect in India in 2005. **Cadila**, **Cipla**, **Ranbaxy**, and **Sun Pharma** have also applied to be licensed to manufacture and distribute the erectile dysfunction drug in India. (December 9, 2000)

AstraZeneca, the Anglo-Swedish pharmaceuticals giant, has acquired **Hinduja Group's** stake in their JV, **Astra-IDL**. The company's other technical partner **ICI India** had opposed themove. (January 18, 2001)

Eli Lilly, the US\$11bn US drug company is looking at developing India as its global clinical research center. The company aims to conduct research into drugs for CNS-related disorders. (January 6, 2001)

Hoechst Marion Roussel India is to buy **Rhone-Poulenc India's** share in the JV company **Rhone-Poulenc Rorer India**. The JV was previously 51% owned by **Aventis** and 49% by Rhone-Poulenc India. Aventis will maintain its 51% holding in Hoechst Marion Roussel India. (January 10, 2001)

Morepen Laboratories of India announced that it will form a JV with **Diamed AG** of Switzerland. The JV will initially sell Diamed's malaria kits in India. (January 23, 2001)

Satyam Computer Services Ltd of India has entered into a JV agreement with the **Centre for Cellular and Molecular Biology** to develop specialized software and computer services for pharmaceutical research and the healthcare industry. (January 26, 2001)

Wockhardt Ltd of India and **Bayer AG** have signed an agreement to co-market the latter's anti-diabetes drug *Acarbose* in India, the first such arrangement for an anti-diabetes product in the country. *Acarbose* is currently being marketed in India under the brand name *Glucobay*. (December 14, 2000)

Wockhardt Hospitals, an associate of Indian pharma major **Wockhardt**, will build two cardiac care hospitals in Mumbai and Bangalore at a cost of Rup2bn (US\$43m) over three years. The hospitals will be commissioned under an alliance formed with Harvard Medical International, a subsidiary of **Harvard Medical School** in the US. The hospitals will be operational by Q1 2003. (January 17, 2001)

JAPAN

Chugai Pharmaceutical, Japan's leading biotechnology company, announced that it would consider a partnership with a foreign group to

strengthen its research and marketing capabilities in the US and Europe. Chugai is currently Japan's 10th largest pharmaceuticals company, with a market cap of US\$4.5bn. (February 5, 2001)

Daiichi Pharmaceutical Co has acquired Japanese marketing rights for **MedGene Bioscience Inc's** therapies such as hepatocyte growth factor (HGF) for circulatory conditions such as peripheral arterial disease. University of Osaka researchers discovered HGF and determined that it plays a role in the regeneration of blood vessels and organs. Genes encoding HGF will be injected into a patient in order to stimulate blood vessel growth. (January 16, 2001)

Kaken Pharmaceutical Co of Japan, and **Institute for Diabetes Discovery LLC** of the US, will form a JV to develop a diabetes drug, which increases the effectiveness of insulin in the body. (December 14, 2000)

Sankyo Pharma Inc of the US, a subsidiary of **Sankyo Co** the Japanese pharmaceutical major, announced that it will acquire from **Pfizer** its stake in their JV, **Sankyo Parke Davis**. (January 18, 2001)

Suntory Ltd, a whiskey distiller, and **Taisho Pharmaceutical Co**, both of Japan, will jointly develop a stroke medication using a chemical compound discovered by Suntory. The firms hope the drug will be available worldwide by 2010 and aim for annual domestic sales of ¥20bn (US\$176m) per year. (December 28, 2000)

Taisho Pharmaceutical Co of Japan has acquired exclusive rights to sell and develop **Neurocrine Biosciences Inc's** diabetes drug worldwide. US-based Neurocrine Biosciences previously sold the rights for the NBI-6024 in Asia and Europe to the same company. (December 12, 2000)

Takara Shuzo Co, a distilled spirit maker, which is also becoming one of Japan's leading biotech companies, has acquired an equity stake in US-based **GeneFormatics**. The firms have also entered a strategic collaboration for developing technologies for research into the human genome. Under the agreement, Takara has obtained exclusive rights to sell the high-speed analysis service using

GeneFormatics' technology in Asia, including Japan, China, Taiwan and South Korea. (January 22, 2001)

Takara Shuzo Co will collaborate with **GenCom Co** of Tokyo, to focus on genomic analysis of mouse embryonic stem cells. GenCom, controlled by **Mitsubishi Chemical Corp**, will offer the cells to Takara Shuzo, which will, in turn, undertake research at its gene analysis centre, **Dragon Genomics Co** in central Japan. (February 1, 2001)

Tomen Corp and **Nichimen Corp**, both of Japan, will combine their pharmaceutical and agrochemical businesses to increase their competitiveness in these areas. The new company will be 40% owned by each company. The remaining 20% will be owned by other companies including some in the Tomen group. As a result of the merger, the two companies expect to increase sales on the global market. (January 9, 2001)

Zeria Pharmaceutical Co has won approval from the US FDA for clinical testing of its *Z-100* drug for controlling reduced levels of leucocytes. The drug may have potential in AIDS therapy, provided that it passes tests combining the use of *Z-100* with the highly active anti-retroviral therapies. (January 17, 2001)

KOREA

Medi-Hut Co Inc of the US has entered into a JV agreement with **COA International Industries Inc** of Korea to manufacture Medi-Hut's passive anti-stick medical syringes in Korea. Medi-Hut will have 44% ownership of the new syringe production facility. Medi-Hut will be able to reduce the cost of safety syringe production and will also significantly increase production levels of both COA's disposable syringe and Medi-Hut's *Elite Safety Syringe*. Capacity at the new facility will be four million syringes a month. (December 5, 2000)

To submit stories to future editions of the *Asian Health Newsletter* please contact Emily Ryder at (44) 20-7655-3753 or email at eryder@bdallc.com.

MALAYSIA

Versatile Corp of Malaysia, a bumiputera medical card and emergency services provider, will expand its services to cover India following an agreement with **India Lease Development Ltd**. The JV, **Versatile Medicare India Ltd**, will be 51% owned by Versatile Corp. (January 16, 2001)

The Malaysian Government is in final stages of drafting three important laws aimed at promoting development of the country's biotechnology industry. The legislation will ensure that companies in Malaysia will fairly benefit from the advances in biotechnology that they have been making. (December 21, 2000)

SINGAPORE

Nanyang Technological University will invest S\$465m (US\$266m) in a life sciences college in Singapore. This development will help Singapore to secure its base in the life sciences industry. (December 4, 2000)

The Singapore Government has set aside S\$4bn (US\$2.3bn) for biotech research, seeding startups and financing JVs. Singapore has already invested heavily in biotechnology parks to lure major life-sciences companies in to making Singapore their base for Asian operations. Already **Schering-Plough**, **Wyeth-Ayerst**, **Merck**, **PerkinElmer**, **Glaxo** and **Genset** have established bases in Singapore. The Singapore China Biotechnology Programme (SCBP) aims to access technologies developed in China and commercialize them in Singapore. (January 18, 2001)

TAIWAN

Arena Pharmaceuticals of the US will set up a JV with Taiwan's **National Health Research Institute**.

The new venture, **TaiGen Biotechnology Co** will develop cancer drugs and vaccines. The firm will be capitalized at US\$67m, including investments and the value of key technologies provided by Arena. Arena currently uses its CART technology on G protein coupled receptors, which are potential drug targets. (January 17, 2001)

Asia Celera Genomics Corp has been established as Taiwan's first bioinformatics firm. The company was a JV between major investors **Celera Genomics Corp** of the US and Taiwan's **Ho Tung Chemical Corp, Walsin Lihwa Electric Wires and Cables, Industrial Bank of Taiwan** and **Cathay Life Insurance** among others. The new firm will conduct research into nucleotides and study the genetic basis of human diseases. (January 18, 2001)

The **Ministry of Economic Affairs** (MOEA) has revealed that investments in biotech in Taiwan will total over NT\$12bn (US\$371m) in 2001. One of the largest of these is a NT\$6bn (US\$187m) investment by **Uni-President Enterprise Co** for pharmaceutical manufacturing. Over the last five years, funds totaling NT\$26.2bn (US\$811m) were invested into the industry in Taiwan. (January 5, 2001)

THAILAND

Trinity Medical Group USA has amended its agreement with US-based **The Immune Response Corporation** regarding the latter's HIV vaccine, *Remune*. *Remune* is the leading IBT (immune based therapy) product in human clinical studies around the world for the treatment of HIV. The original deal required *Remune* to have been approved in Thailand by December 31, 2000, but a revision extends this agreement's termination date to August 2001. (January 22, 2001)

VIETNAM

The **Vietnam Association of Pharmaceutical Producers** has been formed to unite producers, importers and exporters of pharmaceuticals in Vietnam. The association is intended to help its members improve both their domestic and overseas performance. (December 1, 2000)

FOCUS:

Pharmaceutical Patenting in Asia

Many countries such as India and China offer weaker patent protection than Western nations. Under the Paris Convention, to which most nations with patent systems adhere, nations are free to structure their laws on intellectual property however they desire, as long as they do not discriminate between local and foreign investors.

Many nations exclude pharmaceuticals from patentability because they consider drugs to be of great importance to the national welfare. However, the protection of intellectual property in the pharmaceuticals industry has become increasingly favored as it enables research to be adequately financed and encourages the sharing of scientific knowledge to further research. For the multinational pharmaceutical companies, the inability to obtain universal patent protection for their new products is a constraint on their worldwide sales and profits.

We profile below the patent regimes, and development thereof, in two of the biggest pharmaceutical markets in Asia, India and China.

India

The Indian pharmaceutical industry collectively had sales of Rup200bn (US\$4.3bn) in 2000, representing

16% growth over 1999. India is predicted to become a key sourcing base for the pharmaceutical industry globally, due to the low cost of manufacturing and availability of highly skilled professionals. However, the industry will undergo a period of dramatic change as implications of joining the WTO come into effect.

India became the leading producer and exporter of copy-cat drugs to nations lacking product patent protection in 1978 when the law in Italy (previously the leader) changed to grant drugs product patents. As of 1999, India had not implemented legislation for accepting product patent applications, so all drugs were regarded as generic (off patent). Pharmaceuticals have remained one of India's least regulated sectors.

Indian patent regulations previously only allowed the process, rather than the product to be patented. Consequently a drug itself could not be patented. Therefore by using a different process to reach the same end result, a patented drug could be produced and marketed legally.

Pharmaceutical patent legislation is expected to change in the near future to come into line with TRIPS (Trade-Related International Property Rights), a move that may make the market in India more attractive to foreign companies. Under the WTO agreement, pharmaceutical product patents must be introduced in India by 2005.

Indian patent law currently grants exclusive marketing rights (EMR) for five years to the company that seeks it first. Under its TRIPS obligations, India must grant EMRs for drugs patented after January 1, 1995. It has only to take into account patented molecules, not their derivatives.

In Q4 2000, a patent dispute broke out between **SmithKline Beecham ("SKB")** of the UK and Indian pharmaceutical companies **Dr Reddy's, Sun Pharma** and **Torrent Pharma** for violation of its patent of anti-diabetes drug, *Rosiglitazone*, which is an original research product of SKB. Earlier in 2000, SmithKline Beecham applied for EMRs in India for *Rosiglitazone*. Subsequently Dr Reddy's, Sun Pharma, and Torrent Pharma filed for EMRs for their branded formulations of *Rosiglitazone: Enselin* (Torrent Pharma), and *Rezult* (Sun Pharma).

The Indian Pharmaceutical Alliance (IPA) (of which Dr Reddy's and Torrent are members) claimed that the drug was patented pre-1995 and was therefore exempt from the laws on EMRs. The IPA maintained that EMRs could only be granted for basic molecules developed after January 1, 1995. SKB claimed that the EMRs in question was for a derivative of the original product that the pre-1995 patent covered. The Indian patent law is silent on whether patent protection can be claimed for derivatives.

Opportunities for MNCs in India

The impending patent reform is anticipated to make the Indian pharmaceutical sector more attractive to foreign corporate investors and consequently the Indian pharmaceutical industry is expected to see accelerated growth. The legislation will protect the intellectual property relating to R&D so as to allow uninhibited collaborative work by Indian companies and MNCs. Currently only 30% of the Indian pharmaceutical market is occupied by MNCs.

A wave of mergers, acquisitions and alliances of pharmaceutical companies in India will precede the patent legislation. Pharmaceutical majors are weighing their options for entering into JVs and alliances to reap the benefits of joint marketing and patent sharing, a trend that is in line with global consolidation of the pharmaceutical industry. The new regime of allowing product patents should as it is implemented, gradually pave the way for MNCs to introduce patented drugs into India, with full intellectual property protection.

China

China's pharmaceutical market is booming and sales have grown at an average rate of over 14% for the past 15 years. Some analysts predict that China will become the largest pharmaceutical market by 2020. Almost one-third of China's medicines are from foreign companies or foreign-Sino joint ventures in China.

During China's preliminary negotiations to join the WTO, the Government made several serious commitments that will profoundly effect the pharmaceutical industry. These include: increased protection of intellectual property, lowered tariffs on pharmaceuticals, and eliminated restriction of the

import of expensive medical equipment, permitting the wholesaling of pharmaceuticals and opening up the health services sector. From January 1, 2003, foreign companies are expected to be allowed to engage in the wholesale and retail of drugs, including their storage, transportation and after sale services.

The Chinese law allows domestic firms to produce imitations of foreign drugs that are awaiting administrative protection from the central government agency, the State Drug Administration (SDA). Although a drug may hold a foreign patent, in China the drug waits in limbo until the SDA grants it protection. While the SDA reviews the application for a pharmaceutical patent, information is made available to domestic companies for peer review and to ensure that the product is not similar to drugs that are already being produced under protection. At this stage, domestic companies are able to manufacture

and sell copy-cat drugs without breaching current Chinese law on IP. **Eli Lilly & Co** of the US was recently unsuccessful in trying to stop the unlicensed manufacture of *Prozac* in China.

The full implications of China's accession to the WTO remain unclear, as negotiations are still underway. Nevertheless, it is clear that China is moving towards a Western style intellectual property and patent regime.

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ABOUT BDA

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