

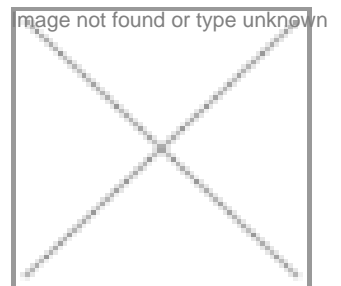
New look Nicholas

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With F Hoffman-La Roche deciding to end its 10-year frame cooperation agreement with Nicholas Piramal, how will it revive its biotech business?

F Hoffman-La Roche (FHLR), world's leading research-based healthcare company based in Switzerland, decided to end the frame cooperation agreement with Nicholas Piramal India Ltd (NPIL), a BioSpectrum Top 20 company, with effect from 3 November 2003 for six products. It has appointed Taksal Pharma Pvt Ltd, a New Delhi-based company as new importer and distributor of its products in India. As per the new equation, NPIL's distribution rights for Roche's strong biotech range of products—CellCept, Zenapax, Cymevene, Mabthera, Xeloda, and Herceptin—have ceased in November 2003. The same for Neupogen and Roferon will end in April 2004. This will follow suit with other Roche products like Vesanoïd, Fortovase, Hivid, and Recormon in future.



This would mean that NPIL would not have access to any new Roche products for distribution. But if any locally formulated product is to be launched by Roche after November 2003, it will be offered to NPIL subject to Roche's requirements of technical standards being met and if NPIL has no product which competes with the Roche's product offering. However pre-1993 Roche products licensed to or distributed through NPIL may continue to remain with NPIL for a long time. Now, Taksal Pharma will market all the above mentioned Roche products in India through.

It may be mentioned that in November 1993, FHLR entered an agreement with NPIL, after which some of the products of Roche were to be distributed in India by NPIL for a specified period of time and certain other brands were licensed to NPIL for manufacturing. In 1997 consequent to Roche acquiring Bohereinger Mannheim its products were also being distributed by

NPIL.

What is intriguing is why FHRL refused to continue its distribution rights with NPIL? Dr GL Telang, managing director, Roche Scientific Company (India) Pvt Ltd informed, "With the growing economic scenario, FHRL has decided to cease the agreement with NPIL. We are looking at focused distributors. NPIL is into diversified areas as against Taksal, which will handle only our products and provide cost-effective new therapies. "

Further intriguing is the fact as to what will NPIL do in the changed scenario. In 2002-03, out of the total revenues of Rs 1,140 crore, NPIL's biotech business was Rs 70.64 crore. Off Rs 70.64 crore, NPIL's business importing and distributing Roche biotech products was close to Rs 50 crore. So the ending of the agreement with FHRL, say industry observers, would result in decrease of NPIL's biotech revenues.

Responding to that Dr Swati Piramal, director, strategic communications, Nicholas Piramal India Ltd, quipped, "Yes you are right. We do lose the revenue. But we are planning to fill the gap introducing other biotech products. We are launching biotech products from an Italian company in December-January timeframe. We are also in discussions with other companies to partner with us to launch newer biotech drugs in India."

About the agreement with Roche, Dr Piramal said, "We know that it will end. The idea was to bring it to certain level and then hand it over to Roche on a platter when it starts its full operation. Now 2005 is near and Roche wants to come on its own. We have maintained very good relations. When we transferred all the things to Roche on 3 November not a single patient was affected. It was a beautiful transaction." She continued, "We not only started the agreement but also ended it properly. We stick to the agreement in letter and spirit. That is why most of the companies will look at Nicholas Piramal for tie-ups and joint ventures. The agreement with Roche has ended on 3 November for six products. We have a long-term agreement with Roche. For some products like diagnostic kits, we had an agreement in 1998, which will end in 2008. For some other products the agreement will end in 2018. So this makes no difference for us," said Dr Piramal.

Dr Swati Piramal definitely has the pulse for the Indian biotech market. She started marketing of biotech products in India as early as 1983 at a time when biotech products were available at Rs 10,000 per unit as against the usual drug of Rs 3 per unit. Substantiated Dr Piramal, "It is a wrong notion that we have distributed the biotech products. Instead, we have marketed the products skillfully. We trained our medical representatives to market biotech products. That doesn't go away."

True. To make up for the deficit, NPIL is getting aggressive. It has increased its research activity in biotechnology. It is focused on four key areas namely, new drug discovery, genomics, clinical and naturals research. It has nominated two scientists of international repute, Prof. Bob Chaudhari and Dr Ravinder Maini as its scientific advisors. NPIL has also made an initial investment of Rs 10 crore and is planning to pour in another Rs 65 crore in its R&D activities. Besides it is also looking at strategic R&D alliances in four specific areas namely vaccines, functional genomics, cancer research and arthritis.

Nicholas entered into strategic alliance with Biogen Idec, one of the largest biotech companies globally. NPIL's Biotech division will market Avonex (Interferon beta 1a) a leading life-saving therapy for multiple sclerosis in India and Nepal. Biogen Idec is a \$2.3 billion revenue.

To start with NPIL will tap 50 patients with multiple sclerosis out of 50,000 patients identified so far in India. During the initial months it is expected to earn about Rs 2.5 crore from Avonex, a Pre Filled Syringe (PFS), which is a proven treatment for effective management of relapsing multiple sclerosis. VP Kamath, senior vice president, NPIL informed BioSpectrum that, "NPIL would launch Avonex by first week of January in India instead of mid December. This is mainly because of technical problems." It also launched Curosurf, a lung surfactant for premature babies with Respiratory Distress Syndrome (RDS). It is a product of Chiese Farmaceutici, a European pharmaceutical company headquartered in Parma, Italy. The strategic tie up with Biogen Idec and Chiese Farmaceutici will bring in some biotech revenues to NPIL's coffers.

To move things rapidly, it has a joint venture with New Delhi-based Institute of Genomics and Integrative Biology, which is into functional genomics. It has also signed an agreement with the Center of Biotechnology (CBT) at Anna University in Chennai for exclusive R&D collaboration in the areas of cancer and inflammation. The agreement is designed to fast track the identification and development of plant extracts in the repository of CBT for the treatment of rheumatoid arthritis and cancer. As NPIL is still into research it may take time to come out with its own biotech products. Nonetheless, it is moving in the right direction.

Biofuel, a national agenda

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Six-point agenda to incubate biodiesel industry in India.

There is no denying that India's import bill of crude oil and petroleum products can be cut down by five percent. Further companies are seriously looking to set shop in this area. Most of them say that a proper policy framework will help speed up the biofuel industry.

1. Legislation to enforce and encourage biodiesel usage in India in a phased timeline and on locally available basis.

EU nations enabled the legislation as the first step in biodiesel initiative with a 20-year horizon. The US is also enacting a similar legislation next year and some states like Minnesota have already enacted legislation as the first step with time horizon for 10 years starting 2005 with an initial blend of 2.5 percent on a locally available basis.

Australia is enacting the legislation soon with a time horizon of 20 years starting 2005 with an initial blend of 5 percent.

Legislation with a time horizon will enable the industry to strategize and initiate the incubation process, as the time lag to incubate biodiesel industry will be a minimum of two-three years.

2. Classification of biodiesel industry as per central revenue act.

To classify biodiesel industry as in the west (EU and USA) in the category of "RENEWABLE ENERGY", "NON-ODS", "GHG REDUCTION" "POLLUTION SUBSTITUTION" refinery.) Biodiesel industry is technically classified to be in all these categories.

Classification will help the industry to enable the clearance of various formalities with state and central government agencies. This should be the second step in the list of priorities for the legislation. Clarity of classification will help financial institutions and lenders to also view this industry in the right perspective.

3. Sales tax and excise duty exemptions.

In view of the uncertainty in feedstock and market pricing and also the initial high cost of technology and feedstock, sales tax and excise exemptions are a must during the initial years (3-5 years) for the biodiesel industry to stabilize. EU, USA and Australia have already enacted legislation to facilitate the same.

4. Customs duty exemption under project imports for biodiesel technology.

Biodiesel technology is highly mature and is being operated in large industrial scale globally. Biodiesel technology is available for transfer into India and as there is no proven technology model in India, Indian industry should be allowed to import technology into India with out any customs duty.

5. Customs duty exemption on import of non-edible grade feed stocks.

To commission industrial scale biodiesel plants, non-edible grade feed stock is not yet available in India as the Jatropha plantations initiative by the government may take some time to incubate and for the said feed stock to become available in sizable scale to commission biodiesel plants. As there is a plenty of non-edible grade vegetable oils available in overseas markets at very reasonable prices, biodiesel industry should be allowed to import these non-edible feed stocks on "selective and temporary basis" until the Indian feed stock is made available. "This will help the biodiesel industry to commission industrial scale plants to be ready to absorb Jatropha oil as and when it is available from domestic sources" and will also help domestic biodiesel industry to give buy back agreements for Jatropha oil to local farming community.

6. Constitute a central biodiesel board of India to monitor and facilitate quality, growth, feed stock and technology.

Such a centrally constituted board with the participation of all channel partners of biodiesel industry will facilitate elimination of any unforeseen bottlenecks and unhealthy practices to promote this industry in India.

Biotech, a chirag for SMEs

The Indian scenario is ripe with possibilities for new biotech entrepreneur.

With an expected industry growth of over 20 percent in biotechnology, investors are looking at biotechnology as a new area of investment, particularly the Small and Medium Entrepreneurs (SMEs). But the thing is they don't know where to invest. What are the opportunities? How to get the funds?

"We are looking at expanding our business in the areas of biotechnology. So we are eager to know the latest technologies coming up in bio fertilizer, tissue culture and other areas of biotechnology, and the government support for making investment," said Edward Menezes, director, Rossari Biotech India Pvt Ltd.

Similarly Deva Drill Tech (I) Ltd, which is into specialty chemicals, is looking at diversifying its area of operations. AV Mohan Kumar, chairman and managing director, Deva Drill Tech said, "I feel people in the next 10 years will look at bioproducts rather than synthetics ones. The opportunities for bio products are enormous. Hence we are looking at tissue culture, industrial enzymes, and stem cell research as areas of our expansion."

India is ripe with possibilities for new biotechnology entrepreneur. Researchers are ready to forge links with other researchers and universities and especially with industry so as to meet its main goals of fundamental research together with technology that would make lasting impact on the health care scenario locally and globally. But the entrepreneurs should be focused said Prof. Jayesh Bellare, head, school of biosciences and bioengineering, IIT Powai. He suggested a seven-point agenda for the potential biotech entrepreneur. "Level of education, interest to take up challenges and willing to do wet lab work, patience, updating of knowledge, awareness about the regulatory affairs and willing to comply with them, a broad spectrum of life science activity and deep pockets."

Availability of technologies

Researchers and scientists at different institutes like IIT, Baba Atomic Research Center, Central Institute of Medicinal and Aromatic Plants (CIMAP), Central Institute of Brackish water Aquaculture (CIBA), The Energy and Resource Institute (TERI), CSIR labs, TIFR, IISc and many other centers-of-excellence are developing many technologies. Some technologies such as shrimp feed technology (CIBA), arbuscular mycorrhiza fungi (TERI), cultivation and processing of spirulina (ICAR), development of non-conventional products from banana, pheromone, biodegradable waste management, seromone (BARC), process for producing alcohol, and process of multiplication of bamboo plantlets (National Chemical Laboratory) are already available for transfer. Since the above institutes are not looking at profits the technology transfer will become easy for the companies.

Following the technology transfer is the financing. To take an early lead in this sunrise sector, many venture capitalists, ministry of Small Scale Industries, nationalized banks, financial institutions are coming forward to lend financial support to SMEs. Dr CP Thakur, union minister for Small Scale Industries, who believes that SMEs are the key for the economic growth of country said, "The ministry is discussing with the finance ministry about the availability of easy credit to biotech entrepreneurs at minimum interest. Grants for upgrading and improving the technology and implementation of credit guarantee scheme are also under consideration."

So there is no dearth. The speed program of ICICI ventures, Nmitli program of CSIR, NABARD, Cross Boarder Group, Rabo India and biotech funds by the state governments will provide the financial support for setting up the ventures in biotechnology. However the SMEs have to start the enterprise on their own with seed funding. Once the SMEs come out with products through novel ideas then the venture capitalists will come forward with back up support. The VCs follow certain funding format. This is the best way for the SMEs to build values feel some of the VCs.

Awareness

Vijay Kumar, deputy director, Small Industries Service Institute, Mumbai, which organized a two-day national convention on avenues in biotechnology for SMEs said, "Organizing conventions is only the beginning. The process will start with such programs. The symposiums will provide only the tips. Regular interaction will help setting up new enterprises."

"Anticipation and looking ahead is the key to success. And one has to think about innovative ideas. India needs more

intellectuals in the field of biotechnology. In the pre-budget submission, the ministry of SSI has asked more packages for SMEs who are looking at biotechnology as a new way to economic growth," informed Dr CP Thakur, union minister for Small Scale Industries. Expressing discontent about not participating in the human genome research, he said, it would have opened up more research opportunities if India participated in it.

"Biotech is the future of India. It is an integrated field. We have to work in close association with other fields. Lack of teamwork and execution is pulling the efforts made by an entrepreneur. The local firms have to stick to global standards in manufacturing process and supplying quality products," said CL Rathi, managing director, Advanced Biochemicals.

Considering the present trend in biotechnology Dr SPS Khanuja, director, Central Institute of Medicinal and Aromatic Plants, Lucknow, observed that in near future both agri and pharma biotechnology will merge with the growth of nutraceutical sector. This will provide wider scope for the entrepreneurs.

The unfurling opportunities, support from the government and industrial bodies in bringing in awareness about the latest technologies, readily available technologies, etc. have opened the doors for SMEs. "But an entrepreneur has to take initial risk to reap the profits," sums up Prof. Bellare.

Narayan Kulkarni