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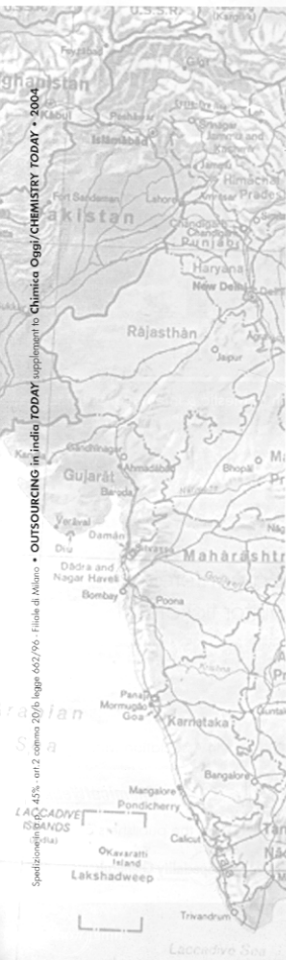
OUTSOURCING

in India

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INDIAN ISLANDS (India)
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Pharma Outsourcing - Destination India

India has become a key destination for outsourcing for countries such as the US as well as in European countries in the last few years. A dramatic growth in outsourcing to India is seen in all areas of technology, especially in the pharmaceuticals sector. The majority of leading pharmaceutical companies all over the world are focusing on India as an outsourcing destination with a view to bring down their costs. It is estimated that a pharma company in the US can save around 55% - 60% of its cost by outsourcing R & D and other related services to India. It is believed that India can offer outsourcing services to the global pharmaceutical industry, which is worth US \$48 billion.

The post-2005 scenario in India is likely to witness an exponential increase in outsourcing opportunities, as India becomes TRIPS compliant, with a product patent regime that may lead pharma companies to seriously consider the huge cost-benefits of outsourcing to India. International companies would also consider establishing their presence in India. India definitely has the twin advantages of lower costs as well as a compressed delivery timeline.

Outsourcing is not just about cost-savings. It is also very essential to find the right partners. India is fast emerging as the most competitive destination for outsourcing development services. Several international pharma companies are already on the lookout for acquisition targets in India, eager to utilize the famed Indian skill sets. In addition, the outsourcing of various functions and operations helps drug companies to reduce the burden of investment as well as avoids labor problems.

As per the report on clinical research by the Confederation of Indian Industry ("CII"), the market for contract research alone is estimated at around US \$9 billion. The trend is towards collaborations and partnerships. The market for the pre-clinical work and clinical research is estimated at around US \$13 billion. Proximare Inc, a business consultant for pharma, biotech and related companies, states that around US \$200-million worth of work is likely to be outsourced to India over the next 12 months in the field of biotechnology and pharmaceuticals.

Outsourcing activities for the pharma industry in India will include contract research, the creation of new pharmaceutical products, bio-informatics and clinical trials. India is well poised to become a specialized hub for outsourcing in the pharma industry.

It would be worthwhile to have a glimpse of the statistics. Between 1988 and 1997 the exports of Active Pharmaceutical Ingredients ("APIs") and formulations from India increased from INR (Indian Rupees) 2.30 billion to INR

41 billion and it is at INR 90 billion plus today. The pharma outsourcing business is growing annually at about 11% with a market potential of approximately US\$ 54 billion. Europe is emerging as the biggest outsourcing market as European companies are functioning under severe cost pressures. The biotechnology industry in India holds a US \$9 billion market potential by 2010 across various industry segments. The industry is expected to grow at 25%-30% per annum from the present level of US \$400 million, as mentioned by Biocon's Kiron Mazumdar Shaw.

The pharma industry the world over is at present looking towards India for the supply of quality ingredients, clinical development and processes for early drug development. India offers distinct advantages: skilled manpower, competitive salary levels, well-equipped training centers and institutions, a wealth of human resources, as well as conducive policies and incentives by the governments both at the Central and State levels. India also has strategic geographic locations and positive environmental and infrastructural factors.

India's strong human resource base includes a vast number of English-speaking graduates and one of the largest pools of highly skilled doctors and engineers in the world. Also the difference in the time zones facilitates 24-hour operations, a crucial factor in the outsourcing business. Another of India's important strengths is the significant number of plants approved by the US's Food & Drugs Authority ("FDA") and other regulatory authorities. This has led to a noticeable improvement in manufacturing standards, resulting in top quality products delivered on a timely basis. It is believed that if India can capture even 5% of the global contract manufacturing business, it would more than double India's exports in the pharmaceutical manufacturing business.

However, there are inherent challenges facing the pharma and biotech outsourcing business such as the lack of appropriate infrastructure, issues arising under the Intellectual Property Rights ("IPR") laws, product liabilities, ensuring exclusivity and the need for increased industry-academia partnerships. Other issues that require attention include but are not limited to: Exchange Control regulations; labour laws; contract terms and conditions; mechanisms for dispute resolution and the tax issues relating to withholding tax, transfer pricing, tax holidays/exemptions, etc.

It is imperative that India understands the opportunities, chooses the right partners, and skillfully manages relationships with them and closely monitors the progress and quality of the services. It is also very essential to define operating procedures and processes and deliverables, both

internally and with the service provider. It is vital that the processes are transferred efficiently. The various models that operate in the process of outsourcing, could be captive, joint venture, third party outsourcing, build-operate-transfer (though not practiced commonly) as well as mergers & acquisitions.

Various important issues

- Legal issues
- Contractual issues
- Issues related to Intellectual Property
- Labour issues
- Product Liability/Negligence
- Exchange Control issues
- Dispute Resolutions
- Tax issues relating to Withholding tax, Transfer Pricing, Tax Holiday/Exemptions etc.

Once a company completes the process of selecting a service provider, it is extremely critical for the parties to enter into a detailed Agreement, since a contract forms the core of a successful outsourcing relationship. The Agreement should be drafted meticulously, capturing the unique business strategies and concerns of the partnership, as well as the commercial understanding of the parties. The Agreement must document the nature of the outsourcing transaction, the type of business processes that are being outsourced, the scope of services to be rendered, responsibilities of the parties, performance specifications, accountability and measurement standards, a pricing structure for the services, a schedule of deliverables and other conditions concerning employment, confidentiality, termination, dispute resolution mechanisms, and governing law. The main agreement may also contain schedules or exhibits that specify some of the terms and conditions in detail. Incomplete documentation of the supplier's obligations can result in customer dissatisfaction. Inaccurate categorization of the service volumes and charges can result in disputes over payment as subsequent changes translate into additional costs for the customer or extra expenses for the service provider.

Also, in any outsourcing agreement, there could be several IP issues involved, such as the licensing or assignment of copyrights, trademarks and patents. The issues concerning IP would largely depend on whether the service provider or the customer licenses the IP, or whether it is developed by the service provider. Another issue, which may occur, may be related to the developed IP. The service provider while providing services to the customer may develop intellectual property. The Agreement should clearly state the ownership of such intellectual property. Such intellectual property would normally vest with the customer and an obligation is imposed on the service provider to assign such IP to the customer.

The Agreement would have to specify that the customer is not under any obligation to make any additional payments for the assignment of such intellectual property. Alternatively, the parties could be co-owners of the intellectual property and they could share the revenues received by licensing such IP to a third party. Contractual issues must be addressed to in the agreement. These issues may be related to Scope of Activities, Liabilities and Indemnities, Adherence to Specifications, Confidentiality, Damages and Termination. There must be inclusions of Warranties and Disclaimers and Governing Laws & Jurisdiction.

To understand and manage these issues it is essential to have an understanding of the international legal dimensions related to factors such as compliance with multi-country laws, common law vs. civil law, cross-border enforceability issues,

bankruptcy laws, cross-border corporate structures, international tax with regard to a branch, subsidiary or SPVs, licensing, transfer pricing, double taxation and intellectual property protection.

The conditions are ripe for India to make the quantum leap into becoming the top choice as a global pharma outsourcing destination. Deep understanding and interpretation coupled with skilful management of the issues, both with regard to the market or regulatory, could well be the keys to unlocking the huge opportunity that now offers itself to India to become the premier pharma outsourcing hub of the world.

Profile of Dr. Milind Antani

Dr. Milind Antani heads the Biotechnology, Pharmaceutical Industry practice group and member of Intellectual Practice Group at Nishith Desai Associates, a prominent International law firm focusing on Tax, Corporate & Technology. The Firm seeks to add value to the existing legal professional client by adopting a multi-skilled research based approach to practice. Besides lawyers, currently the firm consists of chartered accountants, management graduates, engineers and doctor.

He has had 14 years of active practice as an ENT surgeon at Gujarat. He has graduated from Baroda Medical College, MS University, Vadodra, Gujarat. He obtained his degree in Law (LLB) from Sardar Patel University, Vallabh Vidyanagar, Gujarat.

He has authored a research paper "Biotechnology - Legal and Ethical aspects", and presented this paper at Forum Of Free Enterprise meet at Goa. He has authored and presented paper on "Current and Future Patent Legislation and its implications on Pharmaceutical industry" at Pharma Summit 2004 organized by CII-Mumbai and "TRIPS & Its Implications on Indian Markets" at Bio Gujarat 2004 organized by CII Gujarat and Gujarat State Biotechnology Mission in September 2004. He has coauthored a paper on "Legal issues in the Biotech industry in India" which was presented at the 11th Annual "Biotech Investing Conference 2003" in California, USA. He has also coauthored a paper "Biotechnology - Trends and Opportunities in India". He has authored a comprehensive report on "Biotechnology, Legal & Ethical Issues." He has also co-authored a paper "Indian Pharmaceutical Industry - Business, Legal and Tax Issues". Also authored a research report on "Nanotechnology". Presently involved in research for the paper "Nanotechnology, Legal, tax, business and ethical issues". At present he is also involved in developing a practice on "Nanotechnology" at Nishith Desai Associates.

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Strategy for Portals", E.Biz, Mumbai (1999); "Legal Issues in E-Commerce", Economist (1999), FICCI, (1999), CII (1998) and IACC (1997); "Legal Issues for ISPs" Seminar organized by the ISPA (1999); "E-commerce: Legal Strategies for Business Conglomerates" Tata Management Centre, (1999); "Setting up Software Operations in India," The TIE, Santa Clara (1998).
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A brief background about Nishith Desai Associates' ("NDA"):

NDA is a research based, multi-skilled international law firm having offices in Mumbai, Bangalore and the Silicon Valley. NDA focuses on information technology law, Biotechnology and pharma law and Nanotechnology law and the legal and regulatory regime for pharmaceutical companies, international financial and tax laws, corporate and securities laws, media and entertainment laws and telecom laws. NDA has advised several foreign clients on setting up their Indian operations including AyurCore, Prudential, Exult, etc. as well as Indian clients such as Zydus Cadilla and the Dishman Group on their globalization strategies. It has structured and acted for a large number of private equity funds for India. It has acted as underwriter's counsel in Infosys Technologies

and Satyam Infoway's American Depositary Receipt (ADR) offerings in the USA. It also represented Wipro, Rediff.com and Silverline Technologies in their ADR listings. The firm has also worked on several first-time transactions including the first cross-border stock swap merger out of India - that is, BFL's acquisition of Mphasis, besides Silverline's recent acquisition of Seranova Inc in an ADR stock swap deal. The firm also has a dedicated pro-bono team, which represents several not-for-profit organizations including American India Foundation and Digital Partners.

NDA was awarded "Indian Law Firm of the Year 2000" and "Asian Law firm of the Year (Pro-bono)-2001" by the International Financial Law Review, a Euromoney Publication. NDA has also been ranked as having a leading practice in Private Equity, Media and Entertainment and IT and telecommunications law for 2001-02 by the Global Counsel 3000.

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