

Pharma and Life Sciences

STATEMENT OF CAPABILITY

2011

Nishith Desai Associates

Legal & Tax Counseling Worldwide

Mumbai • Silicon Valley • Bangalore • Singapore • Basel • New Delhi

Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Silicon Valley, Singapore and Basel. We specialize in strategic legal, regulatory and tax advice coupled with industry expertise in an integrated manner. We focus on niche areas in which we provide significant value and are invariably involved in select highly complex, innovative transactions. Our key clients include marquee repeat Fortune 500 clientele, of which over 60 per cent are US corporations.

Core practice areas include International Tax, International Tax Litigation, Litigation & Dispute Resolution, Fund Formation, Fund Investments, Capital Markets, Employment and HR, Intellectual Property, Corporate & Securities Law, Competition Law, Mergers & Acquisitions, JVs & Restructuring, General Commercial Law and Succession and Estate Planning. Our specialized industry niches include financial services, IT and telecom, education, Pharma and life sciences, media and entertainment, real estate and infrastructure.

Our Tax, Investment Funds and Technology-Media-Telecom (TMT) practices have been consistently ranked in tier 1 by Legal 500, while Chambers & Partners have ranked us # 1 for Tax, TMT and Real Estate - FDI. We've received honorable mentions in Asian - Counsel Magazine for Alternative Investment Funds, International Arbitration, Real Estate and Taxation for the year 2010. We have been adjudged the winner of the Indian Law Firm of the Year 2010 for TMT by IFLR. We have won the prestigious "Asian-Counsel's Social Responsible Deals of the Year 2009" by Pacific Business Press, in addition to being Asian-Counsel Firm of the Year 2009 for the practice areas of Private Equity and Taxation in India. Indian Business Law Journal listed our Tax, PE & VC and Technology-Media-Telecom (TMT) practices in the India Law Firm Awards 2009 as also Legal 500 (Asia-Pacific) that has ranked us #1 in these practices for 2009-2010. We have been ranked the highest for 'Quality' in the Financial Times – RSG Consulting ranking of Indian law firms in 2009. The Tax Directors Handbook, 2009 lauded us for our constant and innovative out-of-the-box ideas. Other past recognitions include being named the 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. In an Asia survey by International Tax Review (September 2003), we were voted as a top-ranking law firm and recognized for our cross-border structuring work.

Our research oriented approach has also led to the team members being recognized and felicitated for thought leadership. Consecutively for the fifth year in 2010, NDAites have won the global competition for dissertations at the International Bar Association. Nishith Desai, Founder of Nishith Desai Associates, has been voted 'External Counsel of the Year 2009' by Asian-Counsel and Pacific Business Press and the 'Most in Demand Practitioners' by Chambers Asia 2009. He has also been ranked No. 28 in a global Top 50 "Gold List" by Tax Business, a UK-based journal for the international tax community. Nishith Desai is listed in the Lex Witness 'Hall of fame: Top 50' individuals who have helped shape the legal landscape of modern India.

Our Pharma and Life Sciences Expertise

As one of the fastest growing sectors in India, the pharmaceutical and biotech industry is witnessing exponential growth. A key component of such growth is India's ability to provide lower cost research and development to multinational companies. India's rich talent pool of nearly 13.5 million science graduates, growing at the rate of 36% provides an ideal platform for global pharmaceutical companies to outsource drug development processes. Manufacturing costs that are 30-40% lower than those in the United States and Western Europe in addition to labor costs that are one-seventh of that in the United States make India an attractive destination for global multinational drug makers to outsource their business activities to India.

The 2005 Amendment to India's Patent Act significantly catalyzed drug discovery by allowing protection for products. The subsequent increase in the number of issued patents has in turn increased the number of patent litigations between multinational players and domestic generic drug makers. The industry has witnessed a shift in traditionally "generic" companies who are now seeking global recognition by investing in drug discovery rather than being recognized as "copycat" companies. India is in the midst of a never before seen number of mergers and acquisitions in the pharmaceutical space where domestic companies have intensified discovery research in order to strengthen product pipelines. In addition, the number of clinical trials taking place in India is expected to contribute to 5% of the number of global clinical trials by 2012.

Recent development in the regulations for Clinical trials in India would have more companies looking at more legal advice. Stemcell research and medical device sectors which are not regulated are likely to get regulated soon. This would significantly increase India activities for companies which would lead to increase in legal advice. The capability of NDA's Pharma and Life Sciences team to understand the scientific technicalities that are ingrained in pharmaceutical and life sciences and healthcare industry transactions position NDA as a leading multi-disciplinary law firm for the Life Sciences practice.

The Pharma and Life Sciences Practice at Nishith Desai Associates ("NDA") advises international and Indian companies on the legal, IP, regulatory, corporate laws and tax. The Pharma & Life Sciences Practice group includes an attorney with 14 years of practice as medical surgeon, an international commercial law expert, Indian Patent Agents, a United States Patent Attorney, chemical and biomedical engineers and IP attorneys. The ability of NDA's Pharma and Life Sciences team to understand the scientific technicalities that are ingrained in pharmaceutical and life sciences and healthcare industry transactions position NDA as a leading firm for the Life Sciences practice. The firm's multidisciplinary philosophy whereby each attorney is well-versed on each of the firm's practice groups creates a cutting edge advantage that provides comprehensive services to its clients.

Some of the accolades include:

- Ranked highest on 'Quality' in a recent Financial Times-RSG Consulting survey of Indian law firms.
- Listed in the Asian Legal Business Watch list of 'Top 10 Firms to Watch in 2009'
- Recognized by Chambers and Partners as the 'Most In-Demand Practitioners.'

Scope of Services

1. Strategy

We, at NDA, represent life science clients at every phase of their growth cycle, including formation, early stage financing, technology transfer, technology licensing, research and development, development of intellectual property portfolios, initial public offerings and follow-on securities offerings, the protection and litigation of intellectual property and the development and financing of manufacturing facilities as well as tax and IP structuring. The firm is well equipped to provide the legal and tax services associated with multinational clients setting up operations in India.

The firm represents life science and healthcare clients in a wide range of services including the drafting and negotiation of research and collaboration agreements, intellectual property protection and litigation and numerous public finance, Joint Venture, M&A, private equity and venture capital transactions.

2. Regulatory Issues

We advise our clients on various regulatory issues and compliances related to clinical trials, research and development, manufacturing activities, marketing & distribution, medical devices, stem cell research and collaborations in India. We also advise life sciences companies on regulations related to proposed activities in India in the form of joint ventures, partnerships and collaborations.

3. Documentation and Advisory Services

Our team advises clients in the structuring, drafting and negotiation of various contracts including contract manufacturing agreements, contract research, service agreements, marketing and distribution agreements, outsourcing agreements and IP assignment and license agreements. NDA services a number of life sciences companies conducting clinical trials in India in the drafting, structuring and negotiation of clinical trial, master service, non-disclosure, sponsored research, material transfer, and confidentiality disclosure agreements in addition to informed consent forms and other relevant documents apart from conducting due diligence of CRO..We also assist companies in employment related issues in addition to drafting, reviewing and negotiating term sheets, shareholder, share purchase, joint venture and other corporate agreements.

4. IP Advisory

Our team assists clients in the drafting, filing and prosecution of intellectual property applications. We routinely handle the drafting of complex patent specifications for a wide array of technologies in addition to filing domestic, PCT and National Phase patent applications and assisting in the filing of foreign patent applications and freedom to operate opinions. We assist clients in identifying their intellectual property in order to formulate comprehensive strategies to help clients protect and leverage such intellectual property. We also assist companies managing patent compliance, patent landscape study as well as trademark portfolio management with uniquely designed software. Our life science team also assists clients in conducting detailed IP audit of the portfolio of a company.

5. Patent Litigation

The Pharma and Life Sciences team at NDA offers clients an extensive litigation practice that focuses on the protection of patents and other intellectual property. The firm's intellectual property litigation team that includes a surgeon, chemical and biomedical engineers, Indian patent agents, a Pharmacist and a U.S. Patent Attorney is active in the space of Pre-Grant and Post-Grant patent application challenges in India. The firm's Pharma & Life Sciences team brings substantial expertise in fields such as pharmaceuticals, chemical technology, biotechnology, and medical devices.

6. Funds

Our funds team is well equipped with the expertise of structuring and positioning life sciences funds in India. We guide our clients in order to maximize investment decisions in addition to servicing them in all aspects of tax and legal issues that arise when delving into venture investments in India.

7. Investments

Our knowledge and expertise in the Pharma and Life Sciences space has been the main stimulus in the growth of our funds and private equity practice. We advise overseas private equity investors and venture capital funds on their investments in the life sciences sector.

8. Corporate Transactions

Our team provides advice and assistance in various corporate transactions which include investments, Mergers& Acquisitions, Joint Ventures and various collaborations related to the licensing for drug developments in the pharmaceutical, biotechnology and healthcare sectors.

9. Due Diligence:

Due diligence plays an important role in the service and representation of our clients. By specializing in the due diligence of pharma, life sciences and CRO entities, we are able to offer our clients extensive advice in the compliance of intellectual property and corporate regulation. Our expertise in the pharma and life sciences sector enables us to identify critical issues that a financial or strategic investor in life sciences companies should carefully understand and address.

10. Structuring:

Our team advises clients on structuring transactions in view of the tax, legal and regulatory regime in India. On the tax structuring side, we routinely advise and determine tax favorable jurisdictions for investment purposes, permanent establishment, and transfer pricing instruments. We also facilitate the establishment of business in India, including the incorporation of companies and logistical operations of setting up branches and liaison offices in India. We have and continue to advise several new life sciences clients on their India-related operational activities.

11. Litigation:

Our team assists and advises our clients regarding pre-litigation strategies with respect to the current IP and regulatory landscape in India. We represent our international and domestic clients in IP litigation and alternate dispute resolution. We have extensive experience representing clients at every level of the judicial system and virtually all disputes, from relatively simple matters to highly complex cases in product liability, patent infringement, antitrust and securities.

12. Training:

We conduct workshops for employees of pharma and life sciences companies on intellectual property laws and confidentiality issues as well as competition law.

13. Reports:

As a research-based law firm, NDA continues to author Life Science reports and NDA has contributed extensively on pharma and life sciences related issues in various publications both domestically in India and abroad. The firm is active in presenting and characterizing the current pharma, life sciences and IP landscape at national and international seminars.

Representative Clients

- Actelion
- Amgen
- Biogen Idec
- Biosensors
- BIO-VED
- Bristol-Myers Squibb
- Burrill & Company
- Concept Medicals
- Claris Lifesciences
- ClinStar, Codexis
- Gilead Sciences
- Glenmark Pharma
- GlaxoSmithKline
- InVentive Health
- Itero
- IMRI
- Merck & Co.
- Novartis
- Panacea Biotec
- Patheon
- Revogenex
- StemCyte
- TPNA
- Trubion
- VaxInnate
- United Health

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