

Investment in Healthcare Sector in India

June 2016

About NDA

Nishith Desai Associates (NDA) is a research based international law firm with offices in Mumbai, Bangalore, Palo Alto (Silicon Valley), Singapore, New Delhi, Munich and New York. We provide strategic legal, regulatory, and tax advice coupled with industry expertise in an integrated manner.

As a firm of specialists, we work with select clients in select verticals. We focus on niche areas in which we provide high expertise, strategic value and are invariably involved in select, very complex, innovative transactions.

We specialize in Globalization, International Tax, Fund Formation, Corporate & M&A, Private Equity & Venture Capital, Intellectual Property, International Litigation and Dispute Resolution; Employment and HR, Intellectual Property, International Commercial Law and Private Client. Our industry expertise spans Automotive, Funds, Financial Services, IT and Telecom, Pharma and Healthcare, Media and Entertainment, Real Estate, Infrastructure and Education. Our key clientele comprise marquee Fortune 500 corporations.

Equally passionate about philanthropy, social sector and start ups, our role includes innovation and strategic advice in futuristic areas of law such as those relating to Bitcoins (block chain), Internet of Things (IOT), Privatization of Outer Space, Drones, Robotics, Virtual Reality, Med-Tech and Medical Devices and Nanotechnology.

Nishith Desai Associates is ranked the 'Most Innovative Asia Pacific Law Firm in 2016' by the *Financial Times - RSG Consulting Group* in its prestigious **FT Innovative Lawyers Asia-Pacific 2016** Awards. With a highest-ever total score in these awards, the firm also won Asia Pacific's best 'Innovation in Finance Law', and topped the rankings for the 'Business of Law'. While this recognition marks NDA's ingress as an innovator among the globe's best law firms, NDA has previously won the award for 'Most Innovative Indian Law Firm' for two consecutive years in 2014 and 2015, in these elite *Financial Times* Innovation rankings.

Our firm has received much acclaim for its achievements and prowess, through the years. Some include:

IDEX Legal Awards: In 2015, Nishith Desai Associates won the "M&A Deal of the year", "Best Dispute Management lawyer", "Best Use of Innovation and Technology in a law firm" and "Best Dispute Management Firm". IDEX Legal recognized Nishith Desai as the Managing Partner of the Year in 2014.

Merger Market has recognized Nishith Desai Associates as the fastest growing M&A law firm in India for the year 2015.

World Tax 2015 (International Tax Review's Directory) recognized NDA as a Recommended Tax Firm in India

Legal 500 has ranked us in tier 1 for Investment Funds, Tax and Technology-Media-Telecom (TMT) practices (2011, 2012, 2013, 2014).

International Financial Law Review (a Euromoney publication) in its **IFLR1000** has placed Nishith Desai Associates in Tier 1 for Private Equity (2014). For three consecutive years, IFLR recognized us as the Indian "Firm of the Year" (2010-2013) for our Technology - Media - Telecom (TMT) practice

Chambers and Partners has ranked us # 1 for Tax and Technology-Media-Telecom (2015 & 2014); #1 in Employment Law (2015); # 1 in Tax, TMT and Private Equity (2013); and # 1 for Tax, TMT and Real Estate – FDI (2011).

India Business Law Journal (IBLJ) has awarded Nishith Desai Associates for Private Equity, Structured Finance & Securitization, TMT, and Taxation in 2015 & 2014; for Employment Law in 2015

Legal Era recognized Nishith Desai Associates as the Best Tax Law Firm of the Year (2013).

ASIAN-MENA COUNSEL named us In-house Community 'Firm of the Year' in India for Life Sciences Practice (2012); for International Arbitration (2011); for Private Equity and Taxation in India (2009). We have received honorable mentions in ASIAN-MENA COUNSEL Magazine for Alternative Investment Funds, Antitrust/Competition, Corporate and M&A, TMT, International Arbitration, Real Estate and Taxation and being Most Responsive Domestic Firm.

We have won the prestigious 'Asian-Counsel's Socially Responsible Deals of the Year 2009' by **Pacific Business Press**.

We believe strongly in constant knowledge expansion and have developed dynamic Knowledge Management ('KM') and Continuing Education ('CE') programs, conducted both in-house and for select invitees. KM and CE programs cover key events, global and national trends as they unfold and examine case studies, debate and analyze emerging legal, regulatory and tax issues, serving as an effective forum for cross pollination of ideas. Our trust-based, non-hierarchical, democratically managed organization that leverages research and knowledge to deliver premium services, high value, and a unique employer proposition has been developed into a global case study and published by John Wiley & Sons, USA in a feature titled 'Management by Trust in a Democratic Enterprise: A Law Firm Shapes Organizational Behavior to Create Competitive Advantage' in the September 2009 issue of Global Business and Organizational Excellence (GBOE).

Please see the last page of this paper for the most recent research papers by our experts.

Disclaimer

This report is a copyright of Nishith Desai Associates. No reader should act on the basis of any statement contained herein without seeking professional advice. The authors and the firm expressly disclaim all and any liability to any person who has read this report, or otherwise, in respect of anything, and of consequences of anything done, or omitted to be done by any such person in reliance upon the contents of this report.

Contact

For any help or assistance please email us on conciierge@nishithdesai.com or visit us at www.nishithdesai.com

Contents

1. GLOSSARY OF TERMS	01
2. INTRODUCTION	02
3. OPPORTUNITIES	03
I. Hospitals and Infrastructure	03
II. Technology driven services	04
III. Medical devices and equipment	04
IV. Diagnostics	05
V. Health Insurance	05
4. EMERGING TRENDS	06
I. Consolidation of hospitals – A fast emerging trend	06
II. Emerging Tier 2 and Tier 3 cities	06
III. Inclination of doctors towards debt funding	06
5. INVESTMENT IN HEALTHCARE SECTOR	07
I. Foreign Direct Investment	07
II. Foreign Venture Capital Investment	07
6. LEGAL AND REGULATORY ASPECTS	09
I. Authorities	09
II. Hospitals	09
III. Medical Devices	10
7. TAXATION IN INDIA	11
I. Corporate Tax	11
II. Dividends	11
III. Interest, Royalties & Fees for Technical Services	11
IV. Capital gains	11
V. Withholding taxes	12
VI. Patent Box Regime	12
VII. Double tax avoidance treaties	12
VIII. Anti-Avoidance	12
IX. Structuring investments	12
X. Indirect Taxes	13
XI. Benefits/Concessions	13
8. ISSUES AND CONCERNS	15
9. OTHER DEVELOPMENTS	16

10. CONCLUSION	17
ANNEXURE A Schematic representation of various business models	18
ANNEXURE B	20

1. Glossary of Terms

AERB	Atomic Energy Regulatory Board
AIF	Alternate Investment Funds
CAGR	Compound Annual Growth Rate
CDSCO	Central Drugs Standard Control Organization
Department of AYUSH	Department Of Ayurveda, Yoga And Naturopathy, Unani, Siddha And Homoeopathy
DDT	Dividend Distribution Tax
DIPP	Department of Industrial Policy and Promotion
Drugs Act	Drugs and Cosmetic Act, 1940
FDI	Foreign Direct Investment
FEMA	Foreign Exchange Management Act, 1999
FIPB	Foreign Investment Promotion Board
FVCI	Foreign Venture Capital Investor
GAAR	General Anti Avoidance Rule
ICDR Regulations	SEBI (Issue of Capital and Disclosure Requirements) Regulations, 2009
ICMR	Indian Council of Medical Research
IMA	Indian Medical Association
INR	Indian Rupees
IPO	Initial Public Offering
IRDA	Insurance Regulatory and Development Authority of India
IT	Information Technology
LLP	Limited Liability Partnership
MCI	Medical Council of India
MoHFW	Ministry of Health and Family Welfare
NBFC	Non-Banking Financial Company
NEHA	National e-Health Authority
NOC	No Objection Certificate
POEM	Place of Effective Management
QIB	Qualified Institutional Buyer
QIP	Qualified Institutional Placement
RBI	Reserve Bank of India
SEBI	Securities Exchange Board of India
STT	Securities Transaction Tax
Takeover Code	SEBI (Substantial Acquisition of Shares and Takeover) Regulations, 2011
USD	United States Dollars
VCF	Venture Capital Fund

2. Introduction

India, one of the biggest emerging markets, is currently an important destination for foreign direct investment (“FDI”). Despite India’s potential to become one of the most dominant economies in the world, its economic progress since gaining independence in 1947 has generally been masked by a perception of India being a closed, developing country. However, this perception has changed in the recent past and India is today accepted as one of the most stable and robust economies.

The healthcare sector as an industry is expanding rapidly in India and has not been as severely impacted by the economic slowdown as some of the other industries. It comprises of hospital services, diagnostic services, diagnostic products, medical devices, medical technology, e-Health service, clinical trial services, and clinical research organizations. This sector is predominantly privatized with almost 75 to 80 percent of hospitals being managed by the private sector.

This sector is expected to grow at a CAGR of 15 percent and will reach around USD 280 billion by 2020.¹ It is undergoing a metamorphosis by broadening the focus of its services using technology, deliverables, and newer applications. Hospitals that were confined to a specified area with limited infrastructure and services are now expanding, mainly due to the foreign investment being received by the sector.

There is a need for an additional 600,000 to 700,000 beds in India over the next five to six years.² This will lead to organic and inorganic expansion of existing hospitals in India. India has witnessed the emergence of various multi-specialty, single-specialty, and super-specialty hospitals in Tier 1 and Tier 2 cities. These hospitals are predominantly managed by corporates.

Foreign investors are playing a significant role in the development of the hospital and diagnostic sector. According to data released by the Department of Industrial Policy and Promotion (“DIPP”), hospitals and diagnostic centers attracted foreign direct investment of USD 3,133.81 million between April 2000 and June 2015.³

1. <http://www.ibef.org/industry/healthcare-india.aspx>

2. *Ibid*

3. http://dipp.nic.in/English/Publications/FDI_Statistics/2015/india_FDI_June2015.pdf

3. Opportunities

The Indian healthcare sector is ripe for expansion and significant growth.

I. Hospitals and Infrastructure

There is tremendous demand for tertiary care hospitals and specialty hospitals in India and there is a gap between the availability of beds and required beds. The Indian medical tourism industry is expected to reach USD 6 billion (around INR 36,000 crore) by 2018.⁴ Due to increasing medical tourism, there is a need to upgrade service standards and provide state-of-the-art facilities to bring service levels on par with global standards. This demand has created excellent opportunities for investors.

Most healthcare players have been setting up additional facilities to cater to critical care or super-specialty healthcare and some leading hospital players are aggressively raising funds for their expansion. India is also witnessing growth in the medical infrastructure sector, including advanced diagnostic equipment. Separately, there is also a need for institutions that train professionals, both nursing and paramedic, to overcome the shortage of trained professionals in the health care sector in India.

The healthcare sector in India, especially hospital services, is dominated by the private sector which comprises of individual doctors or group of doctors running clinics or private nursing homes, and various corporates or trusts running single-specialty/multi-specialty hospitals. Hospitals in India operate under various models. We have described them briefly below:

A. Trust and management services company model

This model is the prevalent model in India and this is how it works: A trust procures land from the government or local municipal body on a long lease and constructs a hospital on this land. The trust may then manage the hospital itself or, if it does not have the management capability, it may engage professional service providers to run and manage the hospital. Regarding profit sharing, several commercial models have evolved. The challenges in this model are the restrictions imposed in the lease by the government body, such as restrictions on expansion and requirements of rendering services to poor patients. Another challenge is employee management, as often the hospital will have trust employees as well as management company employees.

B. Corporate hospital model

Of late this model is becoming popular. A company buys land, then constructs, sets up and manages a hospital. This model requires more funding, on account of the land cost, and consequently, reputed and well established corporate houses would tend to use this model. In another allied model, the corporate house sets up a trust and the trust manages the hospital. The corporate house may also hire a management services company to run and manage the hospital. This model gives more comfort to investors when compared to trust models. Another recent trend is corporate hospitals partnering with successful doctors/specialists. The corporate house would acquire the doctor/specialist's practice, and consequently its patients. This also works very well from a branding perspective.

4. http://www.phdcci.in/index.php?route=information/news&news_id=68

C. Group of doctors' model

This model is fast emerging in Tier 2 and Tier 3 cities. Groups of successful doctors from different disciplines are joining hands to start large hospitals.

A partnership, LLP, or private limited company may be used by the doctors who come together. Though these doctors are comfortable with bank debt, they seem to be increasingly amenable to private equity investment as well. The challenge here is the relationship between company and doctors, especially key doctors who are shareholders of the company or partners. It is very important that these key doctors are bound by an agreement to continue serving the hospital.

Annexure A provides the schematic presentation of these models.

II. Technology driven services

A significantly low presence of doctors in rural and semi-urban areas has led to limited access to proper healthcare facilities for people living in these areas. Tele-medicine and e-Healthcare are considered to be some solutions to this lack of access. The growth of the IT sector in India (which plays a crucial role in tele-medicine) has led to the emergence of this sector in India. Tele-radiology has emerged very fast with an increasing number of foreign hospitals active in this space. These hospitals consult Indian experts to provide opinions, i.e., on x-rays of patients in the hospital. Many hospitals have adopted the public-private partnership route to render services through tele-medicine. Recently, the Ministry of Health and Family Welfare proposed to set up the National e-Health Authority (“NEHA”), which would be responsible for the development of an integrated health information system in India. This is a welcome step that would help develop tele-medicine in India.

III. Medical devices and equipment

Generally speaking, a medical device includes any instrument, apparatus, appliance, implant, material, or other article, whether used alone or in combination, including the software intended by its manufacturer, to be used specially for human beings or animals for one or more specific purposes. It also includes a device which is a reagent, calibrator, control material, kit, equipment, or system, whether used alone or in combination, intended to be used for examination and providing information for medical or diagnostic purposes. ‘Medical device’ has been defined in the Consolidated FDI Policy 2015 issued by the DIPP.⁵ Investment in the medical equipment manufacturing sector is one of the most attractive areas for investment. The medical equipment manufacturing industry

5. http://dipp.nic.in/English/Policies/FDI_Circular_2015.pdf
Medical device means:

- a. any instrument, apparatus, appliance, implant, material, or other article, whether used alone or in combination, including the software intended by its manufacturer, to be used specially for human beings or animals for one or more of the specific purposes of-
 - (aa) diagnosis, prevention, monitoring, treatment, or alleviation of any disease or disorder;
 - (ab) diagnosis, monitoring, treatment, alleviation of, or assistance for, any injury or handicap;
 - (ac) investigation, replacement, modification, or support of the anatomy or of a physiological process;
 - (ad) supporting or sustaining life;
 - (ae) disinfection of medical devices;
 - (af) control of conception, and which does not achieve its primary intended action in or on the human body or animals by any pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means;
- b. an accessory to such an instrument, apparatus, appliance, material, or other article;
- c. a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination thereof, intended to be used for examination and providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body or animals.

The definition of medical device above would be subject to the amendment in Drugs and Cosmetics Act.

is expected to grow in tandem with the hospital sector, which is expected to grow to USD 60 billion by 2016. The medical device sector has seen a significant flow of investments over the past few years and the government has allowed 100 percent FDI under the automatic route. We have discussed the Indian medical device sector in detail in a separate research paper available here.

http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Papers/The_Indian_Medical_Device_Industry.pdf

IV. Diagnostics

One also needs to pay attention to the segment of the diagnostic and pathology centers which have begun growing with rapid speed and are lucrative for FDI. These centers have expanded their service to include all kinds of diagnostic services including cardiology and neurology.

V. Health Insurance

The percentage of the Indian population that has been covered under health insurance is unfortunately very insignificant. The domestic health insurance business at INR 12,606 crore (USD 2.03 billion), accounts for about a quarter of the total non-life insurance business in the country.⁶ An increase in people opting for health insurance has been witnessed over a period of time. New products that also cover certain ailments not covered earlier are seeing more buyers of such insurance policies.

6. <http://www.ibef.org/industry/insurance-sector-india.aspx>

4. Emerging Trends

I. Consolidation of hospitals – A fast emerging trend

As per the Indian Brand Equity Foundation, the health-care industry size is expected to touch USD 160 billion by 2017 and USD 280 billion by 2020.⁷ The increase in life style related diseases and an expanding middle class have led to a growing demand for quality healthcare services over the years. Unfortunately, India's healthcare infrastructure has been unable to keep pace with the demand. The large gap in demand and supply of quality health care services and a growing capital demand owing to operational costs and technology acquisitions have pushed health care service providers to expand inorganically by merging with competitors or by accepting large capital injections.

II. Emerging Tier 2 and Tier 3 cities

Recent times have witnessed tremendous growth in secondary and tertiary care hospitals in Tier 2 and Tier 3 cities. The reasons for this trend are manifold. The per-capita income of residents of Tier 2 and Tier 3 cities has increased significantly in the last decade, resulting in a significant increase in their capacity to pay for healthcare. Another possible reason could be that the markets in Tier 1 cities have reached saturation because of an increase in competition, causing the serious players to explore opportunities outside the Tier 1 cities. The additional attraction of Tier 2 and Tier 3 cities is the availability of land, labour, electricity, etc. at low cost. Yet another major factor that is playing a role is the willingness of doctors who have been practicing for a long time and enjoying goodwill, to join hands to start big hospitals.

7. See more at: <http://www.ibef.org/industry/healthcare-india.aspx#sthash.XtwkL5ur.dpuf>

III. Inclination of doctors towards debt funding

Debt finance is a major source of capital for the health-care service industry. The borrower must offer primary security and a collateral security before securing a loan. Primary security is usually provided in the form of a charge over the asset against which the loan is taken and collateral security is usually given in form of a personal guarantee. The requirement to offer collateral in the form of a personal guarantee is the biggest consideration for promoters of small and medium scale hospitals while accepting debt which, many a times, hinders expansion. Recently, Non-Banking Financial Companies ("NBFCs") have emerged as preferred sources of debt-funding since they usually do not insist on collateral security.

Many new healthcare services are emerging quickly and are looking for funding. **Annexure B** sets out some of these healthcare services.

5. Investment in Healthcare Sector

I. Foreign Direct Investment

The economic reforms launched by the Government of India since 1991 have resulted in substantial economic growth and the integration of India into the global economy. The pace of reforms has gained momentum due to political stability and strong industrial growth.

Foreign investment into India is governed by the Foreign Exchange Management Act, 1999 (“FEMA”), the rules and regulations made by the Reserve Bank of India (“RBI”), and the Industrial Policy and Procedures issued by the Ministry of Commerce and Industry through the Secretariat for Industrial Assistance, DIPP.

The provisions pertaining to FDI are laid down in Schedule I of FEMA (Transfer or Issue of Security by a Person Resident outside India) Regulations, 2000.

While the DIPP issues policy guidelines and press notes/releases from time to time regarding foreign investment into India, it also issues a consolidated policy on an annual basis (“Consolidated FDI Policy”). Currently, foreign investment is regulated by the Consolidated FDI Policy of 2015.⁸

100 percent FDI is permitted in most sectors under the automatic route, i.e., where prior approval of the Foreign Investment Promotion Board (“FIPB”) is not required. Currently, FDI is permitted up to 100 percent under the automatic route in the hospital sector and in the manufacture of medical devices.⁹ In the pharmaceutical sector, FDI is permitted upto 100% in Greenfield projects and 74% in Brownfield projects under the automatic route and FDI beyond 74% in

Brownfield projects requires FIPB approval.¹⁰ Green field projects are new projects that are coming up in India while Brownfield projects are existing projects in India.

The cap on FDI in the insurance sector has been increased from 26 percent to 49 percent (under the Automatic Route subject to approval/verification by the Insurance Regulatory and Development Authority of India (“IRDA”)) with the directive that the ownership of the insurance company be retained in Indian hands. This should lead to a growth in the insurance sector.

II. Foreign Venture Capital Investment

Another vital means of investment into the healthcare, as well as medical and surgical appliances sectors is through venture capital investment by entities registered with the Securities Exchange Board of India (“SEBI”) as foreign venture capital investors. While it is not mandatory for a private equity investor to register as a Foreign Venture Capital Investor (“FVCI”) under the FVCI regulations¹¹, there are some significant advantages to be gained by registering as an FVCI. An FVCI is exempt from compliance with the pricing guidelines under the Consolidated FDI Policy for the acquisition of securities at the time of entry as well as for the transfer/sale of securities at the time of exit. Secondly, in cases where the promoters of the company intend to buy-back the securities from an FVCI, they are exempted from making an open offer under the Takeover Code.¹² It should be noted that SEBI has been granting approvals to FVCIs only for investments in certain identified sectors, amongst them being research and development of new chemical entities in the pharmaceutical sector, and units

8. Consolidated FDI Policy, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy & Promotion, SIA (FC Division), available at http://dipp.nic.in/English/Policies/FDI_Circular_2015.pdf

9. http://dipp.nic.in/English/acts_rules/Press_Notes/pn2_2015.pdf

10. http://dipp.nic.in/English/acts_rules/Press_Notes/pn5_2016.pdf

11. SEBI (Foreign Venture Capital Investor) Regulations, 2000.

12. Reg. 10, Securities Exchange Board of India (Substantial Acquisition of Shares and Takeovers) Regulations, 2011.

of SEBI registered Venture Capital Funds (“VCFs”). Further, the Reserve Bank of India (“RBI”) has made recent amendments to the foreign exchange control regulations to permit FVCIs to invest in SEBI registered Alternate Investment Funds (“AIFs”).¹³

Some of the benefits available to FVCIs are:

A. Free pricing

Registered FVCIs benefit from free entry and exit pricing and are not bound by the pricing restrictions applicable to the FDI investment route.

The exemption from pricing guidelines is a very significant benefit from a FVCIs’ point of view, especially with respect to exits from unlisted companies through strategic sales or through buy-back arrangements with the promoters and the company.

B. Exemption under the Takeover Code

SEBI has also exempted promoters of a listed company from the public offer provisions in connection with any transfer of shares of a listed company, from FVCIs to the promoters, under the Takeover Code.

C. Status of QIB in IPOs

FVCIs registered with SEBI have been accorded Qualified Institutional Buyer (“QIB”) status and are eligible to subscribe to securities in the IPO through the book-building route.

D. QIP route

FVCIs (as well as VCFs and AIFs) by virtue of being QIBs, are eligible to subscribe to the securities of Indian listed companies under the Qualified Institutional Placement (“QIP”) route as prescribed under the SEBI (Issue of Capital and Disclosure Requirements) Regulations, 2009 (“ICDR Regulations”). Under this route, there is no lock-in on the securities allotted (as long as they are traded on the stock exchange).

E. Lock In

Under the ICDR Regulations, the entire pre-issue share capital (other than certain promoter contributions which are locked in for a longer period) of a company conducting an IPO is locked for a period of one-year from the date of allotment in the public issue. However, an exemption from this requirement has been granted to VCFs and FVCIs, provided the shares have been held by them for a period of at least one year as of the date of filing the draft prospectus with the SEBI. This exemption permits the FVCI to exit from its investments, post-listing.

13. SEBI introduced SEBI (Alternate Investment Funds) Regulations, 2012 to govern domestic pooling vehicles. RBI has issued Notification no. FEMA. 355/2015 that permits AIFs and other investment vehicles to accept foreign investments under the automatic route.

6. Legal and Regulatory aspects

The healthcare sector in India is highly regulated. It is governed by a host of laws that govern the establishment of hospitals, services offered, medical professionals, as well as additional services offered by the hospital such as cafeteria, pharmacy, ambulance, etc.

I. Authorities

The following authorities regulate healthcare sector in India:

Ministry of Health and Family Welfare (“MoHFW”):

- Department of Health
- Department of Family & Welfare
- Department of AYUSH
- Central Drugs Standard Control Organization (“CDSCO”)
- Narcotic Controls Bureau

State level and Local Authorities:

- Pollution control boards
- Biomedical waste Disposal
- CDSCO (State)
- Municipal Corporation
- Municipality

Other Institutions/Organizations:

- Indian Council of Medical Research (“ICMR”)
- Medical Council of India (“MCI”)
- Indian Medical Association (“IMA”)

- Atomic Energy Regulatory Board (“AERB”)
- Department of Industrial Policy and Promotion
- Foreign Investment Promotion Board

II. Hospitals

As a part of the due diligence of a hospital, the investor should typically ensure that the investee entity has complied with all applicable laws. There are multiple laws that govern the sub-sets of the healthcare sector, and there are a multitude of permissions and licenses that are required to be obtained. Such permissions and licenses include:

- Municipal permission for construction;
- Consent from State Pollution Control Board to establish and operate facility under the Water (Prevention and Control of Pollution) Act, 1974 and Air (Prevention and Control of Pollution) Act, 1981;
- Fire safety Approvals;
- Municipal Trade license (State Specific);
- Registration under shops and establishment legislation specific to the State;
- Registration of facility with State Government / Authority as a private medical establishment (State Specific);
- Registration under the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and corresponding registration of ultrasound machine with appropriate authority under the Act;
- Compliance with Medical Termination of Pregnancy Act, 1971;
- Authorization for operation of a facility for generation, collection, reception, storage, transportation, treatment, and disposal of bio-medical wastes under Bio-Medical Waste (Management and Han-

dling) Rules, 1998 of the Environmental Protection Act 1986 from the Pollution Control Board and corresponding compliances;

- License to store compressed gas in pressure vessels;
- Approval from State Food and Drug Administration to obtain and possess certain category of drugs for use on patients;
- License to operate X-Ray, CT Scan as well as Cathlab from AERB;
- License to operate a blood bank from State Food and Drug Administration for procession of whole human Blood for preparation for sale or distribution of its components;
- Narcotic drug license;
- Permit for the purchase and possession of denatured spirit;
- Registration under various applicable Labour Laws; and
- Registration under various direct and indirect Tax statutes.

registration and import of medical devices in India on February 21, 2013. These notifications and guidelines are available on the CDSCO official website.¹⁶

The CDSCO has clarified, through an office memorandum dated January 8, 2013, that the import of medical devices, which are not Regulated Devices, will not require prior NOC from it. Therefore, devices that are not Regulated Devices are not regulated in any manner.

The issuance of the Notifications to identify Regulated Devices as “drugs” was the first step towards regulating medical devices in India. However, larger issues still remain to be addressed, such as rules relating to product standards, safety, clinical trials, and manufacturing practices for each of the Regulated Devices.

The Ministry of Health and Family Welfare has now approved certain procedures to be adopted with respect to licensing of import, as well as the manufacturing of Regulated Devices in the country. For manufacturing and/or assembling medical and surgical appliances, the standards are prescribed under the Drugs Act, and the manufacturer/assembler should primarily obtain a license under this law. The standards prescribed under the Bureau of Indian Standards must also be adhered to.¹⁷

III. Medical Devices

The medical device industry was not regulated in India, which led to the import and manufacturing of devices which did not meet globally acceptable standards. The Central Government of India issued notifications in the years 2005 and 2010 (“**Notifications**”), to regulate the manufacture, sale, and distribution of certain sterile medical devices (“**Regulated Devices**”),¹⁴ as “drugs”, as per the Drugs and Cosmetic Act, 1940 (“**Drugs Act**”).¹⁵ In March 2006, the government issued guidelines for the import and manufacture of medical devices. These guidelines have been further supplemented by revised guidelines on the manufacturing of medical devices in India dated January 1, 2013 and a document containing frequently asked questions on

14. A list of these devices is available on the website www.cdscn.co.nic.in

15. The Drugs Act is the relevant legislation that regulates the manufacture, sale, distribution and import of pharmaceutical products in India.

16. www.cdscn.co.nic.in

17. Rule 109-A and 125 A, Drugs and Cosmetics Rules, 1945.

7. Taxation in India

I. Corporate Tax

Income tax in India is levied under the Income Tax Act, 1961. While residents are taxed on their worldwide income, non-residents are only taxed on income arising from sources in India. A company is said to be resident in India if it is incorporated in India or its place of effective management (“PoEM”) is situated in India. PoEM has been defined to be a place where key management and commercial decisions that are necessary for the conduct of business of an entity as a whole are, in substance made.

Resident companies are taxed at the rate of 30%,¹⁸ while non-resident companies are taxed at the rate of 40%. A minimum alternate tax is also payable, by resident and, in certain circumstances, non-resident companies, at the rate of around 18.5%.¹⁹

The Finance Minister in his budget speech in 2015 had proposed to reduce the headline domestic corporate tax rate from 30% to 25% over the next four years, coupled with the rationalization and removal of various exemptions and rebates. The Finance Act, 2016 has initiated this gradual reduction in the corporate tax rate. Manufacturing entities set up on or after March 1, 2016, may opt to be taxed at a lower rate of 25% subject to certain conditions. Furthermore, the headline domestic corporate tax rate has been lowered to 29% for those domestic companies whose turnover in the financial year 2014-15 did not exceed INR5 crores (approx. USD 800k).

II. Dividends

Dividends distributed by Indian companies are subject to a dividend distribution tax (“DDT”) at the rate of 15% on a grossed up basis, payable by the com-

pany. Further, an additional dividend tax (“ADT”) at the rate of 10% is payable on dividends received by a resident individual or firm, where the amount of dividend received exceeds INR 1 million. However, no further Indian taxes should be payable by shareholders not being individuals or firms, on such dividend income once DDT is paid. An Indian company would also be taxed at the rate of 20%, on a grossed up basis, on gains arising to shareholders from distributions made in the course of a buy-back or redemption of unlisted shares.

III. Interest, Royalties & Fees for Technical Services

Interest earned by a non-resident may be taxed at rates ranging between 5% to around 40%, depending on the nature of the debt instrument and the nature of the investor.

The withholding tax on royalties and fees for technical services earned by a non-resident is 10%. These rates are subject to available relief under an applicable tax treaty. The scope of royalties and fees for technical services under Indian domestic law is much wider than what is contemplated under most tax treaties signed by India.

IV. Capital gains

Tax on capital gains depends on the period of holding of a capital asset. Short term gains may arise if the asset is held for a period of less than 36 months (12 months in the case of listed securities and 24 months in the case of shares of an unlisted company). Long term gains may arise if the asset is held for a period of 36 months or more (12 months in the case of listed securities and 24 months in the case of shares of an unlisted company). Long term capital gains earned by a non-resident on sale of unlisted securities are

18. Unless otherwise specified, all tax rates are applicable to Assessment Year 2017-2018 and are exclusive of surcharge and education cess.

19. _____

taxable at the rate of 10%. Long term gains on the sale of listed shares on a stock exchange are exempt and only subject to a securities transaction tax (“STT”). Short term capital gains earned by a non-resident on (i) the sale of listed shares (subject to STT) are taxable at the rate of 15%, or (ii) the sale of any other type of security or capital asset are taxable at the ordinary corporate tax rate (30% for residents, and 40% for non-resident).

India has also recently introduced a rule to tax non-residents on the transfer of securities of a foreign company where the foreign company derives substantial value (directly or indirectly) from assets situated in India.

V. Withholding taxes

Tax would have to be withheld at the applicable rate on all payments made to a non-resident, which are taxable in India. The obligation to withhold tax applies to both residents and non-residents. Withholding tax obligations also arise with respect to specific payments made to residents. Failure to withhold tax could result in tax, interest and penal consequences.

VI. Patent Box Regime

The Finance Act, 2016, to boost indigenous research and development in *inter alia* the pharmaceutical industry, has proposed to introduce a new patent box regime under which worldwide income received by way of royalty in respect of a patent developed²⁰ and registered in India should be subject to tax on a gross basis at a concessional rate of 10%. There is a clear requirement that the patent must be ‘registered’ in India in order for the royalty to be eligible to a concessional tax rate and resident inventors who have filed for patents in offshore jurisdictions rather than under the Patents Act will not be eligible for this proposed benefit.

20. “Developed” has been defined to mean “the expenditure incurred by the assessee for any invention in respect of which patent is granted under the Patents Act”)

VII. Double tax avoidance treaties

India has entered into more than 80 treaties for avoidance of double taxation. A taxpayer may be taxed either under domestic law provisions or the tax treaty to the extent that it is more beneficial. A non-resident claiming treaty relief would be required to file tax returns and furnish a tax residency certificate issued by the tax authority in its home country. The tax treaties also provide avenues for exchange of information between States and incorporate measures to curb fiscal evasion.

VIII. Anti-Avoidance

A number of specific anti-avoidance rules apply to particular scenarios or arrangements. This includes elaborate transfer pricing regulations which tax related party transactions on an arm’s length basis.

India has also introduced wide general anti avoidance rules (“GAAR”) which provide broad powers to the tax authorities to deny tax benefits on the basis of ‘impermissible avoidance arrangements’. GAAR is set to come into effect from April 1, 2018 and would override tax treaties signed by India.

IX. Structuring investments

Foreign enterprises could make investments into the Indian companies through an intermediate holding company set up in a tax friendly jurisdiction. India has a wide treaty network and the judicious use of an appropriate offshore jurisdiction could result in benefits for the foreign company, such as a reduced or nil-rate of

tax on capital gains income, reduction in withholding tax rates, etc. The choice of an offshore entity would depend on the benefits available under the treaty between India and the offshore jurisdiction and the domestic tax laws of that jurisdiction. Additional concerns include economic stability, investment protection, corporate and legal system, availability of high quality administrative and legal support, banking facilities, reputation and costs, etc.

Over the years, a major bulk of investments into India has been structured from countries such as Mauritius, Singapore, and Netherlands, which have been chosen for their favorable tax treaties with India. Till recently and subject to certain conditions, under the tax treaties with India, investments from Mauritius and Singapore benefited from an exemption from capital gains tax in India. However, following the conclusion of a Protocol between Indian and Mauritius amending the India-Mauritius tax treaty, this exemption will no longer be available with effect from April 1, 2017. Under the terms of the amended treaty, India shall have the right to tax capital gains arising to a Mauritian resident from the sale of shares of an Indian company acquired on or after April 1, 2017. However, gains arising from the sale of shares of an Indian company purchased before April 1, 2017 should continue to be exempt from capital gains tax in India.

Due to the relationship between the India-Mauritius tax treaty and the India-Singapore tax treaty, the erstwhile exemption available to a resident of Singapore from Indian capital gains tax arising on the sale of shares of an Indian company shall also fall away on March 31, 2017. However, media reports suggest that the Indian government has reached out to the Singapore government to renegotiate the India-Singapore tax treaty along the lines of the amended India-Mauritius tax treaty.

The changes brought about by the Protocol also make debt structures based out of Mauritius lucrative, since interest income earned by a Mauritius resident from Indian debt holdings should be subject to a reduced withholding tax rate of 7.5%. Debt investments made from the Netherlands may also benefit from a lower

10% withholding tax on interest payment, as well as a limited capital gains tax exemption. Further, Netherlands, being an EU nation, is entitled to the beneficial treatment permitted between EU nations.

X. Indirect Taxes

A number of indirect or consumption taxes are levied at the central and state level. Value Added Tax (VAT) is levied on the sale of goods within a particular State and rates may vary anywhere from 0%-1% to 4%-12.5%. Central Sales Tax (CST) is imposed on the sale of goods in the course of inter-State trade or commerce. Central VAT is a duty of excise which is levied on all goods that are produced or manufactured in India. Further, service tax is payable on all services other than those specifically exempted or set out in a negative list. The current rate of service tax is 14%²¹ payable by the service provider. The government has also introduced a new Goods and Service Tax (GST) which will consolidate all indirect taxes. Currently, it is uncertain whether the Government will be able to push the GST regime from April 1, 2016.

XI. Benefits/Concessions

Capital expenditure incurred in setting up a hospital with capacity of 100 beds or more is fully deductible. A five year tax holiday was available in respect of profits derived operation and maintaining hospital located anywhere in India other than certain excluded areas (mainly larger / metropolitan cities) subject to the satisfaction of conditions including capacity of 100 beds and above. This tax holiday however only applies to hospitals constructed before March 31, 2013. Subject to certain conditions, tax exemptions are available for hospitals that are charitable and not-for-profit.

An exemption from service tax has been provided with respect to health care services by a clinical establishments (including hospitals, nursing homes, clinics, etc.), authorized medical practitioners or

21. Additional cess of 1% is also applicable, making the effective service tax rate 15%.

paramedics. An exemption from service tax has been provided with respect to health care services by a clinical establishments (including hospitals, authorized medical practitioners, para medics, nursing homes, clinics, etc.), authorized medical practitioners, or paramedics. This exemption is also extended to services in relation to ambulance services provided to transport patients to and from a clinical establishment,²² and to life insurance provided by way of Varishtha Pension Bima Yojna.²³

Recently, exemptions have also been granted from basic customs duty of 5%, countervailing duties (CVD) on an artificial heart (left ventricular assist device),²⁴ and life-saving drugs and medicines imported by an individual for personal use.²⁵ Further exemptions from CVD and special additional duty (SAD) have also been granted on specified raw materials used in the manufacture of pacemakers, subject to certain conditions.²⁶

The Ministry of Finance has also introduced a reduction in basic customs duty from 5% to 2.5% on specified inputs for use in the manufacturing of flexible medical video endoscopes²⁷ and a reduction in basic excise duty from 24% to 12.5% on chassis for ambulances.²⁸

In an effort to increase health insurance coverage to a greater part of the population, the government has introduced deduction of up to INR 30,000 incurred as medical expenditure for an individual or his family, on health insurance premiums paid by individuals or by individuals on behalf of their families.²⁹ Similar deductions have been put in place for senior citizens. Individuals are also allowed to deduct INR 50,000 for expenditures, in respect to maintenance and medical treatment of persons with disability (INR 100,000 in the case of persons with severe disabilities).³⁰

22. Notification No.6/2015-Service Tax, dated 1st March 2015

23. Id.

24. Notification No.10/2015- Customs, dated 1st March 2015

25. Notification No. 12/2012- Customs, dated 17th March 2012

26. Supra note 9

27. Supra note 9

28. Notification No.12/2015-Central Excise, dated 1st March 2015

29. Section 80D of ITA

30. Section 80DD of ITA

8. Issues and Concerns

Investments in hospitals carry a host of potential issues which an investor needs to be aware of and concerned with. As mentioned earlier, the hospital sector is a highly regulated sector in India and hence conducting proper due diligence for regulatory approvals and licenses is very crucial.

The major issues that can seriously impact functionality of the hospital arise from non-compliance with the Pre-conception and Pre-natal Diagnostic Techniques Act, 2003, Medical Termination of Pregnancy Act, 1971, Biomedical Waste Disposal, Drugs and Cosmetic Acts for pharmacy, and Atomic Energy Regulatory Board as well as other environmental consents.

Participation of the hospital in clinical trials poses another challenge in view of recent changes in the law regarding compensation to human subjects in clinical trials. It is very important to understand the liabilities of the investigator and the hospital.

Another factor that poses issues and concerns is the operating model of the hospital. Models where hospitals are owned by trusts and managed by hospital management companies may lead to certain concerns from an investment perspective.

9. Other developments

The Central Government has enacted the Clinical Establishments (Registration and Regulation) Act, 2010³¹ to provide for registration and regulation of all clinical establishments in the country. The act prescribes the minimum standards for facilities and services provided by them. The Act has taken effect in four States namely; Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all Union Territories

since 1st March, 2012. Though this is a welcome step for increasing the standard of healthcare in the country, on the downside, it may act as another additional hurdle from the perspective of an investor intending to set up clinical establishment as the compliances required under this law are quite onerous.

31. Available at <http://clinicalestablishments.nic.in/WriteReadData/969.pdf>

10. Conclusion

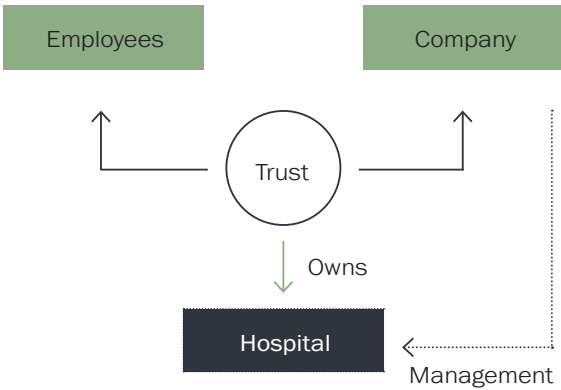
There are many positive implications of foreign investment in hospitals and other healthcare services especially medical device, diagnostics, and e-Health. One major impact foreign investment would have is the creation of the necessary infrastructure. Investments are also needed beyond the metropolitan areas to expand access to healthcare. In addition to helping increase physical capacity in the healthcare sector (such as increasing the number of hospital beds, diagnostic facilities, and increasing the supply of specialty and super-specialty centers), foreign investment can also help in raising the standards and quality of healthcare, in upgrading technology, and in creating employment opportunities, with potential benefits to the health sector and the economy at large. However, the cost of medical care should be affordable most importantly in the Tier 2 and Tier 3 locations.

There is a significant potential for growth in Tier 2 and Tier 3 locations. Even though these Tier 2 and Tier 3 towns have a considerable number of primary healthcare centers, they lack quality healthcare services. While Tier 2 and Tier 3 locations have lower populations when compared to a metropolitan area, they can serve as quality healthcare units to the nearby smaller villages and towns. Consequently, there is significant activity in these locations by both national players as well as regional hospitals who are either setting up hospitals or even tying up with an existing hospitals in these locations. However, a careful analysis and evaluation is required in order to gain considerable returns from these Tier 2 and Tier 3 locations.

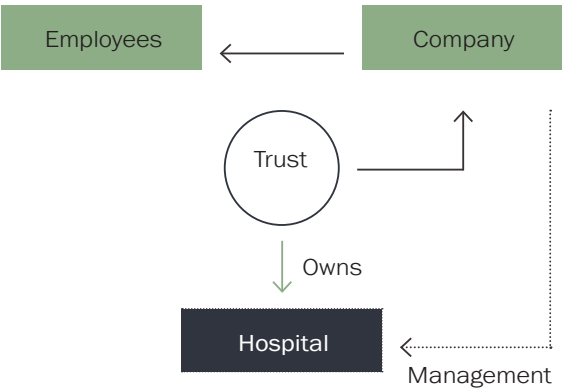
Annexure A

Schematic representation of various business models

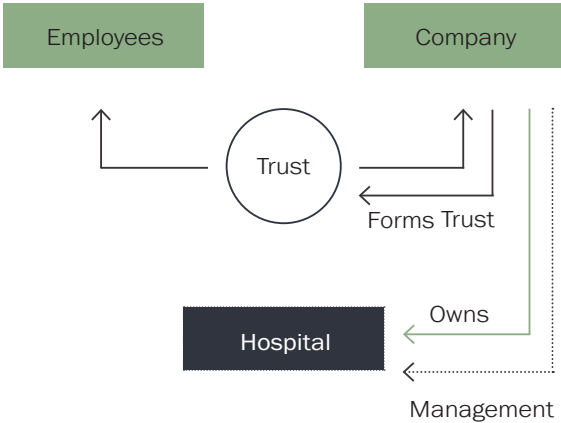
Model: 1



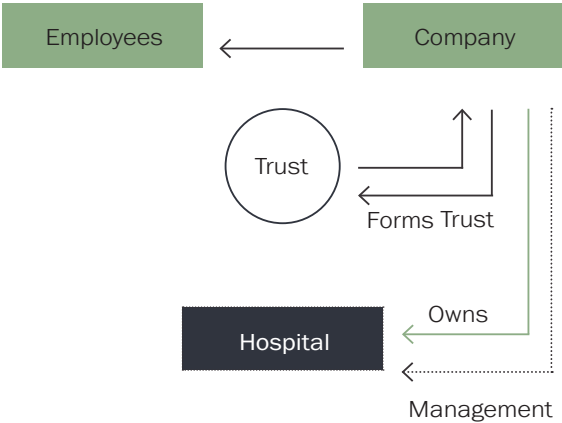
Model: 1a



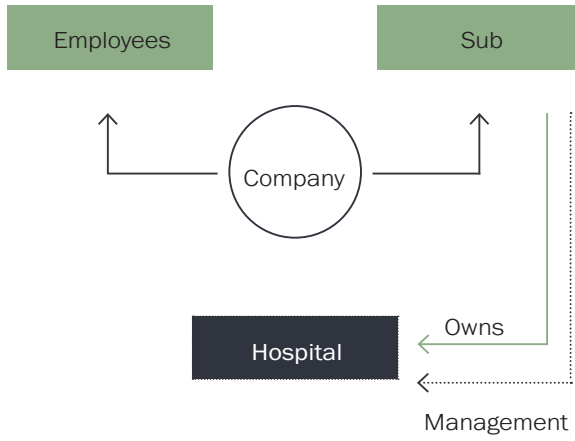
Model: 2



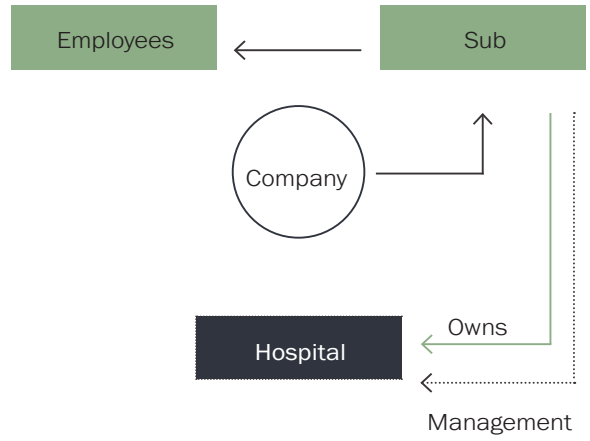
Model: 2a



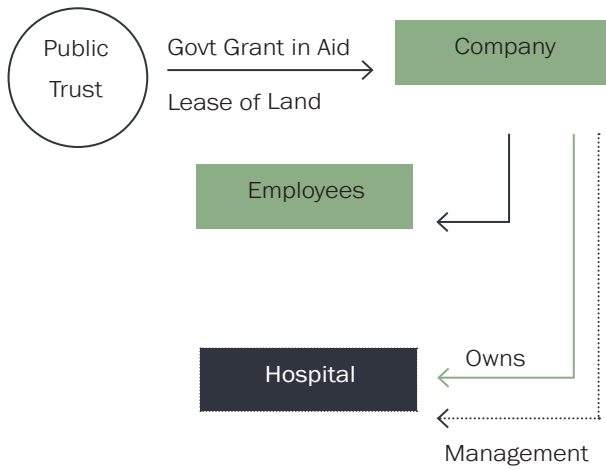
Model: 3



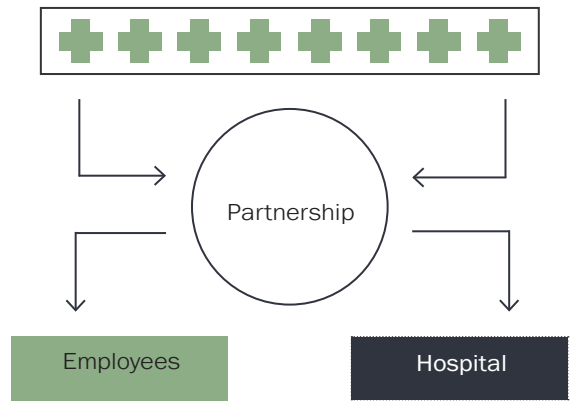
Model: 3a



Model: 4



Model: 5



Annexure B

Medical Device and Diagnostics:

- Possible Targets
 - » Medical device companies
 - » Medical equipment companies
 - » Radio Imaging services
 - » Pathlabs
 - » National chains (less at the moment)

E-Health / Tele Medicine:

- Possible Targets
 - » Division of hospital rendering tele medicine services (tele radiology)
 - » Standalone tele radiology companies
 - » Service providers companies (IT)
 - » Tele monitoring / health monitoring

Preventive & wellness Care:

- Possible Targets
 - » Nutraceuticals and herbals
 - » Dietary supplement companies
 - » Organic foods and health supplements companies

Day care / Short stay centers:

- » Chain of existing centers
- » Hospitals having potential to start such centers
- » Surgery / specific discipline

Critical care centers:

- » Emergency Operation Rooms and recovery centers
- » Basic recovery centers
- » Ambulance services

Geriatric care centers:

- » General care
- » Hospice centers

Physical therapy centers:

- » Post trauma
- » Post-surgery

General diagnostics:

- » Neuro-physiology
- » Advanced Radiology
- » Hematology and Advanced Histopathology

Pain Clinics:

- » Advanced pain relieving centers

Ancillary Care:

- » Nursing
- » Para medics services
- » Hospital Management Services
- » Medical tourism companies
- » Hospital housekeeping
- » Ambulance services
- » Low cost health services
- » Equipment leasing / services

The following research papers and much more are available on our Knowledge Site: www.nishithdesai.com

	Fund Structuring and Operations Global, Regulatory and Tax developments impacting India focused funds July 2016		E-Commerce in India Legal, Tax and Regulatory Analysis July 2015		The Curious Case of the Indian Gaming Laws Legal Issues Demystified September 2015
	Corporate Social Responsibility & Social Business Models in India A Legal & Tax Perspective March 2016		Joint-Ventures in India November 2014		Outbound Acquisitions by India-Inc A Review of Outbound Acquisitions by Indian Companies With a Focus on United States, United Kingdom and Australia September 2014
	Internet of Things Legal & Tax Issues April 2016		Doing Business in India With Special Reference to the Treaties between India and June 2016		Private Equity and Private Debt Investments in India June 2015

NDA Insights

TITLE	TYPE	DATE
Thomas Cook – Sterling Holiday Buyout	M&A Lab	December 2014
Reliance tunes into Network18!	M&A Lab	December 2014
Sun Pharma –Ranbaxy, A Panacea for Ranbaxy's ills?	M&A Lab	December 2014
Jet Etihad Jet Gets a Co-Pilot	M&A Lab	May 2014
Apollo's Bumpy Ride in Pursuit of Cooper	M&A Lab	May 2014
Diageo-USL- 'King of Good Times; Hands over Crown Jewel to Diageo	M&A Lab	May 2014
Copyright Amendment Bill 2012 receives Indian Parliament's assent	IP Lab	September 2013
Public M&A's in India: Takeover Code Dissected	M&A Lab	August 2013
File Foreign Application Prosecution History With Indian Patent Office	IP Lab	April 2013
Warburg - Future Capital - Deal Dissected	M&A Lab	January 2013
Real Financing - Onshore and Offshore Debt Funding Realty in India	Realty Check	May 2012
Pharma Patent Case Study	IP Lab	March 2012
Patni plays to iGate's tunes	M&A Lab	January 2012
Vedanta Acquires Control Over Cairn India	M&A Lab	January 2012
Corporate Citizenry in the face of Corruption	Yes, Governance Matters!	September 2011
Funding Real Estate Projects - Exit Challenges	Realty Check	April 2011

Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our "*Hotlines*". These *Hotlines* provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our *NDA Insights* dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction.

We regularly write extensive research papers and disseminate them through our website. Although we invest heavily in terms of associates' time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our *ThinkTank* discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research reports.

Please feel free to contact us at
research@nishithdesai.com

Nishith Desai Associates

LEGAL AND TAX COUNSELING WORLDWIDE

MUMBAI

93 B, Mittal Court, Nariman Point
Mumbai 400 021, India

tel +91 22 6669 5000
fax +91 22 6669 5001

SILICON VALLEY

220 S California Ave., Suite 201
Palo Alto, California 94306, USA

tel +1 650 325 7100
fax +1 650 325 7300

BANGALORE

Prestige Loka, G01, 7/1 Brunton Rd
Bangalore 560 025, India

tel +91 80 6693 5000
fax +91 80 6693 5001

SINGAPORE

Level 30, Six Battery Road
Singapore 049 909

tel +65 6550 9856

MUMBAI BKC

3, North Avenue, Maker Maxity
Bandra-Kurla Complex
Mumbai 400 051, India

tel +91 22 6159 5000
fax +91 22 6159 5001

NEW DELHI

C-5, Defence Colony
New Delhi 110 024, India

tel +91 11 4906 5000
fax +91 11 4906 5001

MUNICH

Maximilianstraße 13
80539 Munich, Germany

tel +49 89 203 006 268
fax +49 89 203 006 450

NEW YORK

375 Park Ave Suite 2607
New York, NY 10152

tel +1 212 763 0080