Milind Antani – Lead, Pharma, Life Science and Healthcare Practice; Head, Social Sector Practice, Nishith Desai Associates



In terms of innovation, the [Indian pharmaceutical] landscape is evolving, but not at a pace that matches global leaders

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Drawing on a unique background in both medicine and law, Dr Milind Antani today leads the pharma and healthcare practice at Nishith Desai Associates, covering everything from regulatory work to corporate transactions, intellectual property matters, and dispute resolution. Dr Antani highlights the dynamic M&A landscape in Indian healthcare and pharmaceuticals and predicts a shift towards more strategic collaborations and joint ventures, particularly in manufacturing and supply. He also discusses India's potential in the digital healthcare sector, driven by its skilled tech professionals and innovation potential, despite facing challenges such as regulatory compliance and market saturation.

Could you please introduce yourself, highlighting your extensive experience in the field?

My journey at Nishith Desai Associates has been both fulfilling and dynamic. I joined the esteemed law firm in 2001, contributing significantly to the establishment and subsequent growth of its healthcare practice during the initial two to three years. However, I have not always been a lawyer,

as I previously spent 14 years as a medical surgeon, specializing in Ear, Nose, and Throat surgery. This dual expertise in medicine and law has been instrumental in shaping my role as a leader in the pharma healthcare practice.

Since fully transitioning to the legal field in 2004, I have had the privilege of spearheading the entire spectrum of services offered by our pharma and healthcare practice at Nishith Desai Associates. This includes comprehensive regulatory work, intricate corporate transactions, intellectual property (IP) matters, and dispute resolution. Our multidisciplinary approach extends to general commercial law, where we handle diverse aspects such as distribution arrangements and navigate regulatory challenges. In addition to regulatory work, my role encompasses corporate transactions, covering a broad spectrum from mergers and acquisitions (M&A) to joint ventures, private equity investments, and licensing deals. We operate in a diverse landscape that includes startups in the pharmaceutical and healthcare sectors, and our legal counsel often involves IP-driven transactions.

In the realm of dispute resolution, we've observed a notable uptick in cases related to white-collar crimes and investigations, a trend attributed to stringent anti-bribery laws both in India and internationally, such as the Foreign Corrupt Practices Act (FCPA) and UK Bribery laws. Given the extensive interaction with government bodies and organizations, compliance with stringent pricing and promotion legislation in India is imperative, often leading to investigations and litigations.

The regulatory landscape in India's pharma and healthcare industry is intricate, encompassing various segments, including pharmaceuticals, biopharmaceuticals, medical devices, digital health, and healthcare service providers. The pricing regime, managed by the National Pharmaceutical Pricing Authority (NPPA), involves fixing ceiling prices for essential medicines. The promotional activities of pharmaceutical products and healthcare providers are regulated by strict laws to ensure ethical practices. Compliance with Good Manufacturing Practices and adherence to clinical trial rules are paramount for companies operating in this sector.

While regulatory challenges persist, the COVID-19 pandemic has presented unique opportunities. The biopharma sector witnessed significant growth, with a particular emphasis on vaccine development. Additionally, the digital health sector experienced a surge, encompassing telemedicine and med tech. The healthcare service provider landscape, ranging from corporate hospitals to rural clinics, is undergoing consolidation, attracting private equity players and strategic investors.

Our distinctive approach at Nishith Desai Associates revolves around a collaborative model. Our professionals are not confined to siloed departments but rather follow an inverted T and horizontal H model. Professionals are well-versed in a myriad of areas, from regulatory and IP to corporate transactions, ensuring a holistic understanding of the pharma healthcare industry. The firm members develop specific legal skills along with soft skills and management skills. This collaborative spirit allows our teams to seamlessly navigate the intricacies of diverse transactions and matters, providing comprehensive legal counsel.

In essence, our commitment at Nishith Desai Associates is centered on adeptly navigating the complex regulatory framework, fostering collaborations, and facilitating investments to support the continued growth and development of the pharma and healthcare sector in India.

Considering the significant M&A activities in the healthcare and pharmaceutical sector, how do you foresee the evolution of this space? Are there specific considerations, especially concerning major Indian players, that you find noteworthy?

The M&A landscape in the healthcare and pharmaceutical sector has been dynamic, with a total value surpassing USD 3.35 billion in 2021. In my perspective, while traditional mergers and acquisitions will persist, there’s a noticeable shift towards strategic collaborations.

Firstly, I’ve observed a trend where multinational corporations (MNCs) and Indian players are increasingly joining forces, particularly in manufacturing and supply. This collaboration often involves an MNC teaming up with an Indian counterpart for cost arbitrage. India boasts the highest number of FDA-approved plants outside the U.S., ensuring quality, and the technological capabilities in the country have strengthened significantly.

However, the landscape is evolving, and I anticipate more collaborations than outright acquisitions. Rather than large MNCs acquiring major Indian companies, I foresee collaborations where two entities, possibly one MNC and one Indian player, form joint ventures or other collaborative arrangements for manufacturing and selling. This could also involve dividing territories for the supply of pharmaceutical and biopharmaceutical products.

Simultaneously, private equity investments into the healthcare space are gaining momentum, particularly in the medical device and hospital sectors. There’s a growing interest in single-specialty hospitals, such as those focused on oncology or plastic reconstructive surgery.

Beyond traditional healthcare, the digital health sector is experiencing rapid growth. Numerous startups are providing innovative services leveraging the internet, artificial intelligence, and machine learning. However, I anticipate a saturation point in the market. To navigate this, I foresee a trend where multiple digital health or medtech startups will engage in mergers, forming consolidated entities with a broader range of services. This consolidation is likely to attract further investments and partnerships.

In essence, the next two years could witness a surge in collaborative efforts, both in traditional healthcare sectors and the emerging digital health space. This shift towards strategic alliances and mergers is poised to reshape the healthcare and pharmaceutical landscape.

Given India’s strong base of skilled tech professionals and its position as the most populous country in the world, the digital health sector seems poised for significant growth. What role do you envision India playing in the global digital healthcare landscape, considering its vast talent pool and innovation potential? Additionally, what challenges do you foresee in the digital health sector?

India holds immense potential in shaping the global digital healthcare landscape. The abundance of highly skilled tech professionals and innovators positions India as a key player in driving advancements in the digital health sector. The significant talent pool, combined with cost arbitrage, makes India an attractive hub for developing innovative solutions.

From a global perspective, Indian companies specializing in artificial intelligence (AI) are already engaging in discussions with international counterparts for collaborations. The strength of Indian engineers and software developers is expected to result in the creation of cutting-edge technologies and solutions. The focus on AI-based companies in India has the potential to influence and reshape the global digital health market.

However, several challenges lie ahead for the digital health sector in India. Compliance emerges as a key challenge, given the evolving regulatory landscape. The classification of standalone or embedded software in regulated medical devices poses complexities that companies need to navigate. This regulatory uncertainty can impact decision-making and operational strategies.

Another significant challenge is the proliferation of startups in the digital health space. While diversity and innovation are positive aspects, the sheer number of players makes it challenging to identify and choose the right partners. The market might face a saturation point, necessitating

careful selection and collaboration strategies.

Valuation disagreements could emerge as a commercial challenge, with differing perceptions of the worth of digital health startups. Aligning on valuation during transactions may prove to be a hurdle that requires thoughtful negotiation.

In summary, India’s digital health sector is poised to contribute significantly to the global landscape, leveraging its talent and innovation capabilities. However, addressing regulatory uncertainties, navigating the crowded startup space, and managing valuation discussions will be critical aspects in ensuring the sector’s sustained growth and impact.

How do you view India’s role in the global biopharma sector? Is it set to remain a key player in generic manufacturing, or do you see a shift toward becoming a hub for biotech innovation? What challenges and opportunities do you foresee in this context?

India has established itself as a major global supplier for generic medicines, contributing significantly to the pharmaceutical landscape. However, when it comes to biopharma and biotech innovation, India’s current position is more focused on manufacturing biosimilars, particularly in areas like oncology, hormones, and autoimmune disease treatments. Biosimilars represent generic versions of biotech products.

In terms of innovation, the landscape is evolving but not at a pace that matches global leaders. The focus on biosimilars is strong, indicating that India’s strength lies in becoming a reliable backend partner for global pharma in this particular domain.

Several factors contribute to this scenario. First, there’s a need for increased emphasis on incentivizing research and development (R&D) in India. While strides have been made, a more robust ecosystem that supports and encourages R&D activities could accelerate the country’s journey towards biotech innovation.

Secondly, the IP regime in India, including patent laws, requires attention. The absence of data exclusivity laws and concerns about the exposure of data may hinder companies from aggressively pursuing patents and innovative research in India. Strengthening the IP framework could create a more conducive environment for companies to invest in and protect their innovative molecules.

While acknowledging a current gap in India’s biotech innovation compared to countries like China, it’s important to recognize the potential for future advancements. The biopharma sector is

dynamic, and with strategic measures to enhance R&D incentives and fortify the IP framework, India could see a shift towards becoming a hub for biotech innovation in the coming years. The current scenario might be a temporary setback, with the potential for future progress as the ecosystem matures.

The IP landscape in India is often perceived as challenging for global players. How do you see the current state of the IP environment in India, and what initiatives or policies is the government putting in place to address any concerns? Additionally, how do you guide your clients in navigating this IP landscape?

Navigating the IP landscape in India poses certain challenges for global players. One notable concern is the exclusion criteria, where incremental innovations and mere admixtures may not be considered patentable unless significantly enhanced efficacy is established. This can be perceived as a limitation by foreign companies.

Furthermore, India lacks data exclusivity, meaning that certain information may become part of the public domain, and there is no patent linkage, contributing to discomfort among global players. The existence of pre-grant and post-grant opposition mechanisms in the Indian Patent Act allows any person to oppose a patent application before or after its grant, adding an additional layer of complexity.

The government of India has historically aimed at fostering a self-reliant pharmaceutical industry. However, efforts are being made to address concerns and create a more encouraging environment for research and development (R&D) in India. The upcoming amendment to the Patent Act is anticipated to bring changes that may address some of the perceived limitations and make the environment more conducive for innovation.

As for guiding clients, it involves a comprehensive approach. Emphasizing the importance of staying informed about the evolving IP landscape, utilizing available mechanisms like pre-grant and post-grant oppositions, and actively participating in discussions around policy changes are key elements. Additionally, strategic considerations for IP protection and management play a crucial role in maximizing the benefits within the existing framework.

The challenge is to balance the concerns of global players with the broader objectives of India’s pharmaceutical industry. Collaboration and communication between stakeholders, including the government, industry, and legal experts, remain vital for creating an IP landscape that encourages innovation while addressing global expectations.

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