

Research

Killer Acquisitions in Indian Pharma

Emerging Trends

January 2021

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1. Introduction

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"In 2018 research focused on the pharmaceutical industry identified a trend for large incumbents to acquire new nascent firms, and did not adopt and develop the acquired product, as had been assumed, but neglected and discontinued the development of the product. These were labelled 'killer acquisitions'".¹

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Killer acquisitions are generally understood to be the practice of well-established firms acquiring 'nascent' competitors. The acquisition is described as 'killer' because post the merger, the target's innovation projects are subsumed into the acquirer, thereby pre-empting the emergence of future competition.² The Federal Trade Commission (**"FTC"**) recently sued Facebook for alleged maintenance of its monopoly position by acquisition of emerging companies with the intention to quash future competition.³

Killer acquisitions are a topical issue in the pharmaceutical and life sciences sector. The pharmaceutical sector is uniquely placed to encourage killer acquisitions with many start-ups developing innovative formulations that have the potential to be direct competitors to medicines manufactured by established, multinational pharmaceutical companies. Multinational companies, on the other hand, have the resources to continuously monitor the market and patent journals to identify which competing drugs are likely under development. This has led to a trend of pharmaceutical companies acquiring start-ups or product portfolios of other companies which are in direct competition with the acquirer's products.

I. Start-ups, killer acquisitions and merger control, available at: <u>http://www.oecd.org/daf/competition/start-ups-killer-acquisitions-and-merger-control.htm#:~:text=One%200f%20the%20most%20discussed,the%20emergence%200f%20future%20competition (last accessed January 05, 2021).</u>

^{2.} id.

^{3.} FTC File No. 191 034 filed before the Federal Court, District of Columbia, available at: <u>https://www.ftc.gov/system/files/documents/cas-es/1910134fbcomplaint.pdf (last accessed January 05, 2021).</u>

2. Overview of The Indian Pharmaceutical Industry

The Indian pharmaceutical industry has been growing steadily over the past couple of years. As of 2018, it was the third largest in terms of volume and thirteenth largest in terms of value. However, on a global scale, the industry accounts for 20% in terms of volume and only 1.4% in terms of value.⁴

India's pharmaceutical industry is also divided into two types of companies – domestic companies that primarily have generic drugs in product portfolio (such as Zydus Cadilla, Cipla and Sun Pharma) and subsidiaries of foreign multinational companies (such as Boehringer Ingelheim, Pfizer and Allergan) that market exclusively innovative drugs or a mix of generic and innovative drugs.

Domestic companies generally do not invest heavily in research and development and focus on marketing offpatent drugs originally developed by innovator companies. Therefore, most innovative drugs marketed in India are developed outside India by foreign pharmaceutical companies. In the alternative, foreign pharmaceutical companies who do not have a significant India presence may choose to not launch their drug in India under their own brand name but rather license their product to a domestic company which markets the drug under the domestic company's brand name. As a result, shifts in innovation trends abroad or mergers abroad have an indirect impact on the availability of drugs in India.

^{4.} Primer on the Indian Pharmaceutical Industry by India Brand Equity Foundation, available at: <u>https://www.ibef.org/archives/detail/b3ZlcnZpZX-cmMzc2NDQmOTA= (last accessed January 05, 2021).</u>

3. The Process of Launching A Drug in India

Drug development and launch in India is regulated under the New Drugs and Clinical Trial Rules, 2019 (**"CT Rules"**) – a set of rules framed under India's primary drug control legislation, the Drugs and Cosmetics Act, 1940 (**"D&C Act"**). Under the CT Rules⁵, before a 'new drug' can be launched in India, it must undergo local clinical trials to establish that the drug is safe and efficacious for use. Under the CT Rules, a new drug is any drug that does not have a history of use for treating a particular disease or disorder in the Indian population. Therefore, 'new drugs'⁶ includes (i) drugs⁷ which are proposed to be used for the first time on humans, (ii) drugs which are combined for the first time, or (iii) drugs that intended to be marketed for a new disease or disorder than the ones for which it has been approved.

The company interested in marketing the drug (**'Sponsor'**) must conduct the clinical trials in India. Clinical trials in India are typically conducted over four phases. The first three phases are geared towards establishing the safety and efficacy of the drug. On successful completion of the three phases, the Central Drugs Standard Control Organisation (**"CDSCO"**)⁸ grants approval to market the drug in India (**'Marketing Authorization'**). Following the grant of the Marketing Authorization, the Sponsor conducts the fourth phase of the clinical trial. The fourth phase involves post-marketing studies where the Sponsor monitors the way the drug is prescribed to the public and any unintended effects resulting from its use. In the event the data at the earlier stages is not promising or if the drug has adverse effects on the trial subjects, the clinical trial is usually suspended.

^{5.} The CT Rules, available at: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed January 05, 2021).

^{6.} The CT Rules define 'new drug' as

[&]quot;new drug" means,-

⁽i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licencing Authority with respect to its claims; or

⁽ii) a drug approved by the Central Licencing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

⁽iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

⁽iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licencing Authority; or

⁽v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;

^{7.} Section 3(b)(iv) of the D&C Act defines drugs as

 ⁽i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

 ⁽ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

⁽iii) all substances intended for use as components of a drug including empty gelatin capsules; and

⁽iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

^{8.} The Central Drugs Standard Control Organization under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

4. Competition Regulation in India and Killer Acquisitions

Before we discuss the issues with catching killer acquisitions in India, a case study on the issue would provide a pithy substance of their impact.

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Case-Study

The Mallinckrodt ARD Inc. case (formerly known as Questcor Pharmaceuticals, Inc.) illustrates how killer acquisitions play out in the pharmaceutical and lifesciences sector. In the early 2000s, Questcor enjoyed a monopoly in the category of adrenocorticotropic hormone ("ACTH") drugs with its product Acthar which treats rare, serious conditions, including infantile spasms. Subsequently, in the mid-2000s, Synacthen, a synthetic, direct competitor to Acthar was beginning development for the US market. In an effort to pre-empt potential future competition, Questcor acquired the US development rights of Synacthen from Novartis AG in 2013.⁹ Questcor did not develop Synacthen thereby prevent a competing product from emerging in the market. In its antitrust complaint against Mallinckrodt ARD Inc. and its parent company Mallinckrodt PLC. (the subsequent acquirers of Questcor), the FTC argued that *"by acquiring Synacthen, Questcor harmed competition by preventing another bidder from trying to develop the drug and launch it in the United States to challenge Questcor's monopoly over ACTH drugs"*. Ultimately, the matter was settled in 2017 with Mallinckrodt ARD Inc. and Mallinckrodt PLC agreeing to pay USD 100 million.¹⁰ As a remedial measure, Questcor was also required to grant a license to develop Synacthen to treat infantile spasms and nephrotic syndrome to a licensee approved by the FTC.

In this case, Synacthen was already a fully-developed drug developed by Novartis AG (that was already being marketed and sold outside of the United States), which was acquired by a competitor and then never launched in the market. Therefore, Questcor's motivations for 'killing' Synacthen to stifle future competition were apparent on the face of it. However, this may not be as clear in acquisitions where one of the drugs is still in development. This is because, in the early stages of drug development, it remains unclear whether the drug will be approved by the regulator to be launched in the market.

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As stated above, most drugs launched in India are developed and tested abroad before those drugs are launched in India. Therefore, killer acquisitions abroad have an impact on the Indian market. Given this, we have analyzed the provisions under India's antitrust regulation dealing cross-border mergers or mergers between companies located outside India to understand where the regulation is adequately equipped to handle killer acquisitions.

I. Overview of India's Antitrust Regulation

The Competition Act, 2002 (**"Competition Act"**) embodies the antitrust prosecution and merger regulation in India. is India's antitrust and merger regulation. Under the Competition Act, the Competition Commission of India (**"CCI"**)^{II} has the power to investigate anti-competitive agreements and instances of abuse of dominance. In the event the CCI finds that an enterprise has entered into an anti-competitive agreement or abused its dominant position thereby causing an appreciable adverse effect on competition, the CCI is empowered to impose fines and/ or require the parties involved to take corrective measures.

^{10.} Press Release by FTC on the Settlement, available at: https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-millionsettle-ftc-state-charges-it (last accessed January 05, 2021).

^{11.} The CCI is India's competition regulator responsible for enforcement of competition laws.

Section 3 of the Competition Act prohibits enterprises from entering into agreements which are likely to have an appreciable adverse effect on competition. This includes both horizontal and vertical agreements. In the past, the CCI has penalized various druggist and chemists associations in India for actions that had the effect of creating barriers to new entrants to the market.¹² However, merger agreements for killer type acquisitions have not been examined by the CCI so far.

Section 4 of the Competition Act prohibits abuse of dominance and includes actions by a dominant firm to acquire nascent competitors with the objective of eliminating competition from a potential competitor. The CCI is yet to prosecute a firm in the pharmaceutical and life sciences sector for killer type conduct. That said, the pharmaceutical and life sciences sector is high scrutiny sector. In the aftermath of the COVID-19 pandemic, it is more likely that the CCI will be more active in this area. In this article, we have provided an overview of how the pharmaceutical industry is organized in India, analyzed the process of drug development and examined the potential impact of *'killer acquisitions'* on the Indian pharmaceutical sector.

II. Merger Control in India

The Competition Act requires that mergers which exceed a certain threshold should be notified to the CCL¹³ The CCI also has extra-territorial jurisdiction under the Competition Act to examine arrangements/combinations between foreign companies if the enterprises which are part of the arrangement/combination have significant assets in India or generate a significant amount of turnover in India.¹⁴ The Competition Act prescribes thresholds for the India-based assets/turnover on crossing which the merger notification requirement is triggered. The thresholds prescribed by the CCI are available <u>here.¹⁵</u> The Competition Act also provides for de minimis exemption where targets which hold fewer than INR 3.5 billion worth of assets in India or generate a turnover of less than INR 10 billion in India are exempt from the merger notification requirement.¹⁶

The CCI then examines the merger to determine if it is likely to cause an appreciable adverse effect on competition ("AAEC"). Based on the CCI's findings, it may approve the merger unconditionally, provide a conditional approval subject to structural or behavioral modifications or reject the merger. The CCI can block killer type acquisitions under its merger control provisions, provided the merger is caught within its jurisdictional thresholds.¹⁷ Since, killer acquisitions involve the acquisition of a startup, the transaction usually qualifies in the small target exemption and is not required to be notified to the CCI.¹⁸ The CCI has so far cleared all the mergers in the pharmaceutical and life sciences sector. While the CCI does have extra-territorial jurisdiction and can examine mergers taking place outside of India (which are likely to have an impact in India), this power is limited to high-value mergers. Further, acquisitions of start-ups by well-established players taking place outside India are not likely to be examined in India due to the de minimis exemption as the target is unlikely to have significant assets or turnover in India.

13. Section 5 of the Competition Act, Revised Thresholds, available at:

14. Section 5 read with Section 32 of the Competition Act.

^{12.} MRTP Case No. C127120091DG1R4128 (Varca Druggist & Chemist and others vs CDAG and Case Ref: Case No: C-87/2009/DGIR (Vedant Biosciences and Chemists and Druggists Association, Baroda)

http://cci.gov.in/sites/default/files/quick_link_document/Revised%20thresholds.pdf (last accessed January 05, 2021).

^{15.} Revised Thresholds, available at:

http://cci.gov.in/sites/default/files/quick_link_document/Revised%20thresholds.pdf (last accessed January 05, 2021).

^{16.} Notification by Ministry of Corporate Affairs dated March 27, 2017, available at: https://www.cci.gov.in/sites/default/files/notification/S.O.%20 988%20%28E%29%20and%20S.O.%20989%28E%29.pdf (last accessed January 05, 2021).

^{17.} Sections 5, 6 and 31 of the Competition Act bestow the power to the CCI to review and block mergers. The latest jurisdictional thresholds are available here: http://cci.gov.in/sites/default/files/quick_link_document/Revised thresholds.pdf

^{18.} Mergers and amalgamations where the target either hold assets less than INR 3.5 billion or generates turnover of less than 10 billion in India are currently exempt from mandatory CCI notification obligation. Asset acquisitions where the value of the relevant assets being acquired is less than INR 3.5 billion in India or turnover of the business division being acquired is less than INR 10 billion in India also qualify for this exemption. This exemption is only valid until March 04, 2021, unless re-notified by the MCA.

In the past, the CCI has examined the merger of two prominent Indian pharmaceutical companies i.e. Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited.¹⁹ While the merger was approved, the CCI imposed certain pre-conditions to the merger, including requiring both parties to divest seven drugs from their product portfolio. The divestment was proposed as the CCI believed that there may be an appreciable adverse effect on competition in the relevant drug markets if such divestiture was not mandated.

However, the preparedness of the Competition Act to deal with mergers in the pharmaceutical sector has been brought into question in the past as well. In 2011, the High-Level Committee Report on Foreign Direct Investments in Existing Indian Pharma Companies headed by Arun Maira (**"Arun Maira Committee"**) observed that the Competition Act is not adequately equipped to regulate mergers in the pharmaceutical sector. The Arun Maira Committee Report observed that most combination activities in the pharmaceutical sector are carried out through subsidiaries or through special purpose vehicles which do not have significant assets/turnovers. The committee also recommended having separate thresholds for the pharmaceutical sector as the industry produces essential products.

III. Issues with Regulating Killer Acquisitions

Killer acquisitions are usually deemed to be so after the merger has taken place as it is difficult to establish whether a merger is likely to stifle competition that has not even arisen yet. This issue is particularly complicated in the pharmaceutical sector as the competing drug is usually not fully developed but rather in the development stage. As can be seen from the clinical trial process outlined in Section B, drug development is an uncertain process. Most drugs fail in the early stages of trial while a few may also be scrapped at a later stage. Therefore, it can be difficult to determine whether a potential competing drug in development is even likely to reach the market.

The European Commission as a general practice has determined that drugs undergoing Phase III clinical trials are promising competitors to drugs existing in the market. Therefore, an acquirer company acquiring products under development from the target company in the same therapeutic category as the existing products of the acquirer, would be considered to be a horizontal overlap. The European Commission has put this principle in practice in the case of *Novartis/GlaxoSmithKline Oncology Business.*²⁰

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Case-Study

GlaxoSmithKline had proposed to acquire Novartis AG's oncology business.²¹ At the time of acquisition, Novartis had two promising skin cancer treatments LGX818 and MEK162 in stage 3 clinical trials. If successful, these drugs would compete with existing skin cancer treatments in GlaxoSmithKline's product portfolio as well as skin cancer treatments marketed by Roche. The European Commission's assessment revealed that the merger would not only have led to the abandonment of Novartis' current efforts to launch its skin cancer treatment, but also to the abandonment of the broader clinical trial program in respect of those drugs. Accordingly, the European Commission approved the merger on the condition that Novartis return its rights over one of the drugs to its owner and licensor Array BioPharma Inc. and to divest the other drug to Array BioPharma Inc. as well.

20. Case No COMP/M.7275, available

^{19.} Combination Registration No. C-2014/05/170

at:<u>https://ec.europa.eu/competition/mergers/cases/decisions/m7275_20150128_20212_4158734_EN.pdf</u> (last accessed January 05, 2021). 21. Case No. COMP/M.7275, available at:

https://ec.europa.eu/competition/mergers/cases/decisions/m7275_20150128_20212_4158734_EN.pdf (last accessed January 05, 2021).

IV. Impact of Killer Acquisitions

In addition to the difficulty of determining whether a drug under development is a potential competitor, the CCI must also examine whether *killing*'the drug is likely to have an AAEC in India. As already discussed, most mergers in the pharmaceutical sector are likely to escape merger scrutiny due to high merger thresholds. For the remaining mergers, the CCI would be required to not only determine whether there is a horizontal overlap between products of the acquirer and target company, but also whether such overlap is likely to cause an AAEC in India.

This is particularly difficult in the Indian context as it is unclear during the drug development stage whether the drug will be launched in India even if it is available abroad. Most pharmaceutical development takes place abroad; many innovative drugs are not launched in India if companies believe they may not be profitable or relevant in the Indian market. Further, to avoid increased scrutiny of the India leg of a worldwide merger, the acquiring company may refrain from making definite plans to launch the drug in India prior to the merger. Arguably in such a scenario where the drug is launched abroad, and the merger takes place abroad, there is no effect on competition in India. Due to this, the Indian market is heavily dependent on decisions made by competition regulators in the United States and Europe as merger control in those countries has a significant impact of drug availability in India.

In the event a merger does take place abroad that is likely to have an AAEC in India, the CCI has the power to make structural and behavioral modifications to the merger structure. This includes the power to call upon the parties to merger to divest part of the undertaking to third parties to mitigate the AAEC. In exceptional cases, the CCI also has the power to declare a merger void as if the merger or acquisition had never taken place. This is clearly a drastic measure and has not been exercised by the CCI so far in any case. Declaring mergers void is also likely to dissuade companies from doing business in India and so, the CCI is relatively cautious while exercising drastic measures.

V. Utilizing Section 4 to Avert Killer Acquisitions

Section 4 of the Competition Act prohibits enterprises from abusing their dominant position. Practices such as restricting production of goods or services or restricting technical or scientific development relating to goods to the prejudice of consumers are considered to be abuse of dominant position.

Therefore, in cases (i) where a merger has taken place with the intention of maintaining an enterprises' dominance in respect of a particular drug/treatment area, and (ii) the relevant drug for the protection of which the merger took place is launched in India, the CCI may investigate the case under Section 4 for abuse of dominance. In the event the CCI believes that the merger amounts to abuse of dominance (either by restricting the production of the competing drug which was not developed/launched or by restricting scientific development in the therapeutic field), the CCI may impose a penalty on enterprises involved. The CCI may also impose other behavioral and structural remedies on the enterprise as well. This may involve transfer or divestment of property or rights, including the development rights of the competing drug.

Mergers that do not meet the merger thresholds under Section 5 of the Competition Act or are eligible for the de *minimis* exemption may be indirectly examined under Section 4 of the Competition Act for abuse of dominance. In the event such mergers are found to constitute abuse of dominance, remedies similar to those applicable for mitigating the AAEC in case of combinations may be considered.

5. Conclusion

The Competition Act can be better equipped to deal with not only killer acquisitions but also pharmaceutical industry mergers in general. Regulating mergers indirectly under Section 4 is a long-winded and cumbersome process and may only be utilized once the damage is already done. It is time to consider implementing tweaking the small target exemption for the pharmaceutical and life-sciences sector to ensure that killer type acquisitions are caught. One way of achieving this could be adding an explanation to the small target exemption, declaring it inapplicable to acquisition of competitors in the pharmaceutical and life sciences sector. This way when big pharma (who would otherwise meet the merger thresholds under Section 5 of the Competition Act) acquire start-ups, the transactions would no longer qualify for the small target exemption and would be notifiable to the CCI.

Separately, the Indian pharmaceutical industry needs to simultaneously shift its focus on producing innovative drugs. Many domestic pharmaceutical companies are generally of the view that India's patent laws are not conducive to innovation. Further, Indian pharmaceutical companies (especially small and mid-size firms) do not have the resources required to invest in pharmaceutical research and development, which generally tends to be a capital intensive process with uncertain returns on investment. Encouragement for this could be provided by the Indian government through greater tax incentives for expenditure incurred in research and development as well as by providing funding for the indigenous development of new drugs. The CCI could in tandem commission a study to suggest measures that could prove to promote a conducive environment for innovation in India.

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Every member of the firm is required to participate in research activities. The seeds of research are typically sown in hour-long continuing education sessions conducted every day as the first thing in the morning. Free interactions in these sessions help associates identify new legal, regulatory, technological and business trends that require intellectual investigation from the legal and tax perspectives. Then, one or few associates take up an emerging trend or issue under the guidance of seniors and put it through our "Anticipate-Prepare-Deliver" research model.

As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparallel mastery. Our TMT practice, IP practice, Pharma & Healthcare/Med-Tech and Medical Device, practice and energy sector practice have emerged from such projects. Research in essence graduates to Knowledge, and finally to *Intellectual Property*.

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular "Hotlines", which go out to our clients and fraternity. 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 Lab Reports 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 articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged. Although we invest heavily in terms of 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.

As we continue to grow through our research-based approach, we now have established an exclusive 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. **Imaginarium AliGunjan** is a platform for creative thinking; an apolitical eco-system that connects multi-disciplinary threads of ideas, innovation and imagination. Designed to inspire 'blue sky' thinking, research, exploration and synthesis, reflections and communication, it aims to bring in wholeness – that leads to answers to the biggest challenges of our time and beyond. It seeks to be a bridge that connects the futuristic advancements of diverse disciplines. It offers a space, both virtually and literally, for integration and synthesis of knowhow and innovation from various streams and serves as a dais to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear your suggestions on our research reports. Please feel free to contact us at research@nishithdesai.com



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