Part I

Shifting Ground

Chapter 1

The Man Who Saw Further

LATE FALL 2001
Hopewell, New Jersey

Dinesh S. Thakur was fastidious. He wore perfectly ironed khakis, a white button-down shirt, a dark sports jacket, and well-polished loafers. Stocky and of medium height, he had a round face, full head of dark hair, and deep-set eyes that gave him a doleful appearance. On this chilly afternoon, the leaves just beginning to turn gold and crimson, the thirty-three-year-old information scientist set out across the grassy slope toward the man-made lake. It was a favorite destination on the Bristol-Myers Squibb campus, where employees went to clear their heads or escape the highly regimented corporate culture, if only for their lunch hour.

But today Thakur had come at the behest of an older and more senior colleague, who'd invited him for a walk to discuss an unspecified opportunity.

Bristol-Myers Squibb's research and development center sat on a manicured campus, just beyond a network of leafy residential streets and imposing stone homes. Inside the gated guard posts, low-slung concrete buildings with dark windows dotted the hillsides. The few trees were planted at regular intervals. The lush grass around the lake had been mowed with such precision that it looked like a striped carpet. Every hundred feet stood an emergency assistance pole, to summon aid if needed. Cars were kept to fifteen miles per hour. Even the lake's turtles had a demarcated crossing lane.

The orderly grounds reflected the painstaking research that went on there. Scientists from this campus developed drugs that had entered the worldwide lexicon, from Pravachol for high cholesterol to Plavix to prevent

blood clots. Decades earlier, what was then Squibb had developed an antibiotic to treat tuberculosis, for which its scientists won the prestigious Lasker Award. Bristol-Myers had forged new ground in cancer research. In 1989, the two companies merged. Nine years later, Bristol-Myers Squibb was awarded the National Medal of Technology and Innovation at a White House ceremony.

Thakur played a small but cutting-edge role in the company's endeavors. He ran a department that built robots, automated laboratory helpmates intended to make the work of drug testing more efficient and reliable. Thakur's lab buzzed with innovation. More than a dozen scientists reported to him. Pulleys, motors, bells, and levers were scattered about, and bright-eyed college students cycled through, pitching in as needed. Thakur set his own hours, which were long and sometimes involved staying overnight to watch the robots. They needed to repeat the same tasks faultlessly, with the goal of eliminating human error from the laboratory.

The results often did not turn out as desired, which was standard for a manufacturing scale-up. On these occasions, Thakur and his team were forced to scrap their work and start again. Yet they felt confident that the company viewed these failures as a normal part of the scientific process. When it came to Thakur's lab activity, the old advertising slogan from Squibb seemed to still hold sway: "The priceless ingredient in every product is the honor and integrity of its maker."

The work, with its scrupulous attention to detail, suited Thakur's temperament. He was promoted steadily with strong performance reviews, one of which noted that he was "very logical, ethical and loyal" in dealing with peers and superiors. Over six years, he had steadily ascended to his hard-won title: Director, Discovery Informatics.

Punctual as ever, he made his way to the walking path that looped around the lake, where his older colleague, Rashmi Barbhaiya, was waiting. Heavy-set, with snowy white hair and dark circles beneath his eyes, Barbhaiya had been developing drugs at BMS for twenty-one years. He had an intimidating aura and the smooth manner of a senior executive. By contrast, Thakur was reserved and somewhat awkward, with little gift for small talk. But this had not hindered him at BMS, where few people understood his robotics work or sought to discuss it.

Both men were originally from India. Two years prior, Thakur had built an automated computer program for Barbhaiya's group. More recently, as

Barbhaiya oversaw BMS's purchase of a small pharmaceutical company, he'd tapped Thakur to help transfer and reconcile the data. Today Barbhaiya was about to propose an opportunity Thakur did not predict.

As they walked along the footpath, Barbhaiya disclosed that he was leaving BMS—and the United States—to become the research and development director of India's largest drug company, Ranbaxy Laboratories, which made generic medicine. Thakur was surprised. Barbhaiya had spent his whole career climbing to the upper ranks of one of the world's top pharmaceutical research companies. At BMS, he had lived and breathed the prestige of creating new molecules. He'd become a recognized expert in whittling down the long odds that any drug maker undertakes when setting out to develop a new cure.

But Barbhaiya was planning to leave it all behind. To go from the brand-name sector in the United States to the generic one in India. By name, it was the same work—pharmaceutical research—but it was a seismic identity shift. The BMSes of the world invented. The Ranbaxys of the world duplicated. BMS did innovative science versus Ranbaxy's copycat engineering. But the more Barbhaiya explained his decision, the less skeptical Thakur became.

In India, Ranbaxy was legendary, and the family that built it, the Singhs, were hailed as corporate royalty. As one of India's oldest and most successful multinationals, Ranbaxy had reinvented the perceived capabilities of an Indian corporation. In 2001, it was on track to clock $1 billion in global sales, with its U.S. sales reaching $100 million after only three years in the American market. The FDA had already approved over a dozen of its drug applications. Ranbaxy had offices and manufacturing plants around the world, including in the United States, but was headquartered in India. Looking to the future, Ranbaxy was going to be investing heavily in innovative research. The company was aiming to develop new molecules. Barbhaiya would be building the company's research capacity, almost from the ground up. "Why don't you come with me?" he proposed. "You'll be closer to your parents and doing something for the country."

It was an offer that, on the face of it, made little sense. BMS had paid for Thakur's ongoing schooling, a master's program in computer engineering. He'd received years of in-house training on the best manufacturing and laboratory practices. But like Barbhaiya, Thakur knew

that the ground was shifting beneath his feet. The generic drug business was booming around the world. Generic drugs—legally produced copies of brand-name drugs—comprised half of the U.S. drug supply, a number that was steadily growing. The patents that protected dozens of best-selling drugs, from Lipitor to Plavix, would expire within the next decade, meaning that generics companies would be able to manufacture and sell copies approved by the Food and Drug Administration (FDA). With the demand for generics growing, all their jobs would be reconfigured soon enough. One of the main drivers behind this shift was India itself, which was fast becoming a global player in the pharmaceutical industry.

As Thakur contemplated the pros and cons of Barbhaiya's offer, he had a further thought. The goal in the brand-name world was to make the best possible drugs for the highest possible price. It was the heyday of the branded drug industry, with companies reaping billions in profits on the success of big-name drugs. The largesse at BMS reflected this. Office Christmas parties included caviar and champagne. Sometimes Thakur caught an empty seat on the corporate helicopter that shuttled executives between the company's hubs in Princeton, New Jersey, and Wallingford, Connecticut, marveling at the easy commute for those at higher pay grades.

In the generic world, the culture would be different because the goal was different: to make the best cures affordable and available to all. But it would mean leaving the United States, where he'd spent decades focused on building the best possible life he could.

Thakur had first come to know America through its movies. In college, as an engineering student in Hyderabad, he had gone to see classic films such as *Citizen Kane* and *Gone with the Wind*.

In college, he took the GRE, applied to graduate programs in the United States, and got a scholarship to the University of New Hampshire, where he lived in the graduate dorm as one of only a few minority students. He had never been out of India before, had never seen snow. In his new home, he marveled at the beauty of the White Mountains, the serenity of old New England towns, each with its own church and town square. He drove to Acadia National Park whenever he could and loved biking its rocky shoreline. Otherwise, he studied almost continuously, producing a doorstop of a master's thesis, which he later published in a journal under the title

“Soluble and Immobilized Catalase: Effect of Pressure and Inhibition on Kinetics and Deactivation.”

Shortly after graduating, he was hired by a small biotechnology company to help automate its laboratories. There, though a picture of Thakur and his robots made it into the company’s annual report, his unsupportive boss told him that he lacked the requisite talent for the job. So he moved on to BMS, where he continued the same work successfully.

As he climbed the corporate ladder, his mother grew worried that he had not yet married. Through a family connection, his parents visited the parents of a young woman named Sonal Kalchuri, who was fun loving and well educated and had long dark hair and almond eyes. Thakur met her on a trip to Mumbai, and the two began a phone relationship and correspondence over the following eight months.

In most ways, they were opposites. He was compulsively organized. She was laid-back. He was a workaholic who “never let his hair down,” as she put it. She was social and loved parties. But they shared an interest in science. Sonal was just completing her undergraduate degree in engineering. And they both loved to sing. His childhood home had been filled with music. Both his parents sang in the classical Hindustan style. Over the years, Thakur had developed an excellent voice and a love of the genre’s sinuous improvisations. He and Sonal would go on to perform together in classical Hindustani bands.

They married in 1995 and had a traditional days-long wedding, with both of them draped in flowers. Thakur wore the customary turban for grooms. Sonal was wreathed in gold jewelry, and her hands were hennaed with intricate patterns. She loved the event, but Thakur found the socializing taxing. Afterward, the couple made a home in Syracuse, and he returned to work. For Sonal, the transition was painful. The twenty-three-year-old had never been away from her family before. Now she was alone in a house in a foreign country.

Nonetheless, she enrolled in a computer-engineering graduate program at Syracuse University and emerged with a master’s degree. She got an excellent job at the Carrier Corporation as a software engineer. Thakur moved up steadily at BMS. In 1999, he was promoted to an associate director position. This involved a move from the Syracuse office to the research institute in Hopewell, New Jersey, just a few miles from the company’s Princeton offices. The couple found a spacious home with a

high-ceilinged family room that appealed particularly to Sonal. They were getting ready to start their own family.

Their son, Ishan, was born a week after the 9/11 attacks. The Princeton area was devastated. Typically, the parking lot at the Princeton Junction train station filled with the cars of workers who commuted an hour to their Manhattan jobs every weekday, then emptied every night. But after 9/11, cars remained, waiting for commuters who never returned from work.

Though Ishan was born amid tragedy, he brought unalloyed joy into the Thakurs' lives. Sonal's mother came to stay for eight months. And Thakur's parents came to visit, too, for the first time since he'd left for graduate school in the United States eleven years earlier. It was during these hectic months that Barbhaiya proposed to Thakur that he return to India.

Thakur did not immediately share the offer with Sonal. He continued to think about it quietly, as his work progressed at BMS. The family moved again, to Belle Mead, New Jersey, which had better schools and was closer to Sonal's work. Thakur continued his ongoing schooling, a master's program in computer engineering, for which BMS was paying. And in-house training in the best manufacturing and laboratory practices also continued. To leave all of this for an Indian generics company seemed like a big step down.

But Thakur was getting restless at BMS and knew that he'd probably risen as far as he could, with little opportunity—at least in the short run—for further advancement. During a summer vacation in 2002, he went to India and stopped by Ranbaxy's research and development center in Gurgaon. He was impressed by the company's bustle and sense of potential. He'd have far more freedom and authority there. The offer was excellent. To his surprise, Sonal also became interested. She missed her family and wanted to return home. They resolved to give it a try.

Thakur set about recruiting several members of his BMS team. It struck his colleague Venkat Swaminathan, a software engineer, as an exciting opportunity. If Ranbaxy was really looking to develop new medications, it could be a welcome change from BMS's restrictive bureaucracy. Dinesh Kasthuril, too, was intrigued. Though he loved his current job and was halfway through Wharton business school, also on BMS's dime, he was impressed that Ranbaxy wanted to try to develop new drugs. And though they were all born in India, none of them had ever worked there before. All

three wanted to contribute to their native country's emergence onto the world stage. "A lot of it was from the heart," Kasthuril recalled.

Their similar views further bolstered Sonal's confidence about the move. She felt that her young family would have friendship and support. The three colleagues thought of themselves as setting off on a momentous adventure: to help build an Indian company dedicated to research, a Pfizer for the twenty-first century. Even as Kasthuril's boss at BMS tried to convince him not to leave, he had to acknowledge that Dinesh Thakur was "able to see things further" than most people could.

Three months before their departure for India, Thakur achieved a long-awaited milestone: he became an American citizen, a fact that he noted proudly atop his curriculum vitae. But by then, he and his colleagues had set their course.

Chapter 2

The Gold Rush

AUGUST 17, 2002
New Delhi, India

On a humid day one year before Dinesh Thakur arrived at Ranbaxy, a company executive boarded a plane at the Indira Gandhi International Airport, bound for Newark, New Jersey. He'd left the office in a "crazy rush," an employee recalled, to catch the almost sixteen-hour flight.

His mission was top-secret. In his luggage were five binders, each about three inches thick, containing reams of data. The documents comprised key portions of what would become an Abbreviated New Drug Application or ANDA, to be filed with the FDA. The application, once completed, would become known in industry parlance as a "jacket."

But this was no run-of-the-mill jacket. The executive carried the most potentially lucrative dossier ever compiled in the generic drug world: the data the company would use in its application to make the first U.S. generic version of the world's best-selling drug of all time: Lipitor. Pfizer's vaunted cholesterol fighter was "the Sultan of Statins," as Wall Street analysts called it. The molecule itself, atorvastatin calcium, was a descendant of Nobel Prize–winning science. Coupled with Pfizer's marketing might, it had become the world's first $10-billion-a-year drug.

Had the Ranbaxy executive's mission been known, a good portion of people in the United States—from patient advocates to members of Congress to the 11 million Americans who relied on Lipitor to lower their cholesterol—would have welcomed him. Everyone in America, it seemed, wanted cheap equivalent drugs. State and federal budgets were buckling under astronomical drug costs. Brand-name Lipitor, though less expensive than its competitors, cost the many uninsured Americans who depended on

it roughly $800 a year. Even for some with insurance, the copays alone were a reach.

In theory, the contents of Ranbaxy's binders could solve that. The data showed that Ranbaxy's version reached roughly the same level of absorption in the bloodstream as Pfizer's and used the same active ingredient, the atorvastatin calcium molecule. If all the claims in its application were true, Ranbaxy's version of the drug would be a godsend for American patients.

At Newark airport, the sun had just risen when a waiting car whisked the man to 600 College Road East in Princeton, New Jersey, Ranbaxy's U.S. corporate headquarters. There the regulatory team—headed by Abha Pant, an intense company loyalist and the only woman to have climbed into Ranbaxy's executive ranks—immediately got to work, combining the core documents from the five binders with other necessary paperwork.

By that night, the final submission was ready. It spanned seventeen volumes and totaled more than 7,500 pages. The jacket covered four different dosage strengths that Ranbaxy planned to make and package at its plant in Paonta Sahib, in the northern Indian state of Himachal Pradesh. The application was handed off to an overnight courier and arrived at the FDA's Rockville, Maryland, campus the next morning, where it was stamped "RECEIVED: August 19, 2002."

But neither Pant nor her colleagues were satisfied, because they had no idea if they'd filed first, which was what mattered most. The first company to file its application, if approved, won the exclusive right to sell the generic for six months, before others joined in. There was a rumor that the generic drug company Teva had already filed. And word had it that the generics companies Sandoz, Mylan, and Barr had also been doing clinical tests. Days and weeks went by with ominous silence.

Inside the FDA, Ranbaxy's application—the cornerstone of the company's plans to reach $1 billion in U.S. sales by 2015—became Abbreviated New Drug Application 76-477. Meanwhile, Ranbaxy executives waited.

Jeffrey Myers, Pfizer's senior patent attorney, was in his office at the company's headquarters on East Forty-Second Street in Midtown Manhattan when he got the notice—a generic drug company had filed an application to make generic Lipitor. That application contained a full-on

challenge of the Lipitor patent, known as a “paragraph IV certification.” Myers sat up straighter in his chair. At that point, Lipitor had been on the market for five years, and its patents were not set to expire until 2011.

Myers learned of patent challenges all the time, but this one drew his attention. “We didn’t have any forewarning,” he recalled.

Of course, Myers knew this day would come. But he was expecting the challenge to come from a well-established generics company, like Mylan or Sandoz. He regularly had lunch with his counterparts from those companies. This was the first challenge he’d ever gotten from an Indian company, one he barely knew. To him, the move was about as legitimate as a pirate scaling the side of his ocean liner.

As he scrutinized the fine print of Ranbaxy’s challenge, he began to see problems. The drug had to be in the same dosage form. Lipitor was sold in tablets. Ranbaxy had filed for capsules, as though its chemists had never seen the original drug. It also proposed to make it in a different molecular form, amorphous rather than crystalline—which was a trick, as Myers well knew, since Pfizer scientists had tried for years to make an amorphous version but had failed because the drug became highly unstable.

Lipitor could not be replicated with ease. It had taken a team of scientists to formulate, the industry’s best marketers to launch, and a manufacturing team that understood its intricacies and challenges. Since 1998, all of the active ingredient for the world’s supply of Lipitor had been made in Cork County, Ireland, at three vast Pfizer-owned plants. Pfizer had expected production to top out with 50 metric tons of active ingredient. Just five years after the drug had launched, that number had quadrupled to 200 tons.

The Ringaskiddy manufacturing plant, which sits on a 200-acre campus and operates twenty-four hours a day, has a “quality culture,” which means that it aims to operate with as close to zero defects as possible. Its employees are routinely trained to GUARD PFIZER QUALITY, as a sign on the wall of one company plant admonished them.

Lipitor is as moody as the slate-gray landscape, but Ringaskiddy has developed a failproof manufacturing system. “The drug is finicky, and we know how to make it,” said Dr. Paul Duffy, Pfizer’s vice president of biopharma manufacturing operations. “When you work with something for twenty years, it’s like your baby, you know its moods.”

In New York, Myers—a lawyer with a PhD in chemistry from Cornell University—suspected that Ranbaxy's chemists were outclassed in the face of a drug they barely understood and probably couldn't even make. Given that, he felt an inkling of excitement for the battle that lay ahead. "I live to obliterate these guys," he later reckoned of his generic drug opponents. "My job is to stop them."

How you saw Ranbaxy depended on where you sat. Myers's view from Pfizer's Midtown Manhattan headquarters was, "once you get down to Ranbaxy, you start to swim with the bottom-feeders." But in many ways, it was an upstart's market. The triumphalism of the branded drug industry was being eroded from beneath by a surging generic drug industry that had both public and political support. Once Ranbaxy's bid to make Lipitor became public, a CNN business reporter assessed it as "a classic David versus Goliath scenario—Pfizer's revenues are about 50 times the size of its diminutive challenger."

Prior to 1984, the Ranbaxys of the world had no way to challenge the Pfizers. There was no clear pathway for a generic drug to be approved in the United States. Under FDA rules, even if a drug's patent had expired, generic drug companies were required to repeat extensive and costly clinical trials, even though the brand companies had already proven the safety and effectiveness of their drugs.

A crusading journalist at the time, William F. Haddad, who relished his role as an underdog, set out to change that. According to one of his colleagues, Haddad had an "extra gland that produces publicity instead of sweat," and he became a media-savvy advocate for generics. He had first worked as an assistant to Senator Estes Kefauver (D-TN), who, as chair of the Senate Antitrust and Monopoly Subcommittee, had fought for consumer protections and battled the pharmaceutical industry. Kefauver had told Haddad about a suspected Pfizer-led cartel to control the price of the antibiotic tetracycline in Latin America. After Kefauver's death in 1963, Haddad wrote a high-profile series about the price-fixing cartel for the *New York Herald Tribune.*

Haddad left journalism and became the head of the all but invisible Generic Pharmaceutical Industry Association. With a small cadre of sympathizers, he began lobbying Congress to create a distinct process for the FDA to approve generic drugs. Politically, the brand companies "had

control of every avenue," he recalled. So Haddad and his group walked the hallways of Congress, trying to make their argument to the few who would listen.

The turning point came in the early 1980s, when Haddad got a meeting with Senator Orrin Hatch, a conservative Utah Republican. He expected the senator to be aligned with the Big Pharma cause. Unexpectedly, Hatch listened with real engagement and interest. In a two-hour meeting, Haddad explained to the senator that the patents for more than 150 drugs had expired, yet the brand-name medications faced no competition because there was no way to get a generic approved through the FDA. As a result, Americans were forced to pay too much for their medicine. "He was questioning me like a district attorney," Haddad recalled.

He was stunned when, a few days after the conversation, Hatch called him up and said, "I think you may be right." The senator joined forces with a Democratic congressman from California, Henry Waxman. Together, they pressured the Big Pharma CEOs into agreement and drafted a law that established a scientific pathway at the FDA to get generic drugs approved. It was the Abbreviated New Drug Application. No longer did generic drug companies have to prove the safety and effectiveness of their drugs from the ground up, as the branded companies did with costly long-term clinical trials. Instead, the companies could win FDA approval with more limited tests to prove their drugs were bioequivalent and performed similarly in the body.

But there was another major hurdle. During the deliberations, one generic drug executive pulled Haddad into a corner and said, "Look, what if I sue and I win. What do I get?" What incentive was strong enough to justify the up-front costs of developing a generic version of a drug, the possibility of litigating against brand-name drug companies intent on defending their patents, and perhaps failing on both counts?

The solution, called the "first-to-file" incentive, transformed the generic drug industry. It allowed the company that first filed its generic application with the FDA to reap a big reward: the right to sell its drug exclusively for six months at close to the brand-name price, before other generic competitors jumped in and the price plunged. Being first became the difference between making a fortune and making a living.

The Drug Price Competition and Patent Term Restoration Act, which became known as Hatch-Waxman, passed unanimously in the House of

Representatives, 362–0, in 1984. Though a huge victory for generic drug makers, it also extended by a few years the length of patents for brand-name companies. President Ronald Reagan signed the legislation in a Rose Garden ceremony that September. Touting the benefits of lower-cost drugs, he told his audience, amid laughter, “Senior citizens require more medication than any other segment of our society. I speak with some authority on that.”

The Hatch-Waxman bill “really started the generics industry,” said Haddad. “It gave it its footing, it gave it its foundation, it allowed the companies to grow, it reduced the prices dramatically.”

It was also clear from the outset that generic drug companies could make a huge profit. The day the bill went into effect, companies sent “tractor trailers full of ANDAs” to the FDA, recalled a former agency bureaucrat. “We got one thousand applications within the first month of the program.” The volume of bids—coupled with the potential jackpot of first-to-file—underscored that a generic drug factory was, as one of the FDA’s earliest generic drug chiefs, Dr. Marvin Seife, claimed, “a place where you put raw materials into a mixing vat, turned the spigot and out comes gold.”

Inside generic drug companies, the first-to-file incentive ignited a frenzy. “Nothing was more important,” said Jay Deshmukh, Ranbaxy’s former senior vice president for global intellectual property. At issue was not just what day the application arrived at the FDA’s Rockville, Maryland, campus, the agency’s headquarters for generic drugs, but in what order. “Minutes mattered,” said Deshmukh.

As the competition grew, so did the waiting. In the run-up to a patent expiration date, it was not uncommon to see generic drug executives asleep in their cars in the FDA parking lot overnight in order to be first at the door when the building opened. Periodically, a tent city would sprout in the parking lot, with executives camping out for weeks at a time. Each company had a strategy for how to wait and how to be first. Some paid line-sitters to wait in the parking lot. Teva booked hotel rooms nearby and rotated staff throughout the night.

On the cold, clear night of December 23, 2002, with Christmas just two days away, the FDA parking lot was crowded. The FDA had shut its doors hours earlier. But representatives from four different generic drug companies—Ranbaxy, Teva, Mylan, and Barr—were waiting in line,

stamping their feet and clapping their gloved hands to stay warm. Ranbaxy had sent two of its most reliable staffers in a stretch limousine, so they could take turns sleeping and waiting.

Everyone had just one goal: to be first through the FDA's doors when the agency opened the next morning. They had all brought applications to make generic versions of a drug called Provigil, manufactured by Cephalon, to combat daytime sleepiness—a bonanza for whichever generics company filed its application first.

As the sky began to lighten, a Ranbaxy executive fully intended to keep his place at the head of the line. But just as the doors opened, a Mylan employee, a petite young woman, pushed him out of the way and rushed through the door to get the coveted time stamp, signifying first place.

Back at Ranbaxy corporate headquarters, the director of U.S. regulatory affairs, Abha Pant, had to console herself with second place. It was not a total loss, because being first was not a guarantee of success. The FDA would consider only applications it deemed "substantially complete." This was to prevent generics companies from tossing down half-baked applications as placeholders so as to be designated first while they figured out how to actually make the drug. So Pant never gave up hope. Being second was as critical. She would be waiting for the first one to trip and fall.

The FDA struggled to put a stop to the camping problem. In July 2003, the agency amended its rules so that any generics company that delivered its application on a certain set day could potentially share six months of exclusivity. In written guidance to the industry, the FDA noted:

> Recently, there have been a number of cases in which multiple ANDA applicants or their representatives have sought to be the first to submit a patent challenge by lining up outside, and literally camping out adjacent to, an FDA building for periods ranging from 1 day to more than 3 weeks. Concerns about liability, security, and safety led the property owners to prohibit lines of applicants before the date submissions may be made.

Though shared exclusivity was somewhat less attractive, first-to-file remained the most lucrative opportunity for generic drug companies.

For Ranbaxy, the applications remained essential to its strategic plan, dubbed "Garuda Vision," after a soaring Hindu eagle. Lest any employee forget the company's goal, a framed poster headlined "2015 Strategy" hung on the walls of the New Jersey office. The first bullet point, in bold, was "significant FTF filings annually" below the headline "USA: $1 billion sustainable profitable business by 2015." As one of Ranbaxy's CEOs,

Davinder Singh Brar, explained in a company-sponsored book, the billion-dollar dream was a “vision . . . etched in every employee’s mind.”

Inside Ranbaxy, overseeing the first-to-file applications fell to Jay Deshmukh, the lean, sardonic attorney who specialized in intellectual property. Back in 1998, as a bored young lawyer in Cincinnati, he saw a surprising ad in the *Journal of the Patent and Trademark Office Society*. Ranbaxy was looking for a patent lawyer. “I had never seen an Indian company asking for a patent lawyer,” Deshmukh recalled. He applied on a whim.

Deshmukh, an Indian-born chemical engineer by training, was intrigued by the prospect of working at Ranbaxy, especially after meeting the visionary managing director Dr. Parvinder Singh, whom he found to be “extremely smart and personable.” Deshmukh ended up taking the job and doubled his salary. He relocated his young family to Princeton, New Jersey. Though it seemed like an excellent career move, above all he viewed the job as a “going home kind of thing, contributing to India.”

Knowing little about Indian corporate culture, he immediately found himself in a “very paternalistic” environment, where “your boss is your father—he’s always right.” Deshmukh immediately locked horns with his boss. Within a year of joining the company, he requested a meeting with Parvinder, in which he asked to report directly to the CEO, D. S. Brar, instead. Parvinder consented. In doing so, Deshmukh cemented his future role in the company, as Brar became Ranbaxy’s managing director a year later. It was Brar who encouraged Deshmukh to aim for generic Lipitor.

Inside the company, the Lipitor quest was not just your average commercial endeavor. “The lure of the drug was irresistible, like a gorgeous naked woman who is not your wife,” said Deshmukh. “It’s hard for guys to say no. How could we not?”

On October 9, 2002, almost two months after Ranbaxy had filed Abbreviated New Drug Application 76-477, the FDA broke its silence, first with a phone call and then with an official letter: Ranbaxy had indeed filed first, and its application to make atorvastatin, the company’s generic version of Lipitor, would be evaluated.

The news led to rejoicing inside Ranbaxy. The FDA parking lot had been empty when Ranbaxy filed its application, because the company was so far ahead of its rivals. Now there was a path to the largest generic drug

jackpot in history. But huge obstacles remained. First, FDA regulators had to deem the science in the dossier to be worthy. Ranbaxy's testing data would have to demonstrate, to the agency's satisfaction, that its generic Lipitor would release an equivalent amount of the active ingredient into a patient's bloodstream. After that, Ranbaxy would have to survive attack by an army of Pfizer's patent lawyers, who'd successfully been standing sentinel around the drug for years. Ranbaxy would have to follow the careful choreography, and withstand the scrutiny, of the world's most dominant drug market.

In theory, all the companies had to follow the same rigid set of good manufacturing practices. But for companies that were inclined to emphasize profits instead of quality, there were many avenues for improvisation—and shortcuts. Deshmukh acknowledged that the incentive of first-to-file created a "Wild West" environment in which companies had to not only become first filers but protect those applications at all costs. That drive—to be first and stay first—led to a stark choice for Ranbaxy, just months before Dinesh Thakur arrived at the company.

In May 2003, Ranbaxy's top executives gathered in the conference room of a hotel in Boca Raton, Florida, for what was supposed to be a nuts-and-bolts operational meeting. The company CEO, D. S. Brar, presided in his impeccable turban. Rashmi Barbhaiya, the director of research and development who had recruited Thakur, was there. So was company president Brian Tempest. Their discussion was quickly subsumed by a topic that had dominated email chains and led to the creation of a closely guarded report, its contents restricted to those in the room.

Three months earlier, the company had launched Sotret, its version of the brand-name anti-acne drug Accutane made by Roche, onto the U.S. market. As the first low-cost version available to American patients, it resulted in instant market share and was another vital step toward the company's larger goal to achieve $5 billion in global sales within a decade.

But just a few days prior to the meeting, the Ranbaxy executives had suspended the profitable Sotret launch. They told U.S. regulators that they had seen a "downward trend" in how rapidly the 40-milligram capsule dissolved and would temporarily withdraw three lots of it from the market while they completed their probe of the cause. But that was a lie. Their random tests of Sotret had shown that the formulation was failing. Under