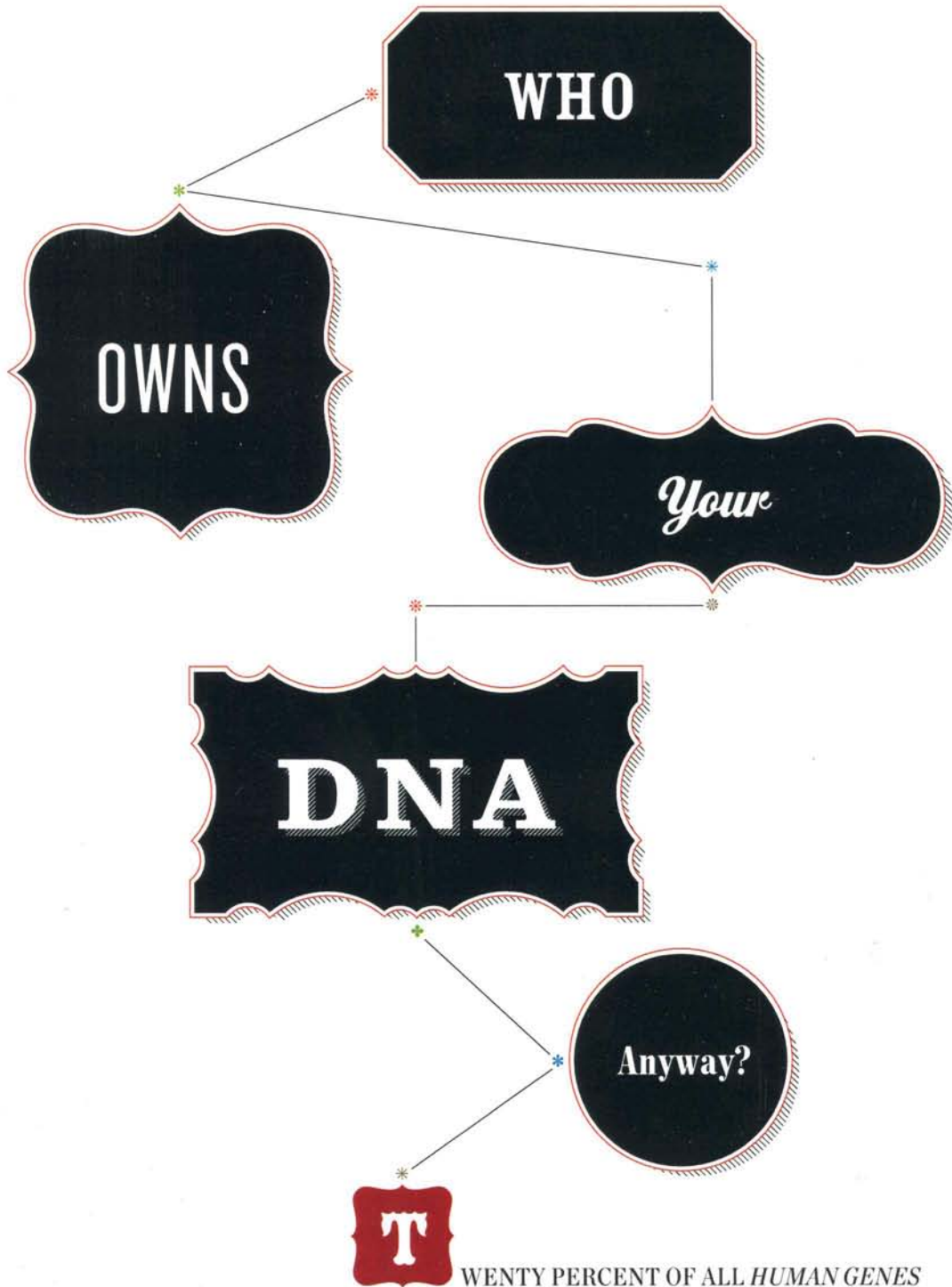




LORI ANDREWS

A LEGAL PIONEER

who focuses on the ethical issues raised by cutting-edge science, photographed on a set inspired by images of life, death and nature.



TWENTY PERCENT OF ALL HUMAN GENES HAVE BEEN *PATENTED* BY THE COMPANIES THAT ISOLATED THEM. THAT MAY NOT SEEM LIKE A BIG DEAL, UNTIL YOU HAVE TO PAY \$3,340 FOR A BREAST-CANCER TEST THAT COULD HAVE COST \$300. BIOETHICIST **LORI ANDREWS** IS FIGHTING BACK—ALL THE WAY TO THE SUPREME COURT

By NINA BURLEIGH / Photographed By DAN WINTERS



I was 14 years old when my grandmother, a laughing, round-faced Swedish immigrant who liked nothing better than taking a brisk walk with her grandchildren, called to announce she'd been diagnosed with advanced ovarian cancer. Within a few weeks she was living in our house, her belly swelled up with the cancerous fluid called ascites, lying

in bed in a state of unrelenting nausea, with my dad—her son—carrying her regularly to the bathroom so she could vomit. A few weeks later, she was in the hospital. And a few weeks after that, she was dead. Witnessing this as a healthy teenager was horrifying. Far from fading, the memory of my grandmother's death has loomed over me ever since, because, it turns out, that exact cancer afflicted her mother, my great-grandmother.

Three decades later, in my forties, I started experiencing pain in my lower right abdomen. It was variously diagnosed as endometriosis or irritable bowel syndrome. At one routine physical, I mentioned the family history, and my GP suggested I get checked out by doctors conducting an ovarian-cancer study at New York University. There, a sonogram picked up an 11-centimeter mass. My doctor thought it was just a fibroid, but she strongly recommended that I get the test for the BRCA gene; if I had the dreaded female cancer mutation, it would make me 15 to 40 percent more likely to get ovarian cancer.

She wrote the prescription, and I called my insurance company for prior approval. It refused, on the grounds that the ovarian cancer is on my father's side of the family, not my mother's, and is therefore less likely to be passed down (though doctors consider maternal and paternal family histories of cancer equally). Of course, I could have had the test if I paid for it myself. But it cost \$3,340, and I had two kids and an underemployed husband.

Fast-forward three years to today: The fibroid is still there. My doctor, who checks on the lump every six months, assures me that if it were cancer, it would be growing, which it isn't. Although that's reassuring, I'd enjoy more peace of mind if I knew my BRCA status. Which I don't. The test still costs thousands of dollars. And I still cannot afford it.

But if bioethicist Lori Andrews succeeds at the U.S. Supreme Court, I may be able to have the test for a price closer to \$300. Right now the BRCA test is very expensive because the gene has been patented by some of the researchers who helped to isolate it. Myriad Genetics, the patent holder and sole provider of the diagnostic test for the gene, has the right not only to set the price for the test but also to approve or prevent any non-Myriad research involving the gene. Should a commercial entity be entitled to patent a human gene, as if it were a product the company had invented? Andrews, who is also a lawyer, says no. "Patenting a genetic sequence is like patenting the alphabet and charging us a royalty each time we speak," she once told CBS News, and since 2005 she has been

working with other lawyers to overturn the patent. Now the case has a good chance of reaching the Supreme Court.

That is why, on a sunny summer day last year, I visit her in Chicago. Even though the skirt suit she's wearing is a TV-ready purple, Andrews, 59, is so slight that she nearly disappears in her large, glass-walled corner office on the fifth floor of the Chicago-Kent College of Law. Petite and fair, she brings to mind Reese Witherspoon's character in *Legally Blonde*. Decades ago, when she was a newly minted graduate of Yale Law School, the elders at her firm openly called her the lawyerette.

Thirty years on, that lawyerette has staked a place for herself on the futuristic edge of her field, where ethics tries mightily to keep pace with technology. "I have been an early-warning system about technologies and about what can go wrong in a society that is hugely enthusiastic about technologies," she says as assistants hand her one document after another. "Throughout my career, I've looked at the impact of technology on individuals and on society as a whole. And women have been central from the beginning."

Fueled by iced tea, chocolate and Coca-Cola, Andrews is variously described by colleagues as a phenomenon and a dynamo. She lives alone in a Chicago town house, where she says she gets by on four or five hours' sleep and spends her off-hours writing mystery novels (in all, she's published 14 books of fiction and nonfiction). Her ex-husband, with whom she has a son, now 23, is apparently still besotted, since he buys her a piece of jewelry every time she notches up another book or major legal win. On the day we meet, she is wearing one of his many postdivorce presents, a delicate antique amethyst-and-gold Art Nouveau necklace.

Born and raised in suburban Chicago, the elder of two daughters of a pharmacist and a homemaker, Andrews has been an overachiever since high school, when she began publishing articles in teen magazines. Her mother was "hugely disappointed" by her decision to go to law school, Andrews tells me. "She said, 'Listen, I don't need a lawyer—I'm not going to divorce your dad, I don't want a name change, and I already have a will. But if you went to beauty school, you could do my hair once a week.' She was serious. This wasn't ribbing me."

Andrews passed the bar exam in 1978, on the day the first test-tube baby was born. Launching her career, she gamely fended off all the era's first-woman-in-the-office sexism, which her personal appearance only exacerbated. After carving out a specialty in the legal twists and turns of reproductive technology, she founded Chicago-Kent's Institute for Science, Law and Technology, which she still heads. "I came of age with the first generation of legal abortion," she says. "Even a conservative female justice of the Supreme Court, Sandra Day O'Connor, talked about how reproductive control was central to women getting educated and having careers."

Eventually, Andrews's niche expertise in reproductive technology made her the person to call for anyone with law-health-tech issues, and in 1995 she was appointed chair of the advisory committee to the Human Genome Project. By that time, the cases that were finding their way to Andrews

had gotten so bizarre that her secretary thought some of the phone messages were practical jokes. A surgeon once called from the OR to ask if it was incest to implant an embryo in a woman's womb if the sperm had come from her brother. A U.S. senator asked if he could ban genetic engineering by making it a crime to insert DNA into an egg. (Her response: only if you are banning all forms of reproduction.) She has considered a variety of unreal-sounding issues, including whether a cryogenically preserved head can inherit property and whether sperm extracted from the comatose can legally be used to make babies. "Usually they are looking for someone who can say, 'Here's the likely legal input if we go down this route,'" says Andrews. There are few precedents to quote in these areas; Andrews uses her experience in the field to engage in highly informed speculation. "In part," she says, "my work is like writing science fiction."

At the same time Andrews was honing her skills, researchers at the University of Utah in Salt Lake City were working toward a breakthrough that would have a tremendous impact on women's health and give Andrews the biggest case of her career. In 1994 researchers sequenced the BRCA genes. One of the researchers had formed Myriad Genetics and under its name applied for patents on the discoveries; the company was awarded 23 patents covering the genes and the testing for them. This means, in practical terms, that every woman who takes the BRCA test must pay a fee to Myriad and that no researcher can study the gene sequence from any woman without Myriad's permission. Myriad has also developed a supplemental test, called BART, that detects another, rare type of mutation in the genes. Cost: an additional \$700. Finally, because the company has done so much testing, it has better information than any other company or research group about which mutations in the gene sequence cause breast and ovarian cancer. It used to share this information with a public database maintained by the National Institutes of Health. But recently Myriad stopped sharing, preferring to build its own database.

All these actions, from taking out the patents to keeping data private, are currently legal in the United States. To understand why, back up to 1980. Under American law, it has long been impossible to patent a "product of nature"—a duck, a lemon, a finger. Patents can be issued only on inventions. Then, in 1980, the Supreme Court held that patents could be granted on "anything under the sun that is made by man." The U.S. Patent and Trademark Office interpreted that decision to mean that once a gene, or any other part of a living organism, was removed from the body and isolated or altered, it could be patented by, and considered the property of, the company that had done the work. The patent office itself determines, on a case-by-case basis as it reviews

applications, what exactly constitutes altering a product of nature. Today, of the estimated 25,000 genes in the human body, 20 percent have been patented, including genes associated with Alzheimer's, colon cancer and asthma.

Of the genes now patented, the one for breast cancer is among the most lucrative. For the fiscal year that ended in June 2011, Myriad's BRCA test accounted for \$345 million, or 86.4 percent, of the company's total revenue. But these profits did not come without a significant initial investment—which is the strongest argument in favor of the practice of patenting. It boils down to economics: Scientists need money to do their work, and without the commercial rewards from gene patenting, say patent holders, research and development will grind to a halt. "Myriad spent over \$500 million between 1995 and 2005," says Myriad chief counsel Richard Marsh. "It took us 10 years to recoup our investment. Nobody will make that investment without the promise of patents." In addition, he points out, the company's patents will start to expire in 2014, 20 years after they were first granted. "Patents are only for a limited time," he says, "and people need to remember that."

When asked about Myriad's decision to stop contributing to the NIH database, Marsh said, "Part of our concern was that people were starting to rely on the data in the database to make clinical decisions, and we were concerned about the rigor and quality of information going into the database. We still want anybody who wants to do research with the BRCA gene to do whatever they want. We encourage people to research and publish, and we have never resisted that." A spokesperson for the company says that Myriad does not charge a fee to use the gene for research and that it has never denied or impeded any research on the genes.

WHEN ANDREWS WENT TO LAW SCHOOL, HER MOTHER SAID, **"Listen, I don't need a lawyer—I'M NOT GOING TO DIVORCE YOUR DAD, I DON'T WANT A NAME CHANGE, AND I ALREADY HAVE A WILL, BUT IF YOU WENT TO *beauty school*, YOU COULD DO MY HAIR ONCE A WEEK."**

But in Andrews's view, Myriad's profits have come at women's expense. For the past decade, she has argued that the restrictions imposed by patent holders cause financial hardship and health risks for millions of women. Big biotech concerns are "putting patents before people," she says, contending that besides forcing sick people in need of tests to pay fees to patent holders, patents restrict researchers from devising better tests and treatments. She argues that under current law, merely "thinking" about patented genes in terms of further research is illegal because the patent holder controls all uses of his or her invention. "This ability to control all uses makes



became the lawyer for the American Medical Association and filed an *amicus curiae* (friend of the court) brief. In 2010 a federal judge trying the case accepted the argument that genes were unpatentable products of nature, a huge victory for Andrews and her side. But Myriad appealed. Court observers were stunned when the U.S. Justice Department, which had previously supported gene patenting, filed a brief supporting Andrews's view.

Then, in July 2011, a three-judge appellate court overturned the trial court's decision two votes to one. The ACLU appealed to the Supreme Court, and lawyers on both sides expect the high court to take the case. "From the beginning, we've known this was destined for the Supreme Court," Andrews told me after Myriad's successful appeal. "There's far too much at stake to leave it in the hands of the lower courts. For the past 150 years, the Supreme Court has said that no one can patent a product of nature, so I feel confident that the justices will right this wrong."

Andrews's passion on the subject has convinced many people, but according to some, it is also her professional weakness. "Andrews has been honing her argument for about 10 years," says Kevin Noonan, a Chicago-based patent lawyer who filed an *amicus* brief in favor of patenting. "She's

certainly a galvanizing force against gene patenting. The problem for patent lawyers is that a lot of the argument is so emotional. Phrases like 'human life commodified.' Well, I say, fine! Let's run the world your way. Then either nobody invests or nobody shares information."

Andrews's personal outrage and "emotional" talk, as Noonan puts it, has attracted powerful enemies. Andrews says she gets hate mail "all the time" from patent attorneys: "I've written on embryo research, and even the right-to-life people who send me hate mail don't write as devastating mail as the lawyers." Chicago-Kent Law dean Harold J. Krent says prospective students have been known to apply specifically to work with Andrews. Yet even he has felt the heat in the wake of controversy she's stirred up. "I have somebody on my board of overseers who wasn't always thrilled with the positions she took, particularly in the genetic-patent area," Krent says. "He understood that there's academic freedom, but he had been general counsel to a big pharmaceutical company. I think it's important in an institution to have people who speak their mind, even if it is adverse to the financial interest of members of the board or members of the community."

sense for a machine," Andrews says, "but not for the information code of the human body." She unpacks example after example in the even, measured tone of someone expert at provoking disagreement without raising blood pressure. The company that has the patents on the hepatitis C genome, she says, has prevented other companies from offering inexpensive tests for the deadly disease, and gene patents have also resulted in people's deaths, when patent holders have withheld use of their genes for diagnostic testing in anything other than the patented use. She insists that a gene is a product of nature even in its isolated form and shouldn't be subject to patent. "If isolating a bodily product were enough to make it patentable," she says, "the first doctor to remove a kidney would have been able to get a patent covering all kidneys and get a royalty each time any other doctor removed one."

In 2005, Andrews enlisted the American Civil Liberties Union to represent women and doctors against Myriad's breast- and ovarian-cancer gene patent, and in 2009 the ACLU and the Public Patent Foundation—representing 150,000 researchers—filed a lawsuit on the grounds that Myriad's patents are unconstitutional. Andrews herself



he Myriad suit may be Andrews's most high-profile case, but it is not her first foray into the legal issues raised by gene patenting. That distinction belongs to a case very close to home, in suburban Chicago. A local family, the Greenbergs, had two babies with Canavan disease, an inherited brain disorder that is always fatal, usually in childhood. Early on, the Greenbergs got involved with trying to help doctors and researchers develop a prenatal test and find a cure. They recruited dozens of other families of children with Canavan to provide samples of blood and urine, and after their own older child died, they even turned over tissue from the autopsy. In 1993 one researcher the Greenbergs had been working with, Reuben Matalon, MD, identified the Canavan gene.

Once the gene was isolated, hospitals around the world started prenatal screening; in 1996 the Canavan Foundation offered free testing at Mount Sinai Hospital in New York City. But in 1997, Miami Children's Hospital, where Matalon then worked, obtained a patent on the gene and would not allow any further testing without a license from the hospital and a royalty payment of \$12.50 per test. The hospital also limited the availability of testing.

Andrews took the Canavan case, as it is popularly called, pro bono on behalf of the Greenbergs. Working on a shoestring budget, she attacked the patent on the grounds that for the first years of research, the Greenbergs and other parents had not given their informed consent. Matalon had taken blood and tissue samples from the Greenbergs without asking them to sign anything; when consent forms were finally written and signed, she alleged, they didn't include any information about patents or about the hospital's intent to commercialize the findings. The case was settled, and per the terms of the agreement, Miami Children's Hospital maintained its patent and the right to charge a royalty for clinical testing but agreed to allow license-free use of the gene for research. "It nearly killed me," Andrews says of the case, describing how she had to fly to Miami repeatedly, on her own dime, and file documents herself, as opposed to hiring a paralegal to do so.

Chicago-Kent associate law professor Ed Kraus worked with Andrews on the Canavan case and recalls the scene as she argued that gene patenting was wrong. "We were meeting with these confident, big-firm intellectual property lawyers," Kraus says. "And Lori explained this brilliant, unexpected legal theory. Seeing this petite, blonde-haired law professor, they dismissed her theory as naive and idealistic. Now, it's a few years later, and Lori's 'naive' theory will soon be considered by the Supreme Court." Kraus is an unabashed fan. "Her brain never stops working," he says. "It's not just the sort of raw intelligence she has. The speed at which she processes information is freaky. She has unbridled energy for pursuing important legal issues."

That energy has led her far beyond legal circles. Andrews likes to involve artists and writers in analyzing the big, vexing philosophical questions she deals with, such as, Who owns our bodies? And what does decoding the genome—the building blocks of life—really mean for humanity? "Philosophers and economists have just started thinking about what society

will look like in the post-genome era, but writers and artists have been thinking about it for a long time," she says. At one conference she organized, she met and became close friends with the author Michael Crichton, in whom she found a kindred spirit. She taught Crichton her bioethics course over the phone—she in Chicago, he in California—inspiring him to write a scathing *New York Times* Op-Ed about gene patenting. Noonan credits the Op-Ed she inspired with kicking off the anti-gene-patent movement. Crichton also wrote a book on the topic, *Next*, before he died in November 2008.

Three years after Crichton's death, Andrews still cannot speak of him without choking up. She wants me to see his last speech about gene patenting and clicks on a video embedded in her laptop. As we watch, she wipes tears off her cheeks. "He was a very private, private person," she says after regaining her composure. "He would show up at my conferences and just sit in the back and leave after and never say who he was. He never wanted attention. He came to the Supreme Court with me. I mean, he is like six foot eight or six foot nine; I'm five one. You can just imagine us walking up the steps there."



As the Myriad case heads for the Supreme Court, Andrews is moving on to something new: the potential perils of social media. She became interested a few years ago when an acquaintance's daughter friended her on Facebook. The young woman was in her early twenties and applying to college. Looking at her Facebook page, Andrews noticed frequent references to a violent Facebook game called Mafia Wars, in which players pretend to be gangsters building their own criminal empires. Andrews, whose professional path was paved with ambition, deliberation and personal restraint, was appalled. She called the young woman and advised her to start deleting. "She didn't believe me when I told her that colleges and employers were turning down applicants because of Facebook posts," Andrews says. "So I started collecting cases and surveys to send her."

In the course of assembling that information, Andrews learned that 35 percent of employers reject job applicants because of information found on social networks and that women bear the brunt of the damage; they are more likely than men to be penalized for revealing themselves online dressed provocatively in photos, or writing about getting drunk, or complaining about past employers, coworkers or clients. Andrews explores the legal pitfalls of social media in her new book, *I Know Who You Are and I Saw What You Did*, out this month.

Andrews wouldn't be caught dead posting a sexy picture of herself, but asked about the *Legally Blonde* comparison, she doesn't bother to deny it. "I realize that as I speak, I'm fiddling with a pink pen with, like, marabou feathers on it," she says. But overall, being cute and short has its career advantages: "Because, you know, people didn't expect that I'd actually be able to write a kick-ass brief." *

NINA BURLEIGH is the author, most recently, of *The Fatal Gift of Beauty: The Trials of Amanda Knox*.