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THE WASHINGTON UNIVERSITY V. CATALONA: 
DETERMINING OWNERSHIP OF GENETIC SAMPLES

Scott F. Gibson*

ABSTRACT: The ownership of tissue samples donated for medical research is an ongoing subject of dispute. Some advocates assert that patients have ongoing ownership rights in their tissues, including an unfettered right to determine what happens to their tissue sample. Researchers argue that giving patients property rights in their samples will turn the human body into a commodity and bring research to a screeching halt. One thing is certain: the creation of commercial products from human tissue has generated very difficult legal and ethical questions that have no clear, universally accepted answers. When those questions have come up in litigation, the courts have struggled to adapt the tradition and precedent of the law to the challenges arising from the biotech era. The case of The Washington University v. Catalona is the most recent instance of a court seeking to resolve this dilemma.


Michael Crichton’s novel Next1 follows various legal, ethical, and moral dilemmas arising in the era of biotechnology and personalized medicine. One of the story lines follows Frank Burnet, a man with a rare genetic makeup that his treating physician had commercially exploited and sold to a biotech company. Burnet filed suit claiming that he had been duped into turning over the rights to his genetic information through ongoing testing, which he believed was a necessary part of his treatment. After losing all legal claims to an ownership interest in his tissue samples held by the biotech company, Burnet conspires to have the cell line destroyed and then disappears.

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Outraged, the company files suit asserting that Burnet, his attorney daughter Alex, and eight-year-old grandson Jamie are in possession of stolen property—the genetic information within their own bodies—and engages the services of bounty hunters to return the “stolen” cells, by force if necessary. The bounty hunters attempt to kidnap the boy from school by posing as an employee from his doctor’s office, but the effort fails when suspicious school officials contact Alex directly. When Alex unexpectedly arrives at the school, the bounty hunters attempt to kidnap her instead, but she escapes with the assistance of pepper spray and a well-placed high heel to the throat. Mother and son flee the bounty hunters while Alex’s law partners frantically contest the legal proceedings in court. Ultimately, Alex and her son are saved from the bounty hunters when, after considering the matter over night, the judge rules that the company’s ownership of Burnet’s tissue “does not entitle them to take these cells from any individual, living or dead, including Mr. Burnet himself.”

2. The novel contains the following exchange of dubious legal advice between legal counsel and the head of the biotech company:

   “Three courts have ruled that Burnet’s cells are your property. You therefore have a right to take them.”
   “You mean, take them again.”
   “Correct.”
   “Except the guy has gone into hiding.”
   “That is inconvenient. But it does not change the material facts of the situation. You are the owners of the Burnet cell line,” Rodriguez [the attorney] said. “Wherever those cells may occur.”
   “Meaning . . . ”
   “His children. His grandchildren. They probably have the same cells.”
   “You mean, I can take cells from the kids?”
   “The cells are your property,” Rodriguez said.
   “What if the kids don’t agree to let me take them?”
   “They may very well not agree. But since the cells are your property, the children don’t have any say in the matter.”
   “We’re talking punch biopsies of liver and spleen, here,” Diehl [the president of the company] said. “They’re not exactly minor procedures.”
   “They’re not exactly major, either,” Rodriguez said. “I believe they are ordinary outpatient procedures. Of course, you would have a duty to make sure that the cell extractions were performed by a competent physician. I assume you would.”
   Diehl frowned. “Let me see if I understand. You’re telling me I can just grab his kids off the street and haul them to a doctor and remove their cells? Whether they like it or not?”
   “I am. Yes.”
   “And how,” Rick Diehl said, “can that be legal?”
   “Because they are walking around with cells that are legally yours, hence with stolen property. That’s felony two. Under the law, if you witness a felony being committed, you are entitled to perform a citizen’s arrest, and take the offender into custody. So if you were to see Burnet’s children walking on the street, you could legally arrest them.”

   Id. at 251–52.

3. Id. at 393. After announcing his decision, the judge embarks on a diatribe against the private ownership of genetic material, arguing that “this situation has arisen out of confusion from prior court rulings as to what constitutes ownership in a biological context.” Id. The judge concludes his statement with an impassioned call for reversal of prior court decisions:

   But in the end, the Burnet case has gone awry as it has because of a profound and fundamental error by the courts. Issues of ownership will always be clouded when individuals are able to manufacture
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Though the scenario in the novel is, at best, far fetched, it highlights the concerns surrounding the ownership of genetic information and products derived from that information. It also accentuates the legitimate concerns raised by Crichton and others about the legal, ethical, and policy implications of allowing patents on human genetic material, as well as concerns about ownership of genetic samples and the commercial products flowing from those samples. “The creation of commercial products from human tissue has raised difficult questions about profit and property, consent and control, and ownership of the human body,” including, among others, the following:

- Should public policy restrict the commercialization and ownership of human genetic material in an effort to prevent the development of an “anticommons,” that is, knowledge that is “the antithesis of the traditional pool of common knowledge that all scientists freely share”?\(^4\)

- In light of the substantial financial incentives for researchers who isolate, patent, and commercialize genetic information, can anything be done to keep researchers from hoarding tissue samples rather than sharing those samples with other scientists studying the same medical condition?\(^5\)

- Is it possible to draft informed consent forms that adequately address the diverse cultural, religious, and personal values of the patients providing samples?

within their bodies what the court has ruled someone else owns. This is true of cell lines; it is true of genes, and of certain proteins. These things cannot reasonably be owned. It is a standing rule of law that our common heritage cannot be owned by any person. It is a standing rule that facts of nature cannot be owned. It is a standing rule of law that our common heritage cannot be owned by any person. It is a standing rule that facts of nature cannot be owned. Yet for more than two decades, legal rules have failed to affirm this concept. Patent court rulings have failed to affirm this concept. The resultant confusions will only increase with time, and with the advances of science. Private ownership of the genome or of facts of nature will become increasingly difficult, expensive, obstructive. What has been done by the courts is a mistake, and it must be undone. The sooner the better.

\(\text{Id. at } 395.\)


5. Gary Stix, Owning the Stuff of Life, SCI. AM., Feb. 2006, at 76, 80. The “tragedy of the anticommons” was identified as a concern in biomedical research in a 1998 article in Science written by two professors at the University of Michigan Law School. Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCI. 698 (1998). They analogized their concerns to the “tragedy of the commons,” which holds that scarce resources held in common are overused because “too many owners each have a privilege to use a given resource and no one has a right to exclude another.” Id. at 698. Anticommons property, they argued, is the mirror image of commons property. “[T]he recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an ‘anticommons’ in which people underuse scarce resources because too many owners can block each other.” Id. The development of the anticommons is “an unintended and paradoxical consequence of biomedical privatization.” Id. Once a body of anticommons develops in an area of biomedical research, “collecting rights into usable private property is often brutal and slow.” Id. Critics argue that if the body of “anticommons” is allowed to expand, exclusionary patent rights will deter discovery and innovation in biomedical research by increasing the cost and complexity of conducting research. Id. at 700.

Because donors have diverse cultural, religious, and personal values, is it ethically permissible to use tissue samples in a manner that varies from the scope of the initial informed consent?

What input, if any, should family or community members have in a donor’s decision to provide tissue?

“Is it appropriate to use stored biological materials in ways that originally were not contemplated either by the people from whom the materials came or by those who collected the materials?”

Can donors prohibit the “unauthorized and unwanted use of, or commercialization of, their tissue samples?”

What remedies, if any, should the law provide donors whose samples are used in unauthorized or unwanted ways?

When and to what extent should donors be allowed to profit from the commercialization of their genetic information?

Are researchers required to disclose their financial interests in the commercialization of tissue samples?

Once patients voluntarily donate their tissue, when and to what extent should they be allowed to direct what happens to that tissue?

Do tissue samples belong to the facility that maintains the biorepository, the researcher who directed the study where the tissue was collected, or to the participants who donated the tissue?

Like many questions arising in the era of biotechnology and personalized medicine, these questions have no clear, universally accepted answers. A recent article summarizes the ambivalence raised by these questions.

How you should feel about all this isn’t obvious. Scientists aren’t stealing your arm or some vital organ. They’re just using tissue scraps you parted with voluntarily. But still, someone is taking part of you. And people often have a strong sense of ownership when it comes to their bodies. Even tiny scraps of it. Especially when they hear that someone else might be making money off those scraps. Or using them to uncover potentially damaging information about their genes and medical histories.

Though these questions inspire varied answers, the law must resolve those diverse viewpoints into a thoughtful, coherent, and useful statement of public policy. Ownership and control of tissue samples are at the heart of this dispute, a dispute that surfaced again in Washington University v. Catalona, which

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held that patients did not have continuing property rights in the research samples they had donated.\textsuperscript{11} Resolving this dispute against the donors engenders the heartfelt emotional response articulated above; resolving the dispute in favor of the donors threatens to devastate the way in which medical research is conducted and turns the human body into a commodity.

This article considers the current state of the law regarding ownership of tissue samples. Part I addresses the massive number of tissue samples currently being stored in the United States. Part II reviews the three reported cases that have considered the ownership of genetic materials, with an emphasis on the recent Catalona decision. Part III raises additional considerations that may have contributed to the Catalona decision.

I. THE UBIQUITOUS NATURE OF TISSUE SAMPLES

Physicians and scientists have been storing human biological materials for more than a century.\textsuperscript{12} As a result of that practice, a staggering number of tissue samples are being stored throughout the United States. A report issued in 1999 makes a “conservative estimate” that more than 307 million tissue samples from more than 178 million people were being stored in the United States, a number estimated to be increasing by some 20 million samples a year.\textsuperscript{13}

“These tissue collections vary considerably, ranging from formal repositories to the informal storage of blood or tissue specimens in a researcher’s freezer.”\textsuperscript{14} “Individual collections of human biological materials range from fewer than 200 to more than 92 million individual quantities of material.”\textsuperscript{15} Those “samples come from routine medical tests, operations, clinical trials and

\begin{itemize}
  \item large tissue banks, repositories, and core facilities
  \item materials collected as part of longitudinal studies
  \item tailored collections for research studies requiring unique tissue collections
  \item pathology specimens, initially collected for clinical purposes
  \item newborn screening tests accumulating in various laboratory sites
  \item forensic DNA banks
  \item umbilical cord blood banks
  \item organ banks
  \item blood banks
  \item sperm, ovum, and embryo banks, and
  \item individual investigators’ collections.
\end{itemize}

\textit{Id.} (internal citation omitted).

\begin{itemize}
  \item\textsuperscript{11} Id. at 997.
  \item\textsuperscript{12} \textsc{Research Involving Human Biological Materials}, supra note 7, at 1; \textsc{Elisa Eiseiman & Susanne B. Haga}, \textsc{Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples}, at xvii (The Rand Corp. 1999).
  \item\textsuperscript{13} Id. at xvii–xviii.
  \item\textsuperscript{14} Id. at xvii–xviii.
  \item\textsuperscript{15} \textsc{Research Involving Human Biological Materials}, supra note 7, at 13. The individual collections of tissue samples are typically either
\end{itemize}
If the Rand Corporation’s “conservative estimate" is accurate, nearly half a billion tissue samples are currently being stored in the United States. “Some tissue samples are coded and not identified with specific individuals; others carry patient names or codes that allow personal identification. Virtually everyone has his or her tissue ‘on file.’”

Additionally, that tissue “on file” may be extremely valuable. Ted Slavin was a hemophiliac who developed “extremely high concentrations of valuable hepatitis B antibodies in his blood” and, until his death in 1985, supported himself by providing those antibodies to pharmaceutical companies developing the hepatitis B vaccine. John Moore, the plaintiff in the seminal case of Moore v. Regents of the University of California, alleged that his rare genetic makeup had a commercial value of $3 billion. But most tissue samples, standing alone, are genetically unremarkable. Their value arises not from high concentrations of antibodies or rare genetic makeup, but from the fact that they enable researchers to piece together the jigsaw puzzle of information underlying genetic causes of disease. It is thus their similarity to samples from other sufferers, not their uniqueness, that gives them value.

With the mapping of the human genome now completed, the nearly half billion tissue samples contain a treasure trove of genetic information. That information not only is the key to unlocking the mysteries of personalized medicine; it is the characteristic that makes the accumulation of tissue samples so threatening to many.

16. Skloot, supra note 9, at 40.
17. EISEMAN & HAGA, supra note 12, at xvii.
18. The Battle Over the Body, supra note 4, at 26.
21. The fact that those samples are genetically unremarkable does not mean they have no commercial value. “[T]he value of human tissue, from both living and dead donors, has increased dramatically in the biotech era.” The Battle Over the Body, supra note 4, at 22. “A human egg can be worth tens of thousands of dollars,” while a cadaver can be dissected and sold in parts—“its skin is worth $36,522, its bones $80,000, its tendons $21,400, and so forth.” Id. In 2005, the University of California noted the black market value of body parts: “cornea, $1,800 to $2,800; heart value, $5,000 to $7,000; patella tendon, $1,800 to $3,000; skin, $1,000 per square foot.” Dan Majors, You Can’t Have Too Many Eyes, PITTSBURGH POST-GAZETTE, Feb. 10, 2005, at A-13. Other estimates place the value of a heart valve at $9,120 and knee cartilage at $14,000. Jeffrey Kluger, The Body Snatchers, TIME, Mar. 22, 2004, at 49, 49.

The commercial value of human bodies had led to some gruesome tales of illicit transactions in body parts. In 2004, for example, police arrested the director of the Willed Body Program at UCLA and a former mortuary worker on charges of grand theft. Id. “Using scalpels, scissors and electric saws, the former autopsy technician would expertly slice off hands, knees and other body parts and pack them in coolers for later shipment to one of 80 clients, including a subsidiary of medical giant Johnson & Johnson.” Andrew Murr, Bad News for the Body Trade, NEWSWEEK, Mar. 22, 2004, at 42, 42. According to his attorney, the mortuary worker gave the director cashier’s checks totaling $704,600 for the right to harvest some 496 bodies donated to the program. Id.

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II. LEGAL RESPONSES IN THE ERA
OF PERSONALIZED MEDICINE

Personalized medicine is exciting and new. It sits on the cutting edge of scientific knowledge, promising cures for dreaded diseases and the ability to detect those diseases when prevention is still possible.

The law, on the other hand, operates on tradition and precedent. When new technologies present disputes that lie at the intersection of legal principles that suggest inconsistent results, the law must resolve those inconsistencies in ways that honor the traditions and precedent of the past, yet still incorporate sound public policy and a secure foundation for the future. For these reasons, the law has been slow to address the concerns raised by personalized medicine, with just three primary cases since 1990 addressing the question of ownership of genetic material donated for research purposes. Each of those cases contained compelling aspects in favor of granting the donors ownership rights in their tissue samples (or the products commercialized from those samples), yet in each case the courts declined to extend those ownership rights to the donors.

A. Moore v. Regents of the University of California

Any discussion of the property rights in genetic materials must begin with the seminal case of Moore v. Regents of the University of California, where the Supreme Court of California declined to give a patient property rights in his genes, despite outrageous behavior by his treating physician. John Moore had his spleen removed in October 1976 as part of his treatment for hairy cell leukemia under the direction of Dr. David W. Golde at the UCLA Medical Center. Without telling Mr. Moore what he was doing, Dr. Golde conducted research using the spleen and, around August 1979, established a cell line from Mr. Moore’s tissue. Shortly afterwards, the Regents of the University of California applied for and received a patent on the cell line, which Mr. Moore asserted had a potential value of up to $3 billion. Dr. Golde negotiated for the commercial development of the cell line, became a paid consultant, and received stock in the company that acquired the development rights.

Mr. Moore returned to the UCLA Medical Center a number of times over a seven-year period after Dr. Golde told him that the visits were “necessary and required for his health and well-being” when, in reality, Dr. Golde used the visits as opportunities to take additional samples of “blood, blood serum, skin, bone marrow aspirate, and sperm” for use, at least in part, in his ongoing research. Those visits continued after Mr. Moore moved to Seattle because

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23. Id. at 480–81.
24. Id. at 481.
25. Id. at 481–82.
26. Id. at 482.
27. Id. at 481.
Dr. Golde insisted that the procedures be done only in the Medical Center under his direction.28

Mr. Moore became concerned when he was repeatedly asked to sign away any rights that he might have in “any cell line or any other potential product” that might be developed from his tissue samples.29 On one visit, Mr. Moore checked that he did not consent; Dr. Golde frantically sought to have him sign the consent form.30 Mr. Moore then retained an attorney who learned through a database search that “weeks before giving Moore the first consent form, Dr. Golde filed for a patent on Moore’s cells . . . and several valuable proteins those cells produced.”31

When Mr. Moore learned that his cells had been patented without his knowledge, he filed suit. He later described his feelings that he had been violated: “What the doctors had done . . . was to claim that my humanity, my genetic essence, was their invention and their property. They viewed me as a mine from which to extract biological material. I was harvested.”32

Among other things, Mr. Moore asserted a claim for conversion, arguing that “he continued to own his cells following their removal from his body, at least for the purpose of directing their use.”33 The court rejected those claims, holding that Mr. Moore had no property rights in his excised cells.34 The court expressed concern that allowing a claim for conversion would “impose a tort duty on scientists to investigate the consensual pedigree of each human cell sample used in research.”35 Allowing a claim for conversion would “destroy the economic incentive to conduct important medical research,” and would mean that “with every cell sample a researcher purchases a ticket in a litigation lottery.”36

Though the court ruled that Mr. Moore lacked a property right in his excised cells, it did not leave him without a remedy, concluding that he could assert a claim based on his physicians’ failure to obtain informed consent and a claim for breach of fiduciary duty.37

B. Greenberg v. Miami Children’s Hospital Research Institute, Inc.

Thirteen years later, a federal district court in Florida relied heavily on Moore to prevent patients from asserting a property interest in their excised cells in Greenberg v. Miami Children’s Hospital Research Institute, Inc.38

28. Id. When Mr. Moore asked about having his follow up care provided in Seattle, Dr. Golde “offered to pay for the plane tickets and put him up in style at the ritzy Beverly Wilshire.” Skloot, supra note 9, at 41.

29. Id.

30. Id.

31. Id.


33. Moore, 793 P.2d at 487.

34. Id. at 497.

35. Id. at 487.

36. Id. at 495–96.

37. Id. at 483.

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In 1987, the families contacted Dr. Reuben Matalon, a research physician, seeking assistance in identifying the gene that causes Canavan disease and in developing tests to determine carriers and allow for prenatal testing for the disease. Working in conjunction with the Chicago Chapter of the National Tay-Sachs and Allied Disease Association, Inc., the families identified other Canavan families and convinced them to "provide tissues (such as blood, urine, and autopsy samples), financial support, and aid in identifying the location of Canavan families internationally." The families and the association also created a confidential database and registry "with epidemiological, medical and other information about the families.

Using the tissue, family histories, contacts, and financial support provided by the families and others, Dr. Matalon and his team isolated the gene responsible for Canavan disease in 1993. Unknown to the families, Dr. Matalon applied for and received a patent for the genetic sequence.

The patent gave Dr. Matalon and his employer, Miami Children’s Hospital, the ability to prevent “carrier and prenatal testing, gene therapy and other treatments for Canavan disease and research involving the gene and its mutations.” The Hospital began to exercise that right, announcing a campaign that would limit testing by licensing use of the patent for a fee.

The families filed suit, alleging that they had not been informed that Dr. Matalon and the Hospital intended to commercialize and restrict the use of the results of their research. As part of their claims, they argued that they had a

39. Canavan disease is a “gene-linked, neurological birth disorder in which the white matter of the brain degenerates into spongy tissue riddled with microscopic fluid-filled spaces.” Medical College of Wisconsin, Canavan Disease, http://healthlink.mcw.edu/article/921391101.html (last visited Feb. 3, 2007). The degenerative disease is a cruel and relentless killer, with death often occurring “before age 4, although some children may survive into their teens and twenties.” Id.

Medical science has no known treatment or cure for Canavan disease, though genetic testing can identify persons at risk for transmitting the defective gene to their children. Though the defective gene can appear in any ethnic population, it occurs most frequently in Ashkenazi Jews and Saudi Arabsians. Id. An estimated 1 in 40 Ashkenazi Jews is a carrier of the defective gene. Canavan Foundation, What is Canavan Disease?, available at http://www.canavanfoundation.org/canavan.php (last visited February 3, 2007). Afflicted children receive a copy of the defective gene from each parent, meaning that parents who carry the defective gene have a 25 percent chance of transmitting the disease to their child. Medical College of Wisconsin, supra.


41. Id.

42. Id. 264 F. Supp. 2d at 1067.

43. Id.

44. Id.

45. Id.

46. Id.

47. Id.

48. Id. at 1068. The Complaint asserted claims for lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets. Id.
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property interest in the tissue and genetic information that they had donated.\textsuperscript{49} The court rejected that position. Citing to \textit{Moore}, the court held that the families “have no cognizable property interest in body tissue and genetic matter donated for research.”\textsuperscript{50} The families could not state a claim for conversion because they made “donations to research without any contemporaneous expectations of return of the body tissue and genetic samples.”\textsuperscript{51} Rather, the court held, any property right in blood and tissue samples “evaporates once the sample is voluntarily given to a third party.”\textsuperscript{52}

The court granted the Defendants’ motion to dismiss the claims for lack of informed consent, breach of fiduciary duty, fraudulent concealment, conversion, and misappropriation of trade secrets.\textsuperscript{53} Nonetheless, the court denied the motion to dismiss the claim for unjust enrichment, holding that the issuance of the patent did not preclude a claim for unjust enrichment in light of the allegations that the parties had agreed to collaborate on the genetic research.\textsuperscript{54} Shortly afterwards, the parties settled their dispute with an agreement that allowed for “continued royalty-based genetic testing by certain licensed laboratories and royalty-free research by institutions, doctors, and scientists searching for a cure.”\textsuperscript{55}

C. \textit{The Washington University v. Catalona}

The most recent court decision concerning donated tissue ownership is \textit{Washington University v. Catalona},\textsuperscript{56} a case involving an ownership dispute between a research university, a research scientist formerly associated with the University, and tissue donors. Both the federal district court and the Eighth Circuit Court of Appeals sided with the University, concluding that donors could not “direct the transfer of their biological materials” to the research scientist after he terminated his employment with the University.\textsuperscript{57} As did the courts in \textit{Moore} and in \textit{Greenberg}, both the district court and the Eighth Circuit concluded that the donors had no property interests in their samples.\textsuperscript{58}

\textsuperscript{49}. \textit{Id.} at 1074.
\textsuperscript{50}. \textit{Id.}
\textsuperscript{51}. \textit{Id.}
\textsuperscript{52}. \textit{Id.} at 1075.
\textsuperscript{53}. \textit{Id.} at 1077.
\textsuperscript{54}. \textit{Id.} at 1072.
\textsuperscript{58}. \textit{Id.}
1. Background of the case

The dispute involved two sophisticated, well-regarded players in the world of medical research. The Washington University (WU) in St. Louis, Missouri is “one of the leading private research universities in this country, if not in the world.” Dr. William J. Catalona, a world-renowned urologist and urologic surgeon, “is about a close as one comes to medical celebrity (he’s been called ‘urologist to the stars’).” Dr. Catalona worked as a full-time employee at WU from July 1976 until February 2003, serving as Chief of the Urology Division at WU from 1984 to 1998. Patients flocked from around the world seeking treatment for prostate cancer from Dr. Catalona who helped pioneer the PSA test used to detect prostate cancer.

While at WU, Dr. Catalona and “several other WU physicians” collected samples of “prostate tissue, blood, and DNA samples for prostate cancer research,” the largest collection of its type in the world. During the litigation, Dr. Catalona referred to the collection as the “Catalona Collection,” while WU referred to it as the “GU Biorepository.”

The GU Biorepository is housed in buildings owned by WU, with the University providing “the majority of the funding necessary to operate and maintain the GU Biorepository.” University employees, including Dr. Catalona, engaged in outside fund raising to support the Biorepository, with Dr. Catalona alone raising “several million dollars in outside funding.”

The tissue bank “is not used for clinical care or follow-up care; it is strictly used for research purposes.” The samples were taken from more than 30,000 men who were enrolled in studies to research the genetic causes of prostate cancer; of these, some 2,500 to 3,000 had been patients of Dr. Catalona. Dr. Catalona and other University physicians had gathered the samples while conducting numerous studies related to the genetic causes of prostate cancer. Each study identified a particular physician as the “principal investigator,” a term designating the person ‘in charge of conducting [a] re-
search protocol.”72 Though one physician was identified as principal investigator in each study, “the named principal investigator generally collaborated with several other individuals in the research studies.”73

The tissue samples in dispute include approximately 3,500 samples of prostate tissue, approximately 100,000 blood samples, and some 4,400 DNA samples.74 The samples of prostate tissue were “taken from patients of Dr. Catalona and other WU physicians within the Urologic Surgery Division.”75 Approximately 75% of the blood samples came from “research participants who were not patients of Dr. Catalona or any other WU physician.”76 Likewise, some of the men who donated samples were patients of Dr. Catalona, while others were not.77

In what appears to be a battle of egos, the seeds of the dispute were sown in 2002 “when the university changed how the tissue bank operated.”78 According to Dr. Catalona, “It was just taken from me.”79 Rather than allowing Dr. Catalona control over the samples, the University now required that he get approval from a Peer Review Board before using samples.80 The change in policy led to a dispute about ownership and control over the collection and to increased tension between the parties.81 In a letter, an official at WU complained that Dr. Catalona gave free tissue samples to researchers at a biotech company in exchange for “the potential for [Dr.] Catalona to get a publication,” something the official determined to be “unacceptable.”82

Dr. Catalona fought back against the restrictions. Beginning in 2001, he made a series of “telephone calls, e-mails, and letters” in which he threatened to take legal action against the University “to assert a purported claim of personal ownership over the GU Biorepository.”83

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72. Id. (quoting the trial testimony; alteration in original).
73. Id. at 990.
74. Id. at 989. Other estimates place the number of prostate samples at 4,000 and blood samples at 250,000. Skloot, supra note 9, at 75. Some 36,000 men donated samples. Id. “Some of these men came to [Dr. Catalona] through newspaper and radio ads he placed seeking donors. Some came from other doctors. But many were his patients.” Id.
75. Catalona I, 437 F. Supp. 2d at 989.
76. Id.
77. Id.
79. Id.
80. Id.
81. Id.
82. Skloot, supra note 9, at 75.
83. Complaint for Declaratory Judgment at 2, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL). Dr. Catalona denies both that he has “threatened legal action” against WU or asserted a personal ownership interest in the samples, arguing instead that “the Catalona Collection was entrusted to him and that the right to re-direct these materials remains with the patients/participants.” Answer, Affirmative Defenses & Counterclaim of Defendant William J. Catalona, M.D., supra note 66, at 2.
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The University argued that Dr. Catalona was not denied access to the samples, but instead had to seek permission to use those samples by submitting an application to the Peer Review Panel, something that Dr. Catalona did successfully at least twice after he no longer served as Division Chief.\textsuperscript{84} WU asserted that the dispute was not one over access, but rather control.

Catalona, however, is not satisfied with access. He demands control. He wants the ability to prevent other qualified researchers from using the materials, even though he himself has no open studies using those materials. Although no longer Chief of the Urology Division or even a WU employee, he wants to remain personally the gatekeeper over the GU Biorepository. He wants the unilateral and unfettered right to send GU Biorepository materials to other researchers across the country with whom he can collaborate and publish papers . . . .\textsuperscript{85}

Dr. Catalona ultimately decided to leave WU. He first sought to go to the University of Virginia, but that deal fell through when he failed to broker a deal to take the samples with him.\textsuperscript{86} Later, he accepted a position at Northwestern University.

On February 18, 2003, just five days before his departure, Dr. Catalona sent a letter to 10,000 patients without telling the University that he was doing so.\textsuperscript{87} The letter went not only to the patients whom Dr. Catalona had treated, but also to patients who had been treated by other physicians at the University and to men who had participated in research studies at the University.\textsuperscript{88} In addition, Dr. Catalona published the letter in the newsletter distributed by the research foundation where he served as Medical Director, bringing the total circulation of the letter to approximately 60,000 people.\textsuperscript{89} Dr. Catalona wrote of his desire to continue his research on prostate cancer and solicited the assistance from the recipients of his letter:

\begin{quote}
[T]o succeed in these goals, I need to have the tissue and blood samples that patients, their relatives, and other research volunteers have contributed to me over the years. You have entrusted me with samples, and I have used them for collaborative research that will help in your future medical care and in the care of others for years to come.\textsuperscript{90}
\end{quote}

\textsuperscript{84} Plaintiff’s Pre-Hearing Brief at 3, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL).
\textsuperscript{85} Id.
\textsuperscript{86} Kaiser, supra note 78, at 346.
\textsuperscript{87} Complaint for Declaratory Judgment, supra note 83, at 8.
\textsuperscript{88} Id.
\textsuperscript{89} Catalona I, 437 F. Supp. 2d at 993.
\textsuperscript{90} Id. (quoting Dr. Catalona’s letter) (alteration in original; emphasis added).
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To continue that research, he wrote, “I need your assistance and your permission.”\(^9\) The letter asked the men to sign and return a “Medical Consent and Authorization” form instructing WU to release the samples to Dr. Catalona.\(^9\) Within a few weeks, some 6,000 men had returned the forms directing WU to release the samples to Dr. Catalona.\(^9\)

2. The district court’s decision

After Dr. Catalona left the University, WU filed a declaratory judgment action in federal district court seeking to establish its ownership of the samples.\(^9\) Dr. Catalona filed a counterclaim asserting that the men who donated samples retained the right to direct the use of their samples and raising six claims against the University: (1) violation of patient-participants’ rights to revoke consent; (2) failure to comply with informed consents; (3) interference with patient relationship; (4) violation of free speech; (5) breach of implied bailment; and (6) defense and indemnity.\(^\text{95}\)

Shortly afterwards, eight men who had donated tissue samples to the biorepository (Donors) were allowed to intervene as defendants in the case.\(^\text{96}\) Ultimately, the district court held a three-day hearing on the defendants’ request for a permanent injunction, a hearing in which the University, Dr. Catalona, and the Donors participated.\(^\text{97}\) After that hearing, the district court granted the University’s motion for summary judgment and denied Dr. Catalona’s request that the University be enjoined from using the samples.

In what the Eighth Circuit later called a “well-reasoned opinion,”\(^\text{98}\) the district court succinctly characterized the nature of the dispute: “once having made voluntary donations of biological materials for medical research to a research institution, do the research participants retain ownership rights in such materials in that they can direct said materials’ use and transfer to third

91. Skloot, supra note 9, at 75 (quoting Dr. Catalona’s letter).
92. Catalona I, 437 F. Supp. 2d at 993. In pertinent part, that form reads as follows:

I have donated a tissue and/or blood sample to Dr. William J. Catalona’s Research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to be used only at his direction and with his express consent for research projects.

Id.

93. Dr. Catalona has repeatedly asserted that he received some 6,000 requests from patients instructing WU to transfer their samples. Nonetheless, as of November 24, 2003, the University maintained that “[Dr.] Catalona has never provided such purported consents to the University.” Answer to Counterclaim at 1, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL).
96. The parties disagreed on the title that should be used to describe the men. WU referred to them as “Research Participants,” while Dr. Catalona and the men called them “Patients.” This article will refer to them as “Donors.”
98. Catalona II, 490 F.3d at 677.
parties.” The district court held that the research participants did not retain those ownership rights, relying on three principal grounds.

First, WU exhibited all indicia of ownership required under Missouri law. WU had continuously held “exclusive possession” of and “exclusive control over” the samples. It had supplied the facilities and incurred the costs of housing the specimens; access to the specimens came only through the Institutional Review Board (“IRB”) and Human Studies Committee (“HSC”) at the University. Though Dr. Catalona had done much of the work on the GU Biorepository, “any decisions made by Dr. Catalona were made as a WU employee.” Moreover, the University “alone bears all legal, regulatory, and compliance risks with respect to all research done in connection with the GU Biorepository.”

Second, the district court held that the Donors made an inter vivos gift of their samples. The patients voluntarily agreed to participate in medical research studies at WU. The Principal Investigator for many of those studies was someone other than Dr. Catalona; many of the Donors were patients of WU physicians other than Dr. Catalona. The informed consent forms typically bore the logo of WU Medical Center and stated that they were not valid until approved by the University’s HSC. The forms directed the Donors to contact WU staff if they had concerns about the investigation and advised that WU would take steps to “protect their privacy and minimize the burdens of participating in the study.”

As a theme in the litigation, Dr. Catalona and the Donors asserted that the Donors had entrusted their samples to Dr. Catalona. If the Donors had specifically intended that result at the time of their donation, the argument would have some significance. Yet, as the district court noted, “[n]owhere in the forms were [the Donors] advised that they were entrusting their samples to Dr. Catalona only.” The statements of “intent” advanced in litigation were not statements of contemporaneous intent, but rather positions advanced for the purpose of litigation. The district court acknowledged that the Donors had a “deep personal connection to Dr. Catalona” and that they “believed that they owed their lives to him.” Nonetheless, the district court held that “their

100. Id. at 1002-03.
101. Id. at 994.
102. Id.
103. Id.
104. Id.
105. Id.
106. Id. 437 F. Supp. 2d at 997.
107. Id.
108. Id.
109. Id.
110. Id.
111. Id.
112. Id. 437 F. Supp. 2d at 999.
testimony regarding intent, especially now after getting Dr. Catalona’s letter, is suspect or at least, shows nothing more than an ‘afterthought of regret’.”

Dr. Catalona and the Donors argued that the tissue samples were not gifts, but rather constituted a bailment. As the district court noted, “however, when a ‘bailment’ is made, the bailor has every expectation of receiving back the subject of the bailment.”114 None of the parties presented any evidence that at the time of the donation, any of the Donors intended to receive back their tissue samples.115 Moreover, “the medical research community itself has never considered the relationship between [a research participant] and a medical research institution to be one of bailment.”116

Third, the district court considered “the possible (if not probable) public policy ramifications” of the position advanced by Dr. Catalona and the Donors.117 Under that position,

these highly-prized biological materials would become nothing more than chattel going to the highest bidder. It would no longer be a question of the importance of the research protocol to public health, but rather who can pay the most. Selling excised tissue or DNA on E-Bay would become as commonplace as selling your old television on E-Bay. The integrity and utility of all biorepositories would be seriously threatened if [research participants] could move their samples from institution to institution at any time they wanted.118

Moreover, the district court held that allowing the Donors to “choose who can have the sample, where the sample will be stored, or how the sample can be used is tantamount to a blood donor’s being able to dictate that her blood can only be transfused into a person of a certain ethnic background, or a donated kidney being transplanted only into a woman or man.”119

Summarizing these positions, the district court held that (1) defendants were not entitled to injunctive relief; (2) WU owns the tissue samples in the GU Biorepository; (3) Dr. Catalona and the Donors do not have “any ownership or proprietary interest” in the tissue samples; and (4) the signed “Medical Consent & Authorization” forms that Dr. Catalona solicited from the Donors

113. Id. The district court’s conclusion is consistent with the Corbin approach of interpreting contracts “in light of the parties’ intentions as reflected by the language and in view of all the circumstances.” Darner Motor Sales, Inc. v. Universal Underwriters Ins. Co., 682 P.2d 388, 398 (Ariz. 1984) quoting Smith v. Melson, 659 P.2d 1264, 1266 (Ariz. 1983). “All of the circumstances” include the actions of the parties before a dispute arose. See id. As one court has stated,

[i]f the construction or interpretation given to the agreement as evidenced by the acts and conduct of the parties with knowledge of the terms and prior to any controversy as to meaning arises is entitled to great weight and when reasonable will be adopted and enforced by the court. The acts of the parties themselves, before disputes arise, are the best evidence of the meaning of doubtful contractual terms.


115. Id.
116. Id.
117. Id. 437 F. Supp.2d at 1002.
118. Id.
119. Id.
are “void and ineffective to transfer ownership and/or possession” of any of the samples.120

3. The Eighth Circuit Affirms the District Court

Dr. Catalona and the Donors appealed the decision to the Eighth Circuit Court of Appeals, which affirmed the decision of the district court.121 Like the district court, the Eighth Circuit succinctly characterized the “pivotal inquiry” of the dispute:

whether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party.122

Like the district court, the Eighth Circuit held that under the facts of this case, the Donors had no remaining ownership interest in their genetic material.123 The Eighth Circuit based its decision on the district court’s finding that the Donors voluntarily donated their tissue samples to the University as inter vivos gifts. The court held that WU showed clear and convincing evidence of each of the three elements of a claim of an inter vivos gift under Missouri law: “(1) present intent of the donor to make a gift, (2) delivery of the property by the donor to the donee, and (3) acceptance of the gift by the donee, whose ownership takes effect immediately and absolutely.”124 Finding that the Donors “unquestionably delivered their biological materials to WU at the time of their donation,” the court addressed only the first and third requirements for an inter vivos gift in detail.125

120. Id. at 1002–03.
121. Catalona II, 490 F.3d 667, 677 (8th Cir. 2007).
122. Id. at 673.
123. Id. The Eighth Circuit’s decision is legally sound, and the court properly affirmed on that basis. Nonetheless, as is the case with virtually all appellate cases, the standard of review on appeal largely dictated the result of the Catalona case. Dr. Catalona and the Donors sought to reverse the district court’s decision granting the motion for summary judgment against them and denying their request for injunctive relief. While an appellate court reviews the granting of summary judgment de novo, see, e.g., Burlington N. & Santa Fe Ry. Co. v. State Tax Comm’n, 188 F.3d 1039, 1041 (8th Cir. 1999), the denial of injunctive relief is reviewed for an abuse of discretion, see, e.g., id., a standard that is very difficult to meet on appeal. The abuse of discretion standard required the appellants to show that the district court “base[d] its decision on an erroneous application of the law or a clearly erroneous factual finding.” Catalona II, 490 F.3d at 673; (emphasis added).

As is noted below, the Eighth Circuit’s decision is based on the district court’s factual finding that the Donors had donated their samples as inter vivos gifts to the University. Dr. Catalona and the Donors could not prevail on appeal unless they could show that the district court’s finding was clearly erroneous. The clearly erroneous standard is extremely difficult to overcome in a case where the evidence equally supports either party’s interpretation. Where the evidence overwhelmingly favors the district court’s factual finding (as in this case), the standard of review dictates that the factual finding be sustained on appeal.

124. Catalona, 490 F.3d at 674, 676-77.
125. Id. at 674.
With regard to the first element, the language of the informed consent forms and the brochure given to the Donors supported the conclusion that the Donors intended to make a gift at the time the samples were taken. Each Donor had signed a consent form bearing the WU logo. The consent forms identified the Donor’s participation in the studies as “a ‘donation’ of bodily tissues or blood;” the forms “emphasized the voluntariness of the [Donor’s] participation and discussed the [Donor’s] right to decline participation in the study or to withdraw consent at any time.”

Moreover, many consent forms did not identify Dr. Catalona as the person to whom the Donors were entrusting their samples. Instead, those of the consent forms identified “someone other than Dr. Catalona as the principal investigator.” Even when the consent form identified Dr. Catalona as the principal investigator, the form referenced “a research study conducted by Dr. William J. Catalona and/or colleagues.”

The consent forms further advised the Donors that their biological samples “may be used for research with our collaborators at [WU], other institutions, or companies.”

In addition, the brochures given to the Donors “characterized [their] donations as ‘a free and generous gift of [biological materials] to research that may benefit society.’ The language of the brochure, ‘considered together with the consent form, cannot reasonably be characterized as reflecting the [Donor’s] intention either to entrust their samples solely to Dr. Catalona or to transfer the samples in some legal form other than a gift.’

Turning to the third element of a claim for an *inter vivos* gift—acceptance of the gift by the donee—the court rejected the contention that the Donors retained rights in the tissue samples and that the transfer to WU was not absolute. The court noted that the University immediately “accepted and retained absolute possession of the biological materials upon donation.” That fact did not change simply because the Donors had the right to revoke their donation and withdraw from the studies in the future. “The attachment of a condition to a charitable donation of property does not negate or void an otherwise valid *inter vivos* gift.” Any rule to the contrary “would make charitable donations wholly impossible or ineffectual.”

The Donors’ right to withdraw from participating in future studies did not give them “the right to revoke and physically repossess the donated biological materials,” nor did they “retain the right to direct or authorized the use, trans-
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fer, or destination of the biological materials after their donation.”

Rather, the Donors’ future rights “were expressly limited to the option to discontinue participation in the study to avoid answering additional questions, donating more biological materials, or allowing their biological materials to be used for further research.”

The court found further support for its holding in “Dr. Catalona’s past conduct, as well as the practical consequences of the research process itself.” Before the dispute arose, Dr. Catalona repeatedly acknowledged that WU owned the genetic materials and took actions consistent with the Donors’ no longer having any residual ownership interest in the samples.

4. The Aftermath of the Decision

As is the case with Moore and Greenberg, reaction to the Catalona decision has been controversial. After the district court’s decision, Dr. Catalona argued that the ruling “runs roughshod on patients’ rights,” and likened the university to Adolph Hitler. “You can’t start infringing on the rights of research subjects,” he said. “You can say it’s for the good of society, but that’s what Hitler said when they started throwing people in ice water and seeing how long it took them to die.”

Lori Andrews, an ethicist at the Illinois Institute of Technology and a law professor at the Chicago-Kent College of Law, called the decision “a big setback for patients’ rights.” The decision, she said “is going to turn patients into treasure-troves rather than partners in research.”

Not surprisingly, the University praised the decision. In a letter published in the St. Louis Post-Dispatch, Larry J. Shapiro, Executive Vice Chancellor and Dean of the Medical School at WU, asserted that the decision “is important to science and protects research participants’ rights.” Actions like those taken by Dr. Catalona, he maintained, “can allow a researcher’s personal agenda to supersede donors’ interests.” After the Eighth Circuit’s decision, Dr. Shapiro reiterated that the ruling would “allow important research into the causes of prostate cancer to continue, with the goal of developing new

137. Id.
138. Id.
139. Id. at 676.
140. See infra text accompanying notes 150–59.
142. Id.
143. Id.
144. Id.
146. Id.
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cures.”147 The ruling, he said, “creates the best opportunity for this extensive collection of tissues to be used to advance understanding of the disease.”148

III. OBSERVATIONS ON THE CATALONA DECISION

Catalona addresses the difficult questions of ownership in a thoughtful manner that looks to the precedent of the past while maintaining an open eye toward the emerging technologies of the future. While the decision raises many important issues for consideration, at least three important points merit special attention.

First, although neither the district court nor the Eighth Circuit explicitly said as much, Dr. Catalona and the Donors harmed their position by taking prelitigation positions that were inconsistent with their positions in the litigation. In the litigation, Dr. Catalona officially maintained that neither he nor WU owned the samples;149 his prelitigation actions and statements were, however, inconsistent with this position.150 The Eighth Circuit specifically referenced Dr. Catalona’s actions that were inconsistent with the position that the Donors retained an ownership interest in the samples.151

For example, Dr. Catalona previously acknowledged that the University owned the samples. On a number of occasions, the University made samples from the collection available to collaborating companies and academic researchers at other institutions, authorizing that use through a material transfer agreement (MTA).152 “Several MTAs personally signed by Dr. Catalona, as

148. Id.
150. See infra text accompanying notes 151–59. Dr. Catalona is not the only one exhibiting this schizophrenic attitude toward the samples. An article sympathetic to Dr. Catalona begins, “Dr. William Catalona just wants his blood and tissue back.” Howley, supra note 60 (emphasis added). Nonetheless, the article notes that Dr. Catalona sought approval from his patients to move the samples, “which he considers theirs, not his.” Id. (emphasis added).
151. The Court excoriated Dr. Catalona for the inconsistencies in his positions:

Dr. Catalona’s past conduct, as well as the practical consequences of the research process itself, also refutes the defendants’ position. While at WU, Dr. Catalona signed numerous MTAs and research agreements acknowledging WU’s ownership of the biological materials. Moreover, during Dr. Catalona’s tenure, he routinely ordered the destruction or “purging” of Biorepository samples in order to create more storage space, and did so without obtaining any additional consent from [the research participants]. Dr. Catalona’s habitual destruction of samples, in a manner consistent with apparent indifference to any proprietary interest of the donors, is at odds with his later assertion the [Donors] own the biological materials. Furthermore, during research involving the use of prostate tissue and blood samples, the research process might consume an entire particular biological specimen, leaving behind no tangible material in which a donor could assert a potential proprietary interest. It is difficult to reconcile the use, consumption, and destruction of biological materials by Dr. Catalona and the events that occurred during the research process with the assertion the [Donors] retained an ownership interest in the donated materials.

152. Memorandum of Points and Authorities in Support of Motion for Summary Judgment at 3, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065SNL). WU uses MTAs providing that the material supplied “shall remain the property of the Provider,” and
the principal or providing investigator, acknowledge WU as the owner of the biological samples.\(^{153}\)

Dr. Catalona did not dispute that WU owned the collection until around the time he decided to leave the University.\(^{154}\) The first time Dr. Catalona attempted to dispute WU’s ownership in an MTA came a year after he left the University. At that time, Dr. Catalona did not claim that the Donors retained property rights in their samples, as he did in the litigation, but rather attempted to redraft an MTA to reflect that he was a joint owner of the biological samples being transferred.\(^{155}\) When WU refused to accept his amended MTA, Dr. Catalona relented and signed the original draft of the agreement, asserting that he was doing so on the advice of his counsel but that he personally believed that he had “proprietary rights” in the samples.\(^{156}\)

At trial, Dr. Catalona denied that he received the samples as unconditional gifts.\(^{157}\) He refused to state who owned the samples, but asserted that he had “a strong proprietary interest in the broad sense of the word.”\(^{158}\) Though he advocated that the research participants should be able to direct samples to another prostate surgeon, “he was unwilling to say that those same participants could direct their tissues to third parties who are not renowned prostate surgeons.”\(^{159}\)

Moreover, the Donors’ position was also inconsistent with their prelitigation position. While the Donors claimed in litigation that they merely had entrusted their samples to Dr. Catalona and still retained the right to control the use of those samples, their prior conduct instead reflected that the samples were gifts. For example, the consent form signed by two of the three Donors who testified at trial stated, “By agreeing to participate in this study, you agree to waive any claim you might have to the body tissues [that] you donate.”\(^{160}\) Another consent form referenced the patient’s “donation” of blood.\(^{161}\)

Identify WU as the “Provider.” \(\text{Id. at 9–10.}\) Those agreements also expressly distinguish the “Provider” from the “Provider Scientist.” \(\text{Id. at 10.}\)

Dr. Catalona was the Provider Scientist on 15 MTAs involving the transfer of samples from the repository. \(\text{Id.}\) Each of those agreements specifically affirms that WU owned the biological materials being transferred. \(\text{Id.}\) Dr. Catalona signed nine of the 15 MTAs; he received and reviewed the other six MTAs in question. \(\text{Id.; Catalona I, 437 F. Supp.2d at 995 (“in all MTAs concerning these materials, including those wherein Dr. Catalona was the ‘Provider’s Scientist’, WU clearly exerted its ownership interest without objection by Dr. Catalona”).}\)

153. Catalona II, 490 F.3d at 672.

154. Memorandum of Points and Authorities in Support of Motion for Summary Judgment, \(\text{supra}\) note 152, at 10.

155. Catalona I, 437 F. Supp.2d at 995. The court discounted Dr. Catalona’s testimony that “he felt he had no choice but to sign” the MTA but still maintained that he had a “proprietary interest in the subject biological materials,” holding that “the document speaks for itself.” \(\text{Id. at 995, n.14.}\)

156. Memorandum of Points and Authorities in Support of Motion for Summary Judgment, \(\text{supra}\) note 152, at 10, n.3.

157. Plaintiff’s Pre-Hearing Brief, \(\text{supra}\) note 84, at 9.


159. \(\text{Id. at 16 (emphasis in the original).}\)

160. \(\text{Id. at 7 (emphasis added).}\)

161. \(\text{Id. (emphasis added).}\)
Furthermore, if the Donors entrusted their samples to Dr. Catalona at the time they made their donation—as they claimed during litigation—they entrusted him with the authority to deal with their samples in the manner he deemed most appropriate. The best way to determine what Dr. Catalona deemed to be most appropriate at the time is to look at his actions. Those actions reflect that he understood that WU owned the tissue samples, as he repeatedly affirmed in the MTAs he signed. That understanding is consistent with the practice in the research community. Although the Donors and Dr. Catalona argued that “the right to discontinue participation includes the right to control over the use and location of [the Donor’s] excised biological materials,” they advanced no examples supporting their contention. Rather, the testimony identified only three possible results when a research participant chooses to discontinue participation in a study: “1) WU may destroy the sample; 2) WU may store the sample indefinitely without any further use; or 3) WU may remove all identifying markers and use the sample in exempt ‘anonymized’ research.” The evidence did not show any instances where a research participant had required that his samples be transferred to another facility for research purposes.

Second, as is noted above, when Dr. Catalona first contested WU’s ownership of the samples, he claimed that he personally owned the so-called Catalona Collection. Indeed, when he contacted the Donors, he asserted that they had contributed their samples to him. While neither the opinions of the district court or the Eighth Circuit nor the pleadings disclose why Dr. Catalona abandoned this position, he may have done so because, as an employee of the University, he could not acquire a personal interest in the samples. As the Restatement (Second) of Agency makes clear, “[u]nless otherwise agreed, an agent is subject to a duty to his principal to act solely for the benefit of the principal in all matters connected with his agency.”

162. Catalona I, 437 F.Supp.2d at 999.
163. Id. at 999. Indeed, that is the practice that Dr. Catalona continues to use after leaving WU. As the district court noted, “even Dr. Catalona, as a researcher at Northwestern University, testified that he is using informed consent forms which only state two (2) options upon a RP’s decision to withdraw participation: 1) destruction of the sample or 2) anonymization of the sample. Northwestern University’s consent form interestingly does not provide the third option advocated by Dr. Catalona and the RPs; i.e., return of the sample to the RP or transfer of the sample to a location chosen by the RP.” Id., at 999–1000 n. 17.
164. See supra note 83 and accompanying text.
165. Among other things, the University’s Intellectual Property Policy made clear that the University owned the fruits of Dr. Catalona’s labors:

"General Statement of Ownership. Except as is noted below, all intellectual property (including lab notebooks, cell lines and other tangible research property) shall be owned by the University if significant University resources were used or if it is created pursuant to a research project funded through corporate, federal or other external sponsors administered by the University."

Complaint for Declaratory Judgment, supra note 83, at 7. Moreover, an employee’s duty of loyalty prohibits him from competing with his principal “concerning the subject matter of his agency” unless the principal and agent agreed otherwise. RESTATEMENT (SECOND) OF AGENCY, § 393 (1958) Indeed, “it is the agent’s duty to further his principal’s interests even at the expense of his own in matters connected with the agency.” Id., cmt. b.

166. RESTATEMENT (SECOND) OF AGENCY, § 387 (1958).
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—possibilities with WU—that is, his employment as a medical researcher—define the scope of the “matters connected with his agency.” The so-called Catalona Collection “is not used for clinical care or follow-up care” but is, instead, “strictly used for research purposes.” For that reason, Dr. Catalona was acting in connection with his agency as a medical researcher when he gathered the samples. As a matter of law, the fruits of his labors—in this case, any property rights in the tissue samples—belonged to the University, particularly because the University incurred all expenses associated with gathering and maintaining the samples.

Similarly, Dr. Catalona cannot claim the right to own or control the samples simply because he raised funds that were used to develop or maintain the Biorepository. Even if Dr. Catalona “raised virtually all of the money for the direct support of the biorepository,” as he claims on his Web site, he did so in his capacity as an employee acting on behalf of his employer. Absent an employment agreement that specifically allowed him to do so (and no such agreement was present in this case), Dr. Catalona cannot claim both the right to be paid for his work and the right to own or control the samples in the biorepository developed as a result of his employment with WU.

Third, Dr. Catalona and the Donors hurt their credibility by overreaching. Lori Andrews, an ethicist at the Illinois Institute of Technology and a law professor at the Chicago-Kent College of Law, frequently argues that donors have an ongoing ownership interest in their samples under a bailment theory. The Donors advanced this legal argument as part of their case. While the bailment theory has, appropriately, succeeded in other litigation involving human organisms, it is not persuasive in the context of donations of tissue samples for research.

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168. Id. at 989.
169. Id. at 994.
171. See Catalona I, 437 F.Supp.2d at 989.
172. See, e.g., Andrews, supra note 62, at 403 (“The fact that the patients cared about what was done with their tissue – and might wish to provide samples only for certain purposes – is consistent with other legal concepts, such as bailment”); Andrews, supra note 4, at 22 (cases involving ownership of human tissues might cross “many areas of law: tort, property, gift, bailment, constitutional rights, and federal regulation”).
174. In York v. Jones, for example, a couple went to a fertility clinic to seek assistance in conceiving a child through in vitro fertilization (IVF). York v. Jones, 717 F. Supp. 421, 423 (E.D. Va. 1989). At the end of the IVF process, the couple had one remaining cryogenically preserved prezygote remaining. Id. at 424. They sought to have the prezygote transferred to another facility for IVF implantation in the wife. Id. The facility argued that transfer was not possible because the informed consent the couple signed limited the couple to one of three possibilities: (1) donating the prezygote to another infertile couple, (2) donating the prezygote to an approved research facility, and (3) having the prezygote “thawed but not allowed to undergo further development.” Id.

The district court found that a bailment existed, even though no specific language in the informed consent created that bailment. Id. at 425. Under Virginia law, “all that is needed [to
Moreover, the Donors and Dr. Catalona could not legitimately claim that the right to withdraw their tissue samples from the research studies also gave them the right to transfer their samples to a new institution. The withdrawal and destruction of a tissue sample cannot reasonably be equated to the transfer of that sample to another facility, particularly when no one was able to cite a single instance where a research facility had transferred a sample to another research facility at the request of the donor.

Not only did Dr. Catalona and the Donors overreach by advancing inapplicable legal theories, they also engaged in revisionist history. While they argued passionately at trial and on appeal that the Donors intended to entrust Dr. Catalona alone with their tissue samples, they could point to no credible evidence that supported their position. Rather, their litigation position was inconsistent with the underlying documents and their actions, which are the best indications of what the parties intended at the time of the donations. Undoubtedly, as is true in most cases, the parties did not consider what would happen in the event of a change of circumstances, for example, if Dr. Catalona leaves WU and wants to take the samples with him. Future researchers, especially prominent researchers, are well advised to negotiate their rights to tissues donated for research purposes prior to any dispute or impending departure.

Many people understandably feel a strong emotional connection with their excised genetic material, particularly if they believe that someone else is making money on that sample or the sample is being used in a manner contrary to their wishes. Nonetheless, as the Catalona decision emphasizes, current practices for the taking and using of samples do not give donors an ongoing ownership interest in excised tissues that they have clearly donated for research purposes.

create a bailment] ‘is the element of lawful possession however created, and duty to account for the thing as the property of another.’ Id. (quoting Crandall v. Woodard, 143 S.E.2d 923, 927 (1965)) (emphasis added). Further, as the court noted, ‘[t]he essential nature of a bailment relationship imposes on the bailee, when the purpose of the bailment has terminated, an absolute obligation to return the subject matter of the bailment to the bailor.’” Id. (emphasis added).

When a couple entrusts their sperm and eggs to a fertility clinic, they do so with the express understanding and expectation that, through IVF, embryos will be developed that can be implanted, leading to the expected birth of a child. The clinic specifically assumes the duty to account for the prezygotes; it has an absolute duty to return the property to the couple.

The recipient of a donation of tissue assumes none of these obligations. As contrasted with an embryo that an infertile couple hopes will develop into a child, no one gives a sample of a cancerous prostate tissue or a vial of blood with the understanding that the sample will be returned. Indeed, the donor more likely understands that the tissue ultimately will be consumed during the research. Moreover, a researcher does not have a duty to account to the donor for how his sample is used. A theory of bailment makes sense in the context of IVF; it is inapplicable in the context of a donation of research samples. As the court held in Catalona, “[t]his argument fails for the simple reason that when a ‘gift’ is made, the giftor/donor has no expectation of getting the ‘gift’ back; however, when a ‘bailment’ is made, the bailor has every expectation of receiving back the subject of the bailment.” Catalona I, 437 F. Supp. 2d at 1001.
A different fact pattern might dictate a different result, but that different result would raise additional legal challenges. For example, if the consent forms had specifically stated that the Donors were entrusting their samples to Dr. Catalona and not to the University, the Donors might have been able to persuade the court that they could require the samples to follow Dr. Catalona to his new employment. In such a case, however, Dr. Catalona might have had the financial, legal, and regulatory responsibilities of storing the samples, a burden that he did not accept and might be unwilling to accept.

If Dr. Catalona initially accepted the responsibilities for the samples and later changed his mind, Donors might feel deceived or offended if he sought to have the samples destroyed or transferred to another researcher. The same circumstances would arise upon the death or retirement of Dr. Catalona. Giving patients control over their samples in perpetuity would increase the cost of research, require cumbersome monitoring systems and processes, and delay life-saving research studies.

Catalona recognizes the only practical method for addressing these critical issues. A tissue donation is a gift. By the specific terms of that gift, donors retain a limited right to withdraw their participation in the study. Otherwise, their donation is an unqualified gift over which they have no control.
Wear a White Hat

Protect Your Intangible Assets

If you are going to help your clients build and maintain growing, thriving businesses, you must help them secure and protect their intangible assets. Ideas and innovations are a company’s most valuable resources, with as much as 85 percent of a company’s value attributable to its intangible assets. New Ways Needed to Assess New Economy, Los Angeles Times, Nov. 13, 2000. Those intangible assets include not only the traditional forms of intellectual property—patents, trademarks, and copyrights—but also a company’s trade secrets, confidential information, and valuable relationships.

At the same time that intangible assets have become pivotal to the financial viability of companies, employees have become more mobile, regularly changing jobs, and sometimes careers, multiple times during their working years. Technological advances have made it increasingly easier for dishonest employees to walk off with trade secrets and other valuable intangible property, often unnoticed by the companies that they fleece.

You must help your clients develop ongoing, comprehensive plans to protect their intangible assets. This type of plan must account for the possibility that you might be compelled to take legal action to protect the intangibles. How can you increase the likelihood that a court will grant the injunctive relief that your client will need? The answer is simple: wear a white hat.

Wear a White Hat

Watch an old-time black and white Western, and you’ll quickly discern the “good guys” from the “bad guys.” The “good guys” invariably wear white hats, while, for some unexplained reason, the “bad guys” feel compelled to wear black hats. When a new character rides onto the screen, the color of his hat reveals the secret intentions of his heart.

Litigation over misappropriated intangible assets will almost always involve a preliminary injunction hearing. Preliminary injunction hearings are expensive, exhausting, and emotionally draining. In a very short time, you must marshal evidence and convince a judge that your cause is just.

Because these proceedings are expedited, judges search for clues on how they should rule. They are, in essence, trying to determine whether your client is wearing a black hat or a white hat. Your job as counsel is to make sure that your client wears a white hat.

If you want a judge to perceive your client as a “good guy,” you cannot simply...
Covenants not to compete violate fundamental principles of free enterprise and, therefore, generally all jurisdictions disfavor them. Nonetheless, most states will encourage narrowly tailored covenants. California is the most notable exception to the general rule of enforceability. Under California law covenants not to compete constitute an unreasonable restraint on trade that violates public policy. Cal. Bus. & Prof. Code §16600 (2008).

The law of non-compete agreements varies substantially from jurisdiction to jurisdiction, so you need to review the law of your state in establishing the details of a plan. A recent publication of DRI, Trade Secrets and Agreements Not to Compete: A State-by-State Compendium, is a great resource for starting your research. Though the law varies substantially, certain basic principles apply in most states. For instance, “To be valid, the covenant must be reasonably limited in scope (time and place), designed to protect a legitimate interest of the employer, supported by valid consideration, and not harmful to the public.” Mark Filipp, Covenants Not to Compete §2.01, 2–3 (3d ed.) 2008. Courts strictly construe covenants not to compete against an employer, and generally courts will only enforce them if the restrictions are reasonable. See, e.g., Pathfinder Communications Corp. v. Macy, 795 N.E.2d 1103, 1109 (Ind. App. 2003).

Designating certain information as a trade secret protects useful business information. The landmark decision Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 94 S. Ct. 1879 (1974) held that neither the Patent Clause of the Constitution nor federal patent law preempted trade secret protection for patentable or unpatentable information. In 1979, the National Conference of Commissioners on Uniform State Law approved the Uniform Trade Secrets Act (UTSA) as a means of protecting valuable intellectual property. Currently, 45 states and the District of Columbia have adopted statutes based on the UTSA. In addition, Massachusetts protects trade secrets through statutory schemes that are not based on the UTSA. New Jersey, New York, Texas, and Wyoming protect trade secrets under the common law.

A trade secret “is one of the most elusive and difficult concepts in the law to define.” Lear Siegler, Inc. v. Ark Ell Springs, Inc., 569 F.2d 286, 288 (5th Cir. 1978). As noted by one court, “In many cases, the question of whether certain information constitutes a trade secret ordinarily is best ‘resolved by a fact finder after full presentation of evidence from each side.’” Carbo Ceramics, Inc. v. Keefe, 2006 WL 197340, at *9 n.1 (quoting Lear Siegler, 569 F.2d at 289).
of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of the measures taken by him to guard the secrecy of the information; (4) the value of the information to him and to his competitors; (5) the amount of effort or money expended by him in developing the information; and (6) the ease or difficulty with which the
tailored plan based on the specific needs of that business. Your efforts to protect the business must be as unique as the business itself. Tailoring appropriate restrictions and policies requires a company and its counsel to carefully consider the following questions:

What unique and valuable information is used in the business? That valuable information may include customer lists, research and development, marketing plans, or other information that helps your client’s business prosper. Specifically identify your information, and then take proper steps to protect it. Does the information qualify for trade secret protection? If so, what are you doing to protect and secure the information as a trade secret?

Who has access to that unique and valuable information? Your client’s employees have different levels of access to the company’s confidential information. Tailor protections based on the level of access that each employee has to that information.

What steps can you take to protect that unique and valuable information? Do you need to protect trade secrets? What role should Non-solicitation agreements play in your plan? Is a non-compete agreement appropriate for some of your employees? What aspects of physical security do you need to implement in the business? Are you adequately training employees on how to protect and secure the company’s valuable information?

How often should you review and update a plan? Remember that nothing remains constant. Employees take on new responsibilities and duties over time. Regularly review a plan to ensure that it still protects your client’s business given current needs and situations.

One Size Does Not Fit All
Clothing manufacturers have for years perpetrated the lie that, for at least some types

**If you want** an enforceable restriction, you must change the way that you think about negotiation.

- **Draft Narrow Restrictions**
  One of the surest indicators of the color of your client’s hat is the scope of restrictive covenants entered into with employees. White Hats have narrowly drafted restrictions, closely tailored to their legitimate business interests. Black Hats seek expansive restrictions. White Hats recognize that employees need to make a living after they leave. Black Hats are oblivious to anything other than their own selfish interests. White Hats focus on unfair competition. Black Hats want to stifle competition.

  If you want an enforceable restriction, you must change the way that you think about negotiation. Stand your thinking on its head. Rather than trying to grab as much as possible, secure the minimum that you need to protect the business’ interests. Think small.

  Americans tend to believe in the value of free enterprise and fair competition. When you ask a judge to enforce your restrictive covenants and prevent someone from competing with your client, you must show her that your restriction is fair, reasonable, and limited. If your restriction is too broad, your client risks being considered a Black Hat. A Black Hat is so obsessed with protecting everything that he ends up protecting nothing.

  Before you draft a restrictive covenant, ask yourself the following questions:
  - What specifically does my client want to protect?
  - Why would it be unfair for this employee to compete in the protected area?
  - Does my client really need this restriction? Why?
  - What is the smallest restriction that adequately protects my client’s business interests?

  Don’t accept the first answer that pops into your head, or that your client gives you, but instead refine your initial responses continuously until you have the narrowest answer possible. Document your answers to these questions, and develop a plan for protecting your client’s intangible assets using these narrow answers. If you eventually have to protect your client’s intangible assets in court, you will have a well-conceived plan that will assist you in obtaining injunctive relief.

  Wear a White Hat. Draft narrow restrictions.
of garments, one-size-fits-all. Look around at the people you know, and you will agree that the “one-size-fits-all” proposition is laughable.

People come in many different sizes and proportions: tall and short, lean and plump, and everything in between. My son and I are about the same height, but if I try to squeeze into a pair of his pants, I will burst the seams. My daughter is drowning in cloth if she puts on one of my shirts. One size does not fit all.

Most people know better than to wear shorts and flip-flops to a black tie event. Nonetheless, those same people often mistakenly try to shoehorn all their employees into signing restrictive covenants that they got from a neighbor or, even worse, from the Internet. These short-sighted efforts are the equivalent of trying to fit a 350-pound defensive tackle into a size 2 sundress. It’s not a pretty sight.

White Hats know that they must specifically draft restrictive covenants for particular employees or positions. A skilled tailor uses no more and no less material than is needed to properly do the job. Counsel for a White Hat carefully tailors a restrictive covenant to fit a particular position. Counsel may have to prepare several different types of restrictive agreements for a client, but a client’s employees will have restrictive covenants that fit them like well-tailored suits.

Black Hats, on the other hand, assume that one-size-fits-all. Not wanting to leave anything uncovered, Black Hats add overly broad provisions and needless verbiage to a restrictive covenant, reasoning that if a non-compete agreement is good enough for a CEO, it’s good enough for a rookie sales representative. This type of drafting, figuratively speaking, is similar to giving a 5XL shirt to a five-year-old child. One size does not fit all.

Tell Applicants About Restrictive Covenants

In your efforts to protect your client’s intangible assets, you cannot forget that you are dealing with real people—often a company’s employees—on the other side of the table. The way you work with them plays a big part in determining whether your client wears a black hat or a white hat.

Black Hats focus only on their objective: get documents restricting employee conduct signed. They drop restrictive covenants and trade secret agreements on their employees unexpectedly and compel employees to sign them without giving employees time to review these documents with counsel. Black Hats see nothing wrong with dumping stacks of oppressive restrictive covenants on new employees during their first day on the job and telling them that they have to sign these documents as a condition of employment. These employees are not concerned that employees may have quit other jobs, sold their homes, or moved their families family from other states to accept employment with these new enterprises.

White Hats, on the other hand, make fairness and honesty part of their companies’ endeavors to protect intangible assets. They live the Golden Rule, and do unto others as they would have others do unto them. White Hats inform prospective employees in interviews that they will be required to sign restrictive covenants, and give the applicants copies of documents that they will be required to sign. They encourage applicants to seek the advice of legal counsel and, in appropriate circumstances, will even tailor the scope of a restrictive covenant to meet an applicant’s specific concerns.

White Hats treat people on the other side of the table fairly. They do so first and foremost because it is the right thing to do. White Hats know, however, that at some point, they may need to defend the scope of their agreements and the manner in which they were implemented. It is much easier to defend those agreements when they have been procured fairly and honorably.

Wear a white hat. Encourage your clients to tell prospective employees that they will be required to sign restrictive covenants, then implement those agreements using policies that are fair to the people on both sides of the table.

Give Adequate Time to Consider Restrictive Covenants

Imagine that you have just started a new job with a great company. You’ve quit your previous job, sold your home, and moved hundreds of miles away from your family and friends to accept this fabulous opportunity.

Now imagine that on your first day at work the director of human resources plops the company’s “standard,” five-page, non-compete agreement in front of you and tells you that you must agree not to work in your industry for three years if you should ever leave the company. What is your initial reaction?

Yeah, I thought so. That’s what judges think, too.

Principles of free enterprise dictate that your clients are subject to the challenges of fair competition. You can, however, help your client protect her business from unfair competition. The way that she goes about protecting the business determines whether she ultimately will be protected.

Black Hats think only about protecting their interests and give no thought to the effects of restrictions placed on employees. Their only concern is that employees sign restrictive covenants, and the sooner the better.

White Hats, on the other hand, realize that human beings sit on the other side of the table. Human beings have parents, spouses, children, and friends. They have personal and professional goals, choices and preferences, wants and needs. In short, they have objectives that may not match your client’s own.

Courtesy dictates that your client gives employees the opportunity to thoughtfully consider the consequences, risks, and rewards before they sign restrictive covenants. They should be encouraged to review them with the important people in their lives and with legal counsel. In appropriate circumstances—for example, if an employee brings a book of business to a company—the company may need to revise its “standard” agreement to accommodate the particular employee’s situation.
Counsel your client to provide prospective employees with a copy of the agreement that they are expected to sign when your client extends job offers. Your client should give prospective employees time to review these agreements before you allow them to sign. Review important portions of the agreement with them, and ensure that their questions are answered before they sign.

When your client gives employees and prospective employees adequate time to review and consider restrictive covenants, the employees more willingly accept these agreements. Your client will develop better agreements from the give and take involved in negotiations. Further, you will increase the likelihood that a court will enforce the agreement.

Don't Overreach
Remember the story about the boy who cried wolf? He tried to manipulate others by falsely claiming that a wolf threatened the town. Though the townspeople were fooled the first few times that he raised the fraudulent alarm, they quickly became weary of his charade and began ignoring him. When he faced a true crisis, no one paid any attention to him.

Black Hats cry wolf incessantly. In the world of the Black Hats, everything about their business is “Confidential,” with a capital “C,” and as such, subject to protection. Give them a “Confidential” stamp and an ink pad, and they can amuse themselves for hours, maybe even days. No piece of information is too insignificant to avoid their grasp.

The truth is that while your client’s business may rely on vast amounts of important information, much of that information does not meet the legal definition of trade secret or confidential information. White Hats recognize that most of their information—though important—does not warrant protection as a trade secret or as confidential information. While Black Hats try to identify as much as they can as warranting trade secret protection, White Hats realize that they need to focus on the information that they can and must truly protect.

Before you identify something as “confidential” or a “trade secret,” take care to specifically identify why the information should be protected. Don’t overreach. Identify with your client why this information should be protected. Thoroughly document your efforts, and take appropriate steps to secure and protect the information.

If you cannot articulate a coherent reason why information is subject to protection, you won’t be able to identify a reason when the information has walked out the door with a client’s former employee. If, when you pitch your case to a judge, you cannot meet your burden of proof, you will draw comparisons between yourself and the boy who cried wolf. By crying “trade secret” when no secret exists, you will annoy a judge and minimize the importance of your client’s truly valuable information.

Not everything is confidential or a trade secret. Carefully and specifically identify the true trade secrets and confidential information in your client’s business, then work aggressively and relentlessly to protect that information.

Create a Culture of Confidentiality
Does your client expect others to secure her trade secrets, protect her patents, and guard her goodwill? Then your client must respect the intangible assets of others.

Even if you have implemented sound policies and procedures to protect your client’s intangible assets, those policies will fail if your client does not have buy-in from his employees. You can talk a good game about protecting intangible assets, but the employees will take their cue from your client’s actions, not his words. Your client must walk the walk, and not just talk the talk.

If your client blathers on about the importance of her trade secrets and confidential information, then tries to hack into a competitor’s computer network to gain a competitive advantage, her employees will recognize her as a charlatan and a fraud. That client’s intangible assets will receive no more respect than she will assign to the assets of others.

Help your client create a “culture of confidentiality” that will reverberate the length and breadth of the company. Help your client conduct himself in a principled and honorable manner at all times. Compete fairly. Speak truthfully, even when it is a disadvantage to do so. Don’t poach. Be respectful and courteous. Make all corners square. Do the right thing, all the time. Businesses that behave ethically have the moral authority to insist that their employees do likewise.

Not only is it the right thing to do, your client will be glad that she did if you have to sue to protect her intangible assets. Imagine how difficult it would be to convince a judge to enforce a non-compete agreement against a former employee who testifies that your client regularly sought to circumvent her competitors’ restrictive covenants. The judge would, with good reason, proclaim your client a Black Hat unworthy of judicial protection.

Implement Immediately
Protecting intangible assets is an ongoing, continuous job. Your client cannot simply draft a plan and leave it in his top, desk drawer. If he does not implement the plan, it will all be for naught.

But when is that plan ready for your client to implement? The longer I think about a plan, the more detailed it becomes. If I don’t stop myself, I end up with a plan that may be impossible to implement, much less complete.

A few years ago, a speaker at a conference for entrepreneurs taught me how to implement complex plans. The topic was how to prepare a pitch for prospective investors.

“How do you know when your presentation is ready?” the speaker asked. “The answer is simple: always and never.”

Your presentation is always ready, he explained, because you may have to give it today. And it is never ready, because once you give it, you will continue to work on it and improve it.

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The key is to not worry about whether a plan is perfect before it is implemented, but rather to immediately implement the best plan currently available, when sufficiently developed, then continuously refine and upgrade that plan.

If your client waits to implement a plan until she thinks everything is perfect, she will never implement anything. No matter how well-conceived the plan, you can always improve and enhance it. Your client will never find a perfect time to implement the plan because something will always stand in the way. Instead of waiting for a perfect time, your client has to decide when a plan is sufficiently developed to begin implementing it.

White Hats do the best that they can today, and work on improving their plans tomorrow. Implementing a plan shows a court that your client approached with seriousness the responsibility to secure and protect her intangible assets.

Enforce Consistently

White Hats understand that taking reasonable steps to protect their intangible assets involves more than drafting a boilerplate plan that sits in their CEOs’ desks. A plan is useless if not incorporated into a company’s culture and practice.

In fact, a plan may be worse than useless if not properly implemented. If, for example, a plan states that a company will store certain documents in password-protected files accessible only by a select few people and then fails to do so, the company may lose the ability to protect those files as trade secrets. If a company has identified a “reasonable” procedure for protecting its trade secrets and then fails to implement that procedure, you will have a difficult time persuading a court to protect the company’s trade secrets. Unsurprisingly, a court will be reluctant to do for a company what the company was unwilling to do for itself.

White Hats develop reasonable policies to protect their intangible assets, then implement and enforce their policies consistently. This type of employer regularly trains company employees about their responsibility to protect the company’s intangible assets. That training and teaching is always and never done. White Hats train when they hire, when they promote, and when they meet, in regular staff meetings. They teach employees what their obligations are, and then help them fulfill those obligations.

White Hats review and update their policies and procedures regularly. At least annually, they audit and account for their intangible assets, determine who has access to those assets, and assess whether their current policies are still effective. They ensure that all employees with access to critical information have signed narrowly tailored restrictive covenants that are appropriate for each employee’s position. In conjunction with their counsel and with security consultants, they revise their policies and procedures to account for company growth, and for new intangible assets and employees. When necessary, White Hats take appropriate disciplinary action against employees who disregard those reasonable policies and procedures.

Consistent enforcement takes discipline and effort by both you and your client. In some ways, consistently enforcing reasonable intangible asset policies may be the most important way that your client can demonstrate that he wears a White Hat.

Conclusion

As the cowboys in the old-time Western movies, your client can convey the clear and unmistakable message that he wears a white hat. With this white hat securely in place, your client can protect his valuable, intangible assets from theft and misappropriation.

Your job as counsel is to help your client find and wear this white hat by working with him to develop and implement appropriate strategies and procedures to reinforce and strengthen the impression that he has approached intangible assets as a White Hat.
By Scott F. Gibson

Maintaining trade secrets may seem overwhelming, but you must help your client start now.

Your client’s intangible assets are at risk—and its employees pose the greatest threat to those assets. Those intangible assets walk out the door with your client’s employees at the end of each work day. If all goes well, they will return intact the next day. Intangible assets can be downloaded, duplicated, and distributed to competitors, or used to help an employee set up a competing business. They can be posted on the Internet, or transmitted instantaneously around the world with the click of a mouse. Your client’s success heavily depends on its ability to protect those assets from misappropriation and misuse.

Intangible assets make up as much as 85 percent of the value of your client’s company. New Ways Needed to Assess New Economy, L.A. Times, Nov. 13, 2000. Traditional intellectual property law covering patents, trademarks, and copyrights protects many of those assets, but trade secrets make up an increasingly greater portion of intangible assets. If your client wants to protect its business from disloyal employees and from unfair competition, the law requires it to take “reasonable efforts” to maintain the secrecy of its trade secrets.

A trade secret audit is a key component of the “reasonable efforts” to protect the secrecy of trade secrets. Properly done, a trade secret audit helps a company (1) identify intangible assets entitled to trade secret protection and document the scope of the company’s legally protectable interest, (2) segregate and secure the assets, and (3) develop appropriate protocols and procedures to protect the assets. A proper audit addresses every interaction that employees, vendors, customers, and outsiders have with the company’s intangible assets, and it identifies appropriate methods for securing the assets from misuse or misappropriation. It allows a company to determine whether it needs restrictive covenants or confidentiality agreements with particular employees who have access to trade secrets and other valuable intangible assets.

Perhaps most importantly, a well-conceived audit helps establish an employer as a “White Hat” and strengthens the likelihood that a company will obtain injunctive relief if litigation becomes necessary to protect its trade secrets or other intangible assets. See Scott F. Gibson, Protect Your Intangible Assets: Wear a White Hat, For The Defense, Mar. 2010, at 40 (discussing “white hat” employers).

Value of Intangible Property
In the not too distant past, a company derived its value largely from its hard
assets—its land, resources, and inventory. A company’s intellectual property and other intangible assets, while valuable, played a secondary role in creating value for the company. As late as the early 1980s, publicly traded companies in the United States derived only 40 percent of their value from their intangible assets. A Market for Ideas, The Economist, Oct. 22, 2005.

Those days are long gone. The American economy has undergone a transition from a manufacturing economy to a service economy; technological advances have emphasized ideas and innovations. During the dot-com era, companies transformed an idea to a publicly traded company without ever selling a product. Patent portfolios and licensing agreements have become key components determining a company’s financial standing. Companies conduct business through cyberspace without any tangible physical presence, and they prosper because of their ideas. As Alan Greenspan, former chairman of the Federal Reserve, noted, “The economic product of the United States [has become] predominantly conceptual.” Id.

Intangible assets—ideas and innovations—have become your client’s most valuable resources. Those intangible assets take many forms, ranging from traditional intellectual property—patents, trademarks, and copyrights—and electronic data, to branding strategies and financial profiles, to customer goodwill and secret formulas. Intangible assets help a company differentiate itself from its competitors and establish the foundation for the company’s marketing niche. No matter the industry, every company has valuable intangible assets that it must leverage and protect.

At the same time that intellectual property has become more central to the financial viability of companies, employees have become more mobile, regularly changing jobs from one company to another. Current and former employees constitute the greatest threat to intangible assets. ASIS Int’l, Trends in Proprietary Information Loss, Aug. 2007, at 29. [http://www.asisonline.org/newsroom/surveys/spi2.pdf] (last visited Dec. 29, 2010). Technological advances have made it increasingly easier for thieves to walk off with that intellectual property, often unnoticed by the companies that they fleece.

As bad as the risk of theft is, losses from careless or untrained employees are worse. Employees often inadvertently compromise their employer’s intangible assets by misdirecting e-mails or faxes, observing information without authorization, or by exposing them in written communications or in oral presentations at trade shows. Id. at 29. One recent study disclosed these shocking facts:

- One of every 50 files on file shares and desktops contain exposed confidential data.
- One of every 400 outbound e-mail messages contains confidential data.
- 95 percent of data loss incidents are unintentional. Most breaches are the result of careless or untrained employees, or legacy automated processes,
- 41 percent of violations contained intellectual property, insider information, or trade secrets.
- 58 percent of violations may be subject to review under state and federal regulations.
- The average number of data loss incidents per year per employee is four.


The losses associated with the theft of trade secrets are staggering. For example, a recent survey of Fortune 1000 companies and 600 small and mid-sized companies belonging to the U.S. Chamber of Commerce estimates that the companies suffered between $53 billion and $59 billion in losses of proprietary information and intellectual property in 2001. ASIS Int’l, Trends in Proprietary Information Loss, Sept. 2002, at 1. Some 40 percent of the companies participating in the survey reported incidents of known or suspected losses of proprietary information. Id.

If your client wants to avoid becoming part of these staggering statistics, it must take appropriate steps to protect and safeguard its intangible assets. Your job as counsel is to help your client do so.

Defining a Trade Secret

Part of the challenge of protecting trade secrets is that, well, they are intangible and, therefore, difficult to define and conceptualize. Indeed, a trade secret “is one of the most elusive and difficult concepts in the law to define.” Lear Siegler, Inc. v. Ark Ell Springs, Inc., 569 F.2d 286, 288 (5th Cir. 1978).

To successfully protect those ethereal assets, you must first understand how the law protects ideas and innovations. The law of trade secrets initially developed through the common law. Two major sources of law—the Uniform Trade Secrets Act and the Restatement of Torts—outline the legal principles primarily used to secure and protect trade secrets.


Trade secrets are particularly well suited for the Information Age: “Machinery and mechanisms were the brainchildren of the Industrial Age, and patent law was designed to protect them. In the Information Age, trade secret protection is better suited to the fast-moving and unpatentable confidential information we need to run our companies.” R. Mark Halligan and Richard F. Weyand, The Sorry State of Trade Secret Protection, [http://www.thetso.com/info/sorry.htm] (last visited Dec. 29, 2010).

In 1934, the Restatement of Torts outlined the definition of a trade secret:

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not now it or use it. It may be a formula for a chemical
compound, a process of manufacturing, treating or preserving materials a pattern for a machine or other device, or a list of customers.

Restatement of Torts §757, cmt. b (1934).

The Restatement definition quickly became the most common legal approach to handling trade secrets. The law did not develop consistently and uniformly under

Your challenge is to make the intangible tangible, to give substance to the ephemeral, and to help a court visualize the invisible.

the Restatement definition, however, and when the American Law Institute published the Restatement (Second) of Torts in 1977, it failed to discuss liability for misappropriation of trade secrets.

In 1979, the National Conference of Commissioners on Uniform State Law approved the Uniform Trade Secrets Act as a means of protecting intangible assets. In doing so, the commissioners noted that while trade secret law had considerable commercial importance, “this law has not developed satisfactorily.” Unif. Trade Secrets Act, Commissioners’ Prefatory Note. The UTSA was designed to resolve the “uneven” development of the law and the “un duly uncertainty concerning the parameters of trade secret protection, and the appropriate remedies for misappropriation of a trade secret.” Id. If all goes well, your client will never have to file suit to protect its intangible assets. It will faithfully implement the plan that you have developed to protect its trade secrets. Employees will care for and guard the company’s trade secrets, former employees will respect the legal boundaries placed on them through restrictive covenants and the common law, and competitors will stay within the limits of fair competition. Life is wonderful when things work the way they were designed.

But real life is often messier than it should be. When people fail to honor their commitments, you must litigate to protect your client’s trade secrets.

A court likely will first consider the merits of your client’s case in a preliminary injunction hearing. Preliminary injunction hearings are abbreviated and fast paced. You may not have time to fully develop the evidence supporting the virtue of your client’s case. What can you do to increase your odds of success? The answer is simple: wear a white hat.

The old black and white Western movies use visual clues to help an audience distinguish the “good guys” from the “bad guys.” The “good guys” wear white hats; “bad guys” wear black hats. This simple dress code allows even the least attentive patron to determine where to place his or her allegiance.

In similar vein, judges look for clues to determine which party should prevail on a claim for injunctive relief. If your client is a White Hat—that is, if it has behaved ethically and fairly—the court will award your client with the injunctive relief it desperately needs. If not, the court will deem it to be a Black Hat, and allow those critical intangible assets to dissipate away.

The UTSA has received widespread acceptance, with 44 states and the District of Columbia adopting statutes based on it. The other six states—Massachusetts, New Jersey, New York, Pennsylvania, Texas, and Wyoming—protect trade secrets either under the common law or through a state-specific statutory scheme. The Restatement definition plays a vital role in the states that have not adopted the UTSA. See, e.g., Ashland Mgmt v. Janien, 82 N.Y.2d 395, 407, 624 N.E.2d 1007, 1013 (N.Y. 1993).

Wear a White Hat

If all goes well, your client will never have to file suit to protect its intangible assets. It will faithfully implement the plan that you have developed to protect its trade secrets. Employees will care for and guard the company’s trade secrets, former employees will respect the legal boundaries placed on them through restrictive covenants and the common law, and competitors will stay within the limits of fair competition. Life is wonderful when things work the way they were designed.

But real life is often messier than it should be. When people fail to honor their commitments, you must litigate to protect your client’s trade secrets.

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The challenge with intangible assets is that, as mentioned before, they are intangible and difficult to conceptualize. Judges are reluctant to protect that which they cannot see or comprehend, particularly when the putative owner can only vaguely describe the asset and has difficulty proving that he or she actually owns it. Your challenge is to make the intangible tangible and to help a court visualize the invisible. Judges cannot see or comprehend, particularly when the putative owner can only vaguely prove that he or she actually owns it. Your challenge is to make the intangible tangible and to help a court visualize the invisible. You must clearly show a judge that your client deserves the relief that he or she seeks.

A trade secret audit helps establish your client as a White Hat by allowing it to identify and document, segregate and secure, and develop the appropriate procedure and protocols to protect its trade secrets.

White Hats document and inventory their intangible assets early and often. They show that they value their trade secrets by taking reasonable steps to protect those assets. They can demonstrate how their trade secrets differ from an employee’s general knowledge and skills, which courts do not consider proprietary. White Hats validate their trade secrets before these valuable assets have been compromised.

**Conducting an Audit**

The specific scope of a trade secret audit varies depending on a client’s industry and the nature of its intangible assets. Regardless of the industry, however, an audit locates assets and establishes the restrictions placed on the people who have access to the assets, including job applicants, employees, former employees, vendors, and business partners.

### Trade Secrets Audit Checklist

**Identify categories of potential trade secrets.**

- Technical information
  - Proprietary technical information
  - Research and development
  - Formulas
  - Compounds
  - Prototypes
  - Processes
  - Lab notebooks
  - Experiments and experiment data
  - Analytical data
  - Calculations
  - Computer programs
  - Business know-how, including negative know-how
  - Drawings
  - Design data and manuals
  - Vendor and supplier information

- Production and processing information
  - Cost or pricing data
  - Proprietary information concerning production and processes
  - Special production machinery
  - Processing or manufacturing technology
  - Specifications for production processes and machinery
  - Production know-how and negative know-how
  - Business methodologies
  - Distribution sources

- Sales and marketing information
  - Sales and marketing plans
  - Sales forecasts
  - Proprietary information about sales and marketing
  - Sales-call reports
  - Customer lists and databases
  - Customer needs and buying habits
  - Proprietary sales and marketing information

- Financial information
  - Proprietary financial information
  - Internal financial documents
  - Budgets and forecasts
  - Computer printouts
  - Product margins
  - Product costs and pricing
  - Operating reports
  - Profit and loss (P&L) statements

- Internal administrative information
  - Proprietary administrative information
  - Internal organization
  - Information about key personnel

- Strategic business plans
- Internal computer software

**Document trade secrets.**

- Identify storage media
  - Electronic
  - Physical documents
  - Human memory

- Identify storage systems and devices.
  - Filing cabinets
  - File server
  - Workstations
  - Voice-mail system
  - Portable objects
    - Lap tops
    - PDAs
    - Flash drives
    - CDs and other electronic media

- Identify trade secrets storage locations.
  - Company headquarters
  - Satellite offices
  - Work sites
  - Offsite locations
    - Employee homes
    - Subcontractors
    - Clients, customers, vendors, and business partners

**Restrict access to confidential information.**

- Security procedures
  - Premises
  - Network
  - Backup of network
  - Access
  - Authorization
  - Portability
  - Espionage

- Review and update company policies on a regular basis.
- Conduct regular audits of policies and procedures used to protect confidential information. Update and amend policies as needed.
- Develop procedures for correcting inadvertent disclosure.
- Establish a policy of pursuing theft of trade secrets and other confidential information.
- Develop an appropriate document-retention policy.
Identify and Document
The first step of a trade secret audit will identify the trade secrets and other intangible property a company needs to protect. That analysis should cover every aspect of a company’s business, including research and development, manufacturing, production, sales, marketing, and human resources. The Trade Secrets Audit Checklist on page 39 identifies key components of an audit.

To determine whether your client’s information qualifies for trade secret protection, focus on three key questions: (1) Is the information commonly known in the industry? (2) Does the company receive economic value from the information because it is not commonly known in the industry? (3) Has the company taken reasonable steps to protect the secrecy of the information?

Once you have identified the relevant trade secrets, prepare a confidential list of them. The list should identify each trade secret with reasonable particularity, and it should outline how the trade secret was developed.

Work with company representatives to identify specifically why the information is valuable to the company. One of the primary rules of marketing is that, to succeed, a company must differentiate itself from its competitors in ways that are meaningful to its customers. The same rule applies to trade secrets and other intangible assets. You must be able to demonstrate and communicate how each asset differs from industry standards, and why that difference is meaningful in your client’s industry.

If you are required to go into court to protect a trade secret, you will need an articulate witness who can explain both the value of that trade secret and the efforts that its owner has taken to develop and protect it. Most companies do not begin gathering information on their trade secrets until a disloyal employee has walked out the door with one. Don’t make that mistake. As part of an audit, begin preparing a company representative to testify about the trade secret during a trial. If things go well, you will never need to finalize that direct examination. You will find, however, that contemplating the scope of testimony will help you better understand the information that your client wants to protect and will allow your client to more effectively protect and secure its intangible assets than otherwise.

One of your main objectives is to help your client make its intangible assets substantial and real. You can do so by mani-

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**Trade Secrets and Employee Relations Protocols**

**Prehiring**

- Have a written job description for every position that
  - identifies the essential job functions of the position;
  - identifies the interactions that the employee will have with trade secrets, confidential information, and intangible assets;
  - identifies the types of agreements that the employee must sign with the employer—confidentiality agreements, trade secrets agreements, non-compete agreements, and other restrictive covenants; and
  - has been reviewed and updated within the last 12 months.
- All job postings should identify the essential job functions for the position.
- All candidates should complete a standard application form that
  - states that the company protects the trade secrets, confidential information, and intangible assets of others;
  - states that the company protects its own trade secrets, confidential information, and intangible assets;
  - requires a candidate to disclose any agreements that would impact his or her ability to perform the essential job functions of the position—confidentiality agreements, trade secrets agreements, non-compete agreements, and restrictive covenants; and
  - requires a candidate to affirm in writing that he or she will abide by any agreements with his former employers;
  - requires a candidate to affirm that he or she will not disclose any trade secrets or confidential information of any current or former employer as part of the application and interview process; and
  - requires the candidate to identify in general terms the types of trade secrets and confidential information that he or she holds.
- All candidates should submit a resume.
- A capable human resources specialist should screen all applications and resumes.
- The company should adopt and follow an approved policy for reviewing the candidate’s job history and references.
- Candidates should sign an approved Non-Disclosure Agreement (NDA) if they will be exposed to any confidential information during the interviewing process.
- A candidate should receive a copy of the completed application.
- A candidate should receive a signed copy of the NDA.
- A candidate should receive a copy of any confidentiality agreements or restrictive covenants that he or she will be required to sign as a condition of employment.
- The company should design and use a standard protocol for interviewing applicants.
  - The interviewer should take notes on a standard form identifying key points to be covered during the interview.
  - The interviewer reiterates key points about confidential information:
    - The company respects and protects the trade secrets and confidential information of others.
    - The company protects its own trade secrets and confidential information.
    - The candidate should not disclose any trade secrets or confidential information of others during the interviewing process.
    - The company expects the candidate to abide by all agreements with any current or former employers.
    - The interviewer explains the types of agreements that the successful candidate will be expected to sign to protect the company’s trade secrets, confidential information, and intangible assets.
- Before a candidate is asked to return for a second interview, the company should review the applications of all
festing intangible assets through a physical means. For example, you can explain an intangible idea in writing, marking the writing “confidential,” and storing it in a secure location with limited access. Likewise, a process becomes tangible when you document and name it, as well as when employees receive ongoing, systematic training on how to properly perform the process. As you help your client identify its trade secrets and other intangible assets, consider how you can best give that intangible property form.

**Segregate and Secure**

Once you have identified and documented your client’s intangible assets, you must next segregate and secure that property. Segregate trade secret materials from intangible assets that are not. When appropriate, label the information confidential and move it to a secure location. Assigning a location to confidential information partly will depend on its format. The following security methods may be appropriate to secure the property:

- Mark documents as “Confidential” or “Trade Secret,” and specifically restrict copying of the documents.
- Limit access to sensitive information on a “need-to-know” basis.
- Create physical security barriers.
- Use password-protected computer files.
- Develop segregated portions of a hard drive.
- Monitor the number of physical copies that document a trade secret.
- Disable the USB ports or other methods of downloading information to storage devices.
- Maintain logs documenting the nature and scope of a trade secret.

**Trade Secrets and Employee Relations Protocols, cont.**

agreements that the candidate has signed with current or former employers.
- The company human resources department should maintain all applications, resumes, agreements, and interview notes in individual files for each candidate.

**Extending a job offer**

- The interviewer should take notes on a standard form identifying key points to be covered during the second interview.
- A candidate should receive copies of all agreements that he or she will be expected to sign if he or she accepts the job and is encouraged to review the agreements with counsel and with family members before signing them.
- The candidate should receive a copy of the company’s employee handbook and confidentiality policies.
- The interviewer should instruct the candidate to remain loyal to the current employer and caution the candidate — to refrain from removing original records from that employer; — not to advise clients of departure prior to resignation; — not to advise coworkers of departure prior to resignation; — not to solicit customers; — not to solicit coworkers to leave that employer; — to work with employer to return coordinate the return of all confidential information; and — to cooperate with the employer in training the candidate’s replacement.

**Employee relations**

- As part of an annual employee evaluation, review the company policies on trade secrets, confidential information, electronic services and communications, among other policies and procedures, with each employee. Have each employee sign an acknowledgment that the person conducting the evaluation meeting reviewed the policies.
- Protect confidential information from employees’ access from remote locations.
- Restrict access to sensitive information on a need-to-know basis. Incorporate appropriate training and agreements with those who have a “need to know.”

**Create a culture of confidentiality in the workplace.**

- Regularly discuss the obligations of confidentiality in employee meetings, at least two times per year.
- Review obligations of confidentiality as part of employees’ annual review.
- Document independent development of trade secrets and other confidential information.
- Keep confidential information off of the company’s website and make sure it is not in other marketing materials. Avoid disclosing confidential information through electronic communications.
- Follow the company’s policy on confidentiality

**Employee departures**

- Determine the type of information the company is most concerned about losing with the departure of the employee.
- Inventory sensitive documents to which the employee has had access.
- Inventory any electronic materials to which the employee has had access, including source code. Note the “last edit” dates and the “edited by” information.
- Review the status of the employee’s agreements with the company, including the annual acknowledgment of the company’s policies. If any acknowledgments are missing, ask the employee to sign an acknowledgment during the exit interview.
- Schedule an exit interview with a human resources representative and with the employee’s manager upon confirming the employee’s departure.
- If management suspects theft of trade secrets or confidential information, immediately arrange for forensic imaging of the hard drive of the employee’s computer.
Trade Secret, from page 41

"Reasonable" depends on the nature of the trade secret, the value the information holds, and the size and sophistication of the business. The definition of “reasonable” is not static. An owner may need to take increasingly more sophisticated efforts to protect a trade secret as a company grows or as the information takes on greater value to the company.

Regularly evaluate the “reasonableness” of the efforts made to protect a trade secret. Your client should audit at least annually, reviewing trade secrets already covered in previous audits, as well as new trade secrets, and regularly should update efforts to segregate and secure them.

Protocols and Procedures

This is where the rubber meets the road. It is easy to talk about trade secrets, but unless your client develops and fully implements appropriate protocols and procedures, your efforts have been in vain. Indeed, if your client does not faithfully implement its trade secrets protocols and procedures, they may serve as evidence against the company’s interests. After all, if a company identifies certain procedures as being “reasonable” to protect its trade secrets and then fails to follow those procedures, it has not taken “efforts that are reasonable under the circumstances” to protect the trade secrets.

Trade secret protocols and procedures will center primarily on a company’s interactions with its employees. “Trade Secrets and Employee Relations Protocols” on pages 40–41 identifies a number of protocols that a company will want to develop for its prehiring, hiring, employment, and postemployment interactions with its employees.

In addition, a company should develop different procedures for handling corporate information based on the nature of the information involved. For example, some information is available for public disclosure, such as press releases, website postings, and marketing materials. Other information is for internal company use only, such as organizational charts and disaster recovery plans. Still other information is sensitive and confidential and employees should access it only on a “need-to-know” basis. This information includes marketing plans, business plans, and financial information. Finally, a company should place the greatest restrictions on highly sensitive confidential information. This information includes highly confidential third-party information, such as information about medical conditions or credit cards. Failure to adequately protect this information may subject a company to legal liability.

Tailor the protocols and procedures to the specific needs of a company. Though the procedures undoubtedly will require a company to make changes to its operations, those changes should not be so overwhelming that they become impossible to implement. If a company makes vast changes, take a more practical approach, implementing the protections and protocols over time.

Conclusion

A company’s efforts to maintain its trade secrets and other intangible assets are ongoing and never ending. The task may seem overwhelming, but you must help your clients start now. Do not delay.

Your client can do nothing and hope that when its most valuable assets walk out the door with its employees at the end of the work day, they will always return intact the next day. Or, your client can recognize the vulnerability of its intangible assets and take appropriate steps to protect the company.
Avoiding a Patent Thicket in Nanotechnology

By Scott F. Gibson
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The United States Patent and Trademark Office ("PTO") is coming under increased scrutiny, with claims that patents are being issued too easily for inventions that are neither novel nor otherwise protected under the patent laws. Other critics claim that many patents are being issued for "inventions" that are products of nature that should not be patentable. These factors raise serious concerns about the creation of a patent thicket, "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." Under a patent thicket, "the risks created by multiple patent holders, each of which has the right to exclude, leads to an underinvestment in R&D." Others describe a patent thicket as contributing to the development of an "anticommons" of knowledge where "multiple owners each have the right to exclude others from the use of a resource and no one has an effective privilege of use," leading to an underuse of the resource.

A patent thicket may already be developing in nanotechnology, with the cross-discipline nature of the science accentuating the challenges the thicket present for future

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1 Member, Gibson, Ferrin & Riggs, PLC, Mesa, Arizona; LLM, Biotechnology and Genomics, Sandra Day O’Connor School of Law at Arizona State University 2007; J.D. (cum laude), Arizona State University 1986.
5 One of the challenges in discussing legal issues related to nanotechnology is that "nanotechnology" has no uniformly accepted definition. Broadly speaking, nanotechnology is "the
growth and innovation. Some commentators suggest that the effects of the patent thicket can be avoided through cross-licensing and patent pools, vehicles that have worked successfully in other fields. Still others assert that open sourcing offers a solution to the patent thicket.

This paper will discuss ways to avoid a patent thicket in nanotechnology, focusing on cross-licenses, patent pools, and open source development. It also will include a brief review of antitrust issues arising from cross-licenses and patent pools.

I. Challenges at the PTO

Intellectual property has become increasingly more important for companies as the economy has evolved from one based on tangible property to an economy based on ideas and innovations.6 The increased emphasis on intellectual property – coupled with judicial decisions allowing patents in areas previously not recognized by the law7 – has overwhelmed the United States Patent and Trademark Office’s (“PTO”) ability to handle patent applications. The number of patents issued by has increased dramatically, rising

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6 See, e.g., “A market for ideas,” The Economist, October 22, 2005. This change affects all aspects of the economy. “As much as three-quarters of the value of publicly traded companies in America comes from intangible assets, up from around 40% in the early 1980s.” Id. Indeed, as Alan Greenspan, former Chairman of the Federal Reserve, has noted, “the economic product of the United States [is] predominantly conceptual.” Id.

from 66,000 patents in 1980\textsuperscript{8} to more than 170,000 patents in 2005, an average of one patent every three minutes.\textsuperscript{9} Nearly 400,000 new patent applications were filed with the PTO in 2005, and more than 900,000 applications remain unexamined, a number that continues to grow.\textsuperscript{10}

Moreover, so many patents are issued in mature industries that it is virtually impossible for companies to avoid unintentionally infringing on patents as they develop new products. For example, the PTO granted nearly 5,000 patents related to “microprocessors” alone, separate and apart from the additional patents granted for the broader “semiconductor” industry that same year.\textsuperscript{11}

Many experts believe that the increased emphasis on patents has diminished the quality of the patents issued, as “measured by whether the invention is truly new and meets its claims.”\textsuperscript{12} The result, critics charge, is that patents are issued for “inventions” that are neither novel nor innovative, leading to a “backlash against the patent system as it is currently operating.”\textsuperscript{13} Many argue that current patents do not meet the standards of novelty,\textsuperscript{14} utility,\textsuperscript{15} and non-obviousness\textsuperscript{16} required by patent law. One critic claims that

\textsuperscript{11} Shapiro, \textit{supra}, note 2, at 3, n. 3.
\textsuperscript{12} “Patent Sense,” \textit{The Economist}, October 22, 2005.
\textsuperscript{13} Shapiro, \textit{supra}, note 2, at 2.
\textsuperscript{14} “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2005).
\textsuperscript{15} \textit{Id.}
\textsuperscript{16} A patent may not issue “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time
“much of what the Patent Office sees as invention is merely science applied to a new field by equation or analogy.”\textsuperscript{17} The fundamental problem with the patent system, he claims, is that “[w]e issue patents too easily for trivial ideas, thus diminishing protection for true breakthrough ideas.”\textsuperscript{18} Another asserts that “our patent system, while surely a spur to innovation overall, is in danger of imposing an unnecessary drag on innovation by enabling multiple rights owners to ‘tax’ new products, process and even business methods.”\textsuperscript{19}

Moreover, the PTO grants patents at a rate that is significantly higher than the European and Japanese Patent Office. For fiscal years 1993-98, the PTO had a “Grant Rate”\textsuperscript{20} ranging “from 80% to 97%, depending on the extent to which prosecution of abandoned applications was prolonged in continuing applications.”\textsuperscript{21} By contrast, the European and Japanese Patent Offices reported averaged Grant Rates of 67% and 64%,

\begin{quote}
the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103.
\end{quote}

\textsuperscript{17} Greg Blonder, “Cutting Through the Patent Thicket,” \textit{Business Week}, Dec. 20, 2005, located at http://www.businessweek.com/print/technology/content/dec2005/tc20051220_827695.htm (last accessed March 12, 2007). In support of his position, Mr. Blonder – an inventor, scientist, and venture capitalist – notes that much of what is considered an invention is not truly innovative:

I have observed how easy it is for experts to generate good, but similar ideas. While at AT&T in the early 1990s, I sponsored two separate ideation sessions around a potential new market, bringing in 50 experts each time to brainstorm for applications. Both groups generate ideas with real commercial value.

Both groups, however, generated more than 95% of the same ideas in common. They were “obvious” in the fullest sense of the word and would have been commercialized with or without the incentive of a patent. But the Patent Office found them “novel,” an disused AT&T claims by the basketful. I would argue that none of those ideas deserved a patent.

\textsuperscript{18} \textit{Id.}\textsuperscript{18}

\textsuperscript{19} Shapiro, \textit{supra}, note 2, at 3.

\textsuperscript{20} “The Grant Rate is calculated by dividing the allowances by total disposals, where disposals are the sum of allowances and abandonments.” Cecil D. Quillen, Jr. and Ogden H. Webster, “Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office,” \textit{11 FED. CIR. B.J.} 1, 3 n. 11 (2001-2002).

\textsuperscript{21} \textit{Id.}, at 3.
respectively for the years 1995-99. Not only do innovators seek patents at an every accelerating rate, but the PTO also grants a patent for a high percentage of the filed applications. The “vast number of patents currently being issued creates a very real danger that a single product or service” may infringe on numerous patents. “Worse yet, many patents cover products or processes already being widely used when the patent issued, making it harder for the companies actually building businesses and manufacturing products to invent around these products.”

In the face of these challenges, the number of nanotechnology patents is increasing at a dramatic pace, “with the number of patents on average growing by 30% every year since 2000.” In 1985, the PTO handled 125 patent applications involving nanotechnology issues. A recent study shows that more than 3,700 nanotechnology patents were issued in the United States between 2001 and 2003. Using the same methodology as the first study, a second study reveals that an additional 1,929 nanotechnology patents were issued in 2004 alone, bringing the total to nearly 5,700 patents issued between 2001 and 2004. These numbers are likely understated, as the studies used an “intentionally conservative” definition of nanotechnology inventions, one

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22 Id.
23 Shapiro, supra, note 2, at 3.
24 Id.
26 NCI Alliance for Nanotechnology in Cancer, supra, note 9, at 3.
27 Mark A. Lemley, Patenting Nanotechnology, 58 STANFORD L. REV. 601, 604 (Nov. 2005). Other “conservative estimates” suggest that the PTO issued somewhere between 4,000 and 6,000 nanotechnology patents between 2001 and 2003. NCI Alliance for Nanotechnology in Cancer, supra, note 9, at 3. Yet another study suggests that “[w]ell over 5,000 nanotechnology-related patents” have been issued in the United States as of March 2006. Berger, supra, note 25.
28 Lemley, supra, note 27, at 604.
that does not pick up patents that “use different terminology or employ the language in the specifications rather than in the claims.” 29

As astounding as these numbers are, the number of published applications offers a more accurate reflection of the increase in the number of nanotechnology patents. Patents do not issue for approximately three to five years after they are filed, while U.S. law requires that most applications be published 18 months after they are submitted. Using the same parameters as in the prior studies reflects that the number of applications is increasing at a dramatic rate, rising from 403 in 2001 to 3,842 in 2004 – a total of 9,184 nanotechnology applications from 2001 until 2004. 30 Again, that number is likely understated because it relies on the same “intentionally conservative” definition of nanotechnology inventions and because “U.S. law permits applicants who do not intend to file abroad not to publish their applications.” 31

As a result of the increasing number of nanotechnology patents, the patent landscape for nanotechnology materials is “complex and fragmented,” according to Matthew Nordan, Vice President of Research for Lux Research, which released a report in 2005 addressing 1,084 nanotech patents related to five nanomaterials. 32 That report

29 Id., at 605.
30 Id.
31 Id., at 605 n. 19.
32 “Nanotechnology Gold Rush Yields Crowded, Entangled Patents,” PR Newswire, April 21, 2005, located at http://prnewswire.com/cgi-bin/stories.pl?ACCT=109&STORY=www/story/04-21-2005/0003441627&EDATE= (last accessed April 21, 2007). The report analyzed patents covering dendrimers, quantum dots, carbon nanotubes, fullerenes, and nanowires, and rated the nanomaterials “according to how much ‘white space’ remains for new claims and how entangled existing patents look.” Id. As part of its analysis, the report reached the following conclusions:

- “Dendrimers pose the biggest question mark, scoring low on white space and freedom from entanglement for all commercially significant applications.”
- “Quantum dots have particularly knotty entanglement for general claims that cover the materials themselves and not any specific application.”
reflects that “[b]ecause so many patents have been filed relating to nanomaterials, and so many of them seem to overlap, companies that want to use these building blocks in products will be forced to license patents from many different sources in order to do so.”

Moreover, nanotechnology patents are concentrated in the hands of a small group of patent holders. “Although there are some 1,180 patent holders who hold nanotechnology patents, just 95 entities, including IBM and MIT, hold one-half of all nanotechnology patents thus far issued.”

II. Creation of a Patent Thicket

For a number of different reasons, “the basic building blocks of what might be called the enabling technologies of the twentieth century – including the computer, software, the Internet, and biotechnology – all ended up in the public domain.” By contract, “many of the most basic ideas in nanotechnology are either already patented or may well end up being patented.”

Many critics fear that the increasing number of patents over fundamental building blocks will create a body of “anticommons,” knowledge that is “the antithesis of the

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• “Carbon nanotube patents look messy in electronics, but promising in energy and healthcare and cosmetics.”
• “Fullerenes look relatives unentangled, but crowded with abandoned patents.”
• Patents on nanowires “number few and seem distinct.”

Id.

34 NCI Alliance for Nanotechnology in Cancer, supra, note 9, at 4.
35 Lemley, supra, note 27, at 613.
36 Id.
traditional pool of common knowledge that all scientists freely share.”37 Others refer to these overlapping patents as a patent thicket. If that body of overlapping patents is allowed to expand, they argue, the exclusionary patent rights will deter discovery and innovation by increasing the cost and complexity of conducting research.

The “tragedy of the anticommons” was first identified as a concern in biomedical research in an article published in *Science* in 1998.38 The authors analogized their concerns to the “tragedy of the commons,” which holds that scarce resources held in common are overused because “too many owners each have a privilege to use a given resource and no one has a right to exclude another.”39

Anticommons property, they argued, is the mirror image of commons property, one where increasing intellectual property rights leads to “an ‘anticommons’ in which people underuse scarce resources because too many owners can block each other.”40 The development of the anticommons is “an unintended and paradoxical consequence” of privatization of these building blocks.41

Though the concerns about formation of an anticommons first arose in the context of biomedical research, those concerns are equally applicable nanotechnology, an emerging field of study where patents are being granted to fundamental building blocks. One commentator likened nanotechnology patents to “getting into electricity or the

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38 Heller and Eisenberg, *supra*, note 4.
39 *Id.*
40 *Id.*
41 *Id.*
The early discoveries in nanotechnology, he asserts, are going to lead to “unimaginable innovation.”

This “unimaginable innovation” covers considerable territory, as nanotechnology is not a discrete scientific discipline. “Unlike other areas of technological IP, nanotechnology-centered IP is distinctive because the technology is typically developed through multidisciplinary expertise, often in fields such as biology, chemistry, engineering, and materials science.” Moreover, nanotechnology is not a discrete industry. Rather, nanotechnology “exploits the peculiar properties of matter at the nanoscale across many different fields of modern engineering,” which means that a nanotechnology patent may have implications across a wide scope of industries.

Indeed, “the filing of a nanotechnology patent often involves a team of scientists representing many scientific disciplines collaborating on a technology comprising multiple components, each of which might require multiple IP licenses.”

The problems associated with a patent thicket are most severe when the thicket is made up of patents covering “‘upstream’ inventions, that is, patents that claim technologies associated with basic and early stage research and development, as opposed to patents covering ‘downstream’ commercial products.” If patents continue to be issued over the fundamental building blocks of nanotechnology, an anticommons in nanotechnology will continue to develop. Moreover, the risks associated with a patent

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43 Id.
44 NCI Alliance for Nanotechnology in Cancer, supra, note 9, at 2.
45 Lemley, supra, note 27, at 614.
46 NCI Alliance for Nanotechnology in Cancer, supra, note 9, at 2.
thicket “may be exacerbated by the application of pre-nanotechnology patents to nanotech inventions.”48

Further, the effects of a patent thicket vary dramatically depending on whether the innovating company is in the preinvestment or postinvestment period. In the early stages of development, before a company has invested substantial funds on the new product, the value of accessing another company’s intellectual property may be quite low, particularly if the company is able to design around the patents at a relatively low cost.49 Alternatively, the company may be able to negotiate favorable licenses or cross-licenses with the patent owners in lieu of a design around the patents.50 Once the company has made the financial commitment to a particular development path and then, belatedly, found itself trapped in a patent thicket, the company finds itself at the mercy of the patent holders, with substantially reduced bargaining strength.51 “By threatening to halt production of the product, the infringed patent holder theoretically can appropriate most if not all of the returns associated with the infringing firm’s development and marketing investments – much of which may have nothing to do with the patent holder’s technology – thereby forcing that firm to pay royalties that far exceed the preinvestment market value of the patented technology.”52 In other words, “the infringing firm’s investments become

48 Lemley, supra, note 27, at 620-21.
49 Beard and Kaserman, supra note 3, at 352.
50 Id.
51 Id.
52 Id. The timing of the negotiations reflects the fundamental truth of the best negotiating advice I have ever received: The person with the least amount of interest controls the relationship. While the advice came in a courtship and marriage class I took more 20 years ago, I have given the same advice to innumerable clients in preparation for important business negotiations.

In the example given above, the company has considerable negotiating strength (and, therefore, control over the negotiating relationship) before it has invested funds in development because it can opt to design around the patent if the cost of licensing the patent is too great. Consequently, unless the cost of the license is less than the cost of the design around, the prospective licensee will opt for the design around
a bargaining liability, which makes it vulnerable to attack by other firms that hold (or claim to hold) infringed patents. The greater the investment, the more vulnerable the company becomes.

Concerns about emerging patent thickets are not restricted to theoretical analyses by scholars. Three justices of the United States Supreme Court raised concerns about patent thickets in the case of *LabCorp v. Metabolite Laboratories, Inc.*, where the Court took the unusual tact of dismissing a patent infringement case on the grounds that certiorari had been improvidently granted. Justices Breyer, Stevens, and Souter dissented in the dismissal of the case.

As part of their argument against dismissal, the dissenters raised concerns about patents improperly prohibiting important research. Though patents “encourage research

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53. Id.


The case considered whether LabCorp infringed Metabolite’s patent claiming methods for detecting certain vitamin deficiencies. Doctors researching vitamins deficiencies found a correlation between high levels of homocysteine in the blood and the vitamin deficiencies. *Id.*, 126 S.Ct. at ___ (Breyer, J. dissenting). The doctors developed methods for more accurately testing body fluids for homocysteine using gas chromatography and mass spectrometry, and later received a patent for their work. *Id.* LabCorp received a license from Metabolite to use the test described in the patent, and paid royalties under the terms of the license until other companies developed tests that measured homocysteine levels in blood. *Id.*

Metabolite sued. It acknowledged that LabCorp’s use of the alternate test did not infringe the patent claims describing methods for testing for homocysteine. *Id.* Instead, it argued that LabCorp infringed claim 13 of the patent, which, Metabolite argued, “created a protected monopoly over the process of ‘correlating’ test results and potential vitamin deficiencies.” *Id.* LabCorp argued that this interpretation would give improperly give Metabolite “a monopoly over a basic scientific fact rather than any novel invention of its own.” *Id.* Moreover, it argued, under Metabolite’s broad interpretation of claim 13, “infringement took place every time a physician does nothing more than look at a patient’s homocysteine level.” *Id.*, quoting Corrected Brief for Appellant in No. 03-1120 (CA Fed.), p. 28.

The jury found that LabCorp infringed the patent, and the Federal Circuit affirmed the decision. *Metabolite Laboratories, Inc. v. Laboratory Corporation of America Holdings*, 370 F.3d 1354 (Fed. Cir. 2004). The Supreme Court granted certiorari on the question of “[w]hether a method patent . . . directing a party simply to ‘correlate’ test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.” *LabCorp*, 126 S.Ct. at ___ (Breyer, J. dissenting).
by providing monetary incentives for invention,” the dissenters argued, patents also can “discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.”

The dissenters argued that these results are inconsistent with patent law. “Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that under protection can threaten.” For that reason, patent law precludes “inventors” from patenting laws of nature. “[T]he reason for the exclusion is that sometimes too much patent protection can impede rather than ‘promote the Progress of Science and useful Arts,’ the constitutional objective of patent and copyright protection.”

Though the law must recognize intellectual property rights to “promote the Progress of Science and useful Arts,” the protections granted should be no greater than are required to meet this objective. “While patents unquestionably support incentives to innovate generally, in certain technologically dynamic industries they may create a drag on R&D investment that can counterbalance or offset the proinnovation effects of the

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55 Id.
56 Id.
57 See, e.g., Diamond v. Chakrabarty, 447 U.S. 303, 100 S.Ct. 2204 (1980) (“The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”).
58 LabCorp, 126 S.Ct. at ___ (Breyer, dissenting in dismissal of writ of certiorari).
Ironically, granting too much protection ensures that the protection granted is not meaningful.

### III. Avoiding a Patent Thicket in Nanotechnology

Creation of a patent thicket has become a concern in numerous disciplines. That concern is highlighted in the case of nanotechnology, as nanotechnology is not a discrete technology, but instead encompasses a wide variety of materials and systems. A single nanotechnology patents may have implications across a number of industries and may generate numerous products. Moreover, until recently, the PTO did not have a formal classification system for nanotechnology patents, making it difficult to search for prior art. As a result, “searching for nanotechnology-related patents and publications is complicated relative to other technology areas.” Understanding the patent landscape is the first step in determining whether a patent thicket exists and in taking steps to avoid the development of a patent thicket. The inherent nature of nanotechnology increases the complexity of performing that evaluation.

Patents are critical to the future development and profitability of nanotechnology innovations and products because of the high cost of research and development. Unless companies can rely on the limited-term monopoly of patent law, they may not be able to recoup the cost of their research and development. Nonetheless, with companies obtaining patents over fundamental building blocks, the patent landscape for nanotechnology may be so crowded with overlapping patents as to throttle development.

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59 Beard and Kaserman, *supra* note 3, at 351.
61 *Id.*
Some commentators argue that the fundamental characteristics of nanotechnology will motivate patent holders to collaborate and share their intellectual property. Many of the patents for fundamental building blocks in nanotechnology are held by universities, which, as a result of the Bayh-Dole Act, are able to patent and commercialize their innovations. But because universities typically are more focused on conducting basic science rather than on commercializing and marketing products, their greatest economic return is likely to come by widely distributing the technology through non-exclusive licenses with reasonable royalties than by hoarding the technology or by granting exclusive licenses. “Ultimately, universities are likely to be motivated by the benefits of licensing, creating a relatively free flow of building block patents to broader downstream users.”\textsuperscript{62} Sharing the benefits of technology through cross-licensing, patent pools, and open source agreements may be effective ways of avoiding the effects of the emerging nanotechnology patent thicket.

\textbf{a. Cross-licensing and Patent Pools}

When multiple parties hold overlapping patents on basic building blocks of a technology, each party has the right to exclude others from innovating by restricting access to its patented building block. As a patent thicket grows, it becomes virtually impossible for a company to know in advance whether its innovation infringes on an existing patent. When the patent thicket becomes more formidable, “it creates considerable uncertainty regarding the future legal status of any intellectual property created by R&D activities.”\textsuperscript{63} The resulting uncertainty leads to an underinvestment in research and development of new products. Two related concepts – cross-licensing

\textsuperscript{62} NCI Alliance for Nanotechnology in Cancer, supra, note 9, at 4.
\textsuperscript{63} Beard and Kaserman, supra note 3, at 353.
agreements and patent pools – allow companies to contractually avoid these uncertainties by agreeing to share the right to use technology.

**Cross-licensing**

Cross-licensing agreements are used most typically in mature industries such as the semiconductor and computer industries that have a large number of overlapping patents, but their use is expected to increase in emerging industries like nanotechnology as the relevant number of overlapping patents increases. Under a typical cross-licensing agreement, the parties agree not to sue each other for infringement in exchange for access to the other party’s technology. A licensing agreement may take many forms: “[s]ome involve a lump sum up-front payment, some require exclusivity, some cover future patents, some are long-term in nature, and so on.” When each party has a large portfolio of patents, the licensing agreement may allow the parties royalty-free access to the other’s patents. “[M]ost cross licenses require royalty payments and are granted on a non-exclusive basis so that the parties retain the right to license their patents to others.”

Even when companies share their intellectual property through cross-licensing agreements, they still are able to differentiate themselves in the marketplace. “Considerable firm specific know how and trade secrets frequently remain undisclosed under patent cross-license agreements.” Moreover, the ability to successfully take a product to market depends heavily on a company’s managerial and engineering abilities,

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64. *Id.*, at 354 n. 16.
something that is not shared through a cross-licensing agreement. “As a result, even where firms have signed extensive cross-license agreements with competitors, they are not generally able to replicate either the products or performance of their contract partners.”

Cross-licensing agreements create a number of significant benefits for the contracting parties. First, cross-licensing agreements can resolve the problems arising from a patent thicket, allowing each company the freedom to pursue research and development with a “substantially reduced risk of accidental infringement and subsequent legal claims.”

This freedom – often referred to as “patent peace” – allows companies to increase the speed with which they develop new products and concepts. The resulting “patent peace” frequently is more valuable to the company than is the revenue stream derived from licensing the technology.

Second, a cross-licensing agreement virtually eliminates the need to invent around existing patents, allowing companies to focus on improving upon rather than replicating the existing state of the art. This factor is particularly valuable in the case of nanotechnology patents, as the fundamental building blocks of the technology often cannot be invented around.

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68 Id., at 355.
69 Id.
70 IBM’s assistant general counsel described the value of the company’s patent portfolio as follows in 1990:

The IBM patent portfolio gains us the freedom to do what we need to do through cross-licensing – it gives us access to the inventions of others that are key to rapid innovation. Access is far more valuable to IBM than the fees it receives from its 9,000 active patents. There’s no direct calculation of this value, but it’s many times larger than the fee income, perhaps an order of magnitude larger.


71 Beard and Kaserman, supra note 3, at 355.
Third, cross-licensing lowers the cost in the affected market by eliminating royalty stacking.\(^72\) “Royalty stacking occurs when access to multiple patents is required to produce an end product, forcing the manufacturer’s products ‘to bear multiple patent burdens,’ usually in the form of multiple licensing fees.”\(^73\) When the patent burden increases, production ultimately becomes unprofitable, and innovation decreases. Licensing agreements frequently offer a party access to “all the blocking technologies required for production at a lower royalty rate than if each input were independently priced.”\(^74\) As such, portfolio licenses can reduce the “drag on innovation and commercialization of new technologies” created by royalty stacking.\(^75\)

Fourth, cross-licensing substantially reduces transaction costs by eliminating the need to conduct extensive patent searches and negotiations to provide the same level of freedom derived from the cross-licensing agreement.\(^76\)

Finally, “the ability to sign royalty-free cross-licenses tends to facilitate entry into the market.”\(^77\) Without the ability to sign a cross-license agreement, a newcomer to the field would either have to invent around an extensive (and perhaps unknown) number of patents or else negotiate licensing agreements with each patent holder.\(^78\)

Cross-licenses not only allow companies to develop new products, but they also are useful in avoiding the effects of a competitor’s portfolio of defensive patents. A

\(^{72}\) Id., at 356.


\(^{76}\) Beard and Kaserman, supra note 3, at 356.

\(^{77}\) Id.

\(^{78}\) Id., at 354.
company obtains a defensive patent not because it seeks to commercialize the protected invention, but instead to gain a bargaining chip with its competitors. “By aggressively pursuing patents on as many innovations as the company’s research and development department stumbles upon – rather than keeping them a trade secret until it develops a truly pioneering invention – the company develops an arsenal of patents that it would likely be able to assert in cross claims should a competitor ever file a claim of infringement.”\(^79\) The defensive patents operate like nuclear weapons, threatening the mutual economic destruction of both parties if either party should be foolish enough to fire the first shot.

Defensive patents also encourage parties to cross license their technology, an act that helps ameliorate the effects of a patent thicket. The agreements generally do not cover each party’s key “blockbuster” patents, but rather are limited to “a wide swath of a patent portfolio.”\(^80\) In this way, cross-license agreements help advance research and development while providing “defensive legal protection against patent infringement claims, offering firms greater freedom to design their products.”\(^81\)

Some commentators suggest that “nanotech will, for the most part, avoid a self-destructive IP war” through “a flood of cross-licensing agreements by startups, and bundles of IP for specific applications licensed by groups of large corporations.”\(^82\) Others are less optimistic about the likelihood of nanotechnology avoiding the legal battles associated with a patent thicket.

\(^{79}\) Conrad, \textit{supra}, note 65, at 144.

\(^{80}\) \textit{Id.}, at 145.

\(^{81}\) Beard and Kaserman, \textit{supra} note 3, at 355.

Cross-licensing has worked in the semiconductor industry because it is primarily an oligopoly; there are a relatively small number of large firms with similar products and similar patent arsenals. But nanotechnology includes new materials that can be used in a range of different products. Patent holders include big companies, start-ups, universities and government labs working in a variety of different industries. It makes sense for Intel to cross-license with AMD because they both directly benefit from patent sharing. But if CNI wants to sue to enforce its broad claims on nanotubes and methods of making, and CNI’s only business is making nanotubes, what is Nantero or Nanomix going to use to cross-license? . . . The history of litigation in the biotech sphere suggests that litigation between start-ups directly competing is more likely than licensing.83

The same detractors argue that even if holders of nanotechnology patents agree to cross-license their technology in lieu of litigating disputes, “the resulting uncertainty and large transaction costs associated with the nanotech patent landscape could have a particularly significant impact on start-ups.”84 The nature of nanotechnology patents – i.e., the cross-disciplinary scope of the field, the fact that a single patent frequently applies across numerous industries, and the reality that the patent claims cover fundamental building blocks – virtually ensures that patent holders will not cross-license their nanotechnology patents. Unless and until nanotechnology companies take on the characteristics of the semiconductor industry – i.e., a few large companies that make similar products and that each hold numerous complementary patents – cross-licensing may not provide relief from a patent thicket in nanotechnology.

**Patent Pools**

Cross-licenses can resolve the challenges of a patent thicket for two companies that manufacture similar products and that have each developed a substantial pool of complementary patents. They cannot, however, navigate the patent thicket when a large

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83 Serrato, Hermann, and Douglass, *supra* note 82, at 6.
84 *Id.*
number of different companies each hold a few patents needed to develop the technology. “In such cases, patent-pooling agreements may create substantial transaction efficiencies by enabling multiple patent holders to pool their patented technologies and, through a joint entity, license them as a group to each other and to third parties.”

Patent pools often are formed “when multiple patented technologies are needed to produce a standardized product.” Because multiple patented technologies are required to produce the product, licensees receive the “convenience of ‘one-stop shopping.” As such, parties participating in the patent pool avoid the multiple transaction costs from negotiating separately with each patent holder, as well as the royalty stacking that occurs from separate negotiations. Moreover, because producing the standardized product requires all of the patents in the pool, “a subset of the required patents may be of little or not value by themselves.” For that reason, licensees find that “licensing the entire package is simpler and avoids the danger of paying for some patent rights that turn out to be useless without other complementary rights.”

Antitrust issues

Because they involve cooperation between competitors, cross-licenses and patent pools raise concerns about possible antitrust violations. Nevertheless, most experts agree that rather than stifling competition, cross-licenses and patent pools have pro-competitive

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86 Id., at 64.
87 Shapiro, supra, note 2, at 17.
89 Shapiro, supra, note 2, at 17.
90 Id.
effects, at least as long as the companies share complementary rather than substitute patents.

A patent thicket raises the classic “complements problem” of economic theory, a problem first identified by French economist Antoine Augustin Cournot in 1838. Cournot considered the economic impact on a manufacturer of brass that was required to purchase two essential raw materials – copper and zinc – from two separate monopolists. Cournot demonstrated that “the resulting price of brass was higher than would arise if a single firm controlled trade in both copper and zinc, and sold these inputs to a competitive brass industry (or made the brass itself).”91 Moreover, the producers of the raw materials had lower combined profits in the presence of complementary monopolies, leading to the unexpected result that complementary monopolies harm both consumers and suppliers.92 “Divided ownership leads to higher prices and lower quantities than unified (monopolistic) ownership, because of the complement’s cross-price effect.”93 One way to resolve this economic dilemma is for the suppliers to jointly offer their respective raw materials “for a single, package price to the brass industry.”94 By doing so, the suppliers each price their respective raw materials lower than they would when operating separately, yet still reap higher profits.95

The same classic economic problem arises when multiple blocking patents prevent companies from freely innovating. “This basic theory of complements (used in

91 Shapiro, supra, note 2, at 5.
92 Id.
94 Shapiro, supra, note 2, at 5.
95 Id.
fixed proportions) gives strong support for businesses to adopt, and for competition authorities to welcome, either cross-licensees, package licenses, or patent pools to clear such blocking positions.\textsuperscript{96} Rather than stifling competition, these cooperative efforts enable competitors to manufacture their products in a manner that benefits the consumer. “If two patent holders are the only companies realistically capable of manufacturing products that utilize their intellectual property rights, a \textit{royalty-free} cross license is ideal from the point of view of competition.”\textsuperscript{97} Cross-licensing and patent pools allow products to be manufactured without bearing “multiple patent burdens.”\textsuperscript{98} Thus, cooperation among competitors in a patent thicket tends to increase rather than stifle competition. Indeed, “[t]o solve the complements problem generally, and to cut through the patent thicket specifically, requires \textit{coordination} among rights holders.”\textsuperscript{99}

For these reasons, antitrust regulators have recognized that cross-licenses and patent pools are often pro-competitive. In April 2007, the Department of Justice and the Federal Trade Commission published their long-awaited guidance on the interaction between intellectual property rights and antitrust concerns.\textsuperscript{100} The regulators acknowledged that both cross-license agreements and patent pools raise the possibility of antitrust concerns “if the arrangements result in price fixing, coordinated output restrictions among competitors, or foreclosure of innovation.”\textsuperscript{101} Antitrust concerns are

\begin{flushright}
\textsuperscript{96} \textit{Id.} \\
\textsuperscript{97} \textit{Id.} \\
\textsuperscript{98} \textit{Id.} \\
\textsuperscript{99} \textit{Id.}, at 8. \\
\textsuperscript{100} U.S. Department of Justice and the Federal Trade Commission, \textit{supra}, note 85.. \\
\textsuperscript{101} \textit{Id.}, at 58.
\end{flushright}
greater in the case of patent pools because of “the collective pricing of pooled patents, greater possibilities for collusion, and generally larger number of market participants.”\textsuperscript{102}

The agencies concluded that most nonexclusive cross-licensing agreements “generally do not raise competition concerns.”\textsuperscript{103} Indeed, if the cross-licensing agreements allow parties to combine complementary rather than competing technologies, cross-licensing can be procompetitive, particularly for technologies “that require access to a large number of patents” and, as such, should be evaluated under the rule of reason for purposes of antitrust considerations.\textsuperscript{104}

The regulators’ approach also reflects the sound economic principle that “inclusion of truly complementary patents in a patent pool is desirable and pro-competitive, but assembly of substitute or rival patents in a pool can eliminate competition and lead to elevated license fees.”\textsuperscript{105} In other words, “the key distinction in forming a patent pool is that between ‘blocking’ or ‘essential’ patents, which properly belong in the pool, and ‘substitute’ or ‘rival’ patents, which may need to remain separate.”\textsuperscript{106}

The question of whether patents are complementary or substitute must be analyzed on a case-by-case basis. Nonetheless, many nanotechnology patents involve fundamental building blocks that cannot be designed around. As such, they are the types

\textsuperscript{102} Id.

\textsuperscript{103} Id., at 62.

\textsuperscript{104} Id., at 62-63. The “rule of reason” – which the Supreme Court first articulated in \textit{Standard Oil Co. of New Jersey v. United States}, 221 U.S. 1 (1911) – requires an antitrust plaintiff to prove that “a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful.” \textit{Texaco, Inc. v. Dagher}, 547 U.S. 1, 126 S.Ct. 1276, 1279 (2006).

\textsuperscript{105} Carl Shapiro, \textit{supra}, note 2, at 17.

\textsuperscript{106} Id.
of patents that could be included in a cross-license or in a patent pool without raising the antitrust concerns associated with substitute or rival patents.

b. **Open source licenses**

Some commentators advocate for an open source strategy for nanotechnology tools and products, similar to the open source strategy employed in the development of certain types of software. Under that strategy, “[c]ollective action to create intellectual common property offers an alternative which may both complement and substitute for proprietary development of closed intellectual property.”

In an open source environment, various parties collaborate to develop the intellectual property. Each party that contributes to the development is entitled to use the intellectual property. Advocates of the strategy argue that information is not a resource capable of being depleted, but rather is an “inverse commons” where having more users tends to increase, not decrease, the value of the commons in networked information.” The strategy works best for “more basic infrastructure-type standards and for implementation of widely known techniques.” Even the most vigorous proponents of open sourcing recognize its limitations for “valuable secrets which could generate large profits, either from royalties or by preventing competitors from using the techniques.” They argue, instead, that open source and closed source intellectual

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108 Id.
109 Id.
110 Id.
property “each have advantages under different circumstances and can productively coexist.”\footnote{Id.}

Relying on principles of copyright, patent, and other intellectual property law, an open source community creates a set of rules under which the information is made available to participants. For open sourcing to work in nanotechnology, participants must agree on an appropriate set of core principles\footnote{Id.} to “reduce conflicts and encourage appropriate commercial participation.”\footnote{Id., at 13.} Because physical structures are important in nanotech, “open sourcing of nanotechnology needs to address public licensing of patent rights in more detail than do current licenses, perhaps drawing on precedents from current initiatives seeking to develop open computer hardware and open publications.”\footnote{Id.}

Though the concept of open source for nanotechnology has merit, it is unlikely to provide a viable method of escaping the patent thicket, at least in the short term. Companies that have already staked out their nanotechnology territory through patents are unlikely to turn over that valuable resource to competitors for a cooperative endeavor. Moreover, open source works for software because source code can be written in numerous ways to reach the same effect, e.g., word processing. Because nanotechnology patents frequently involve fundamental building blocks, those patents cannot easily be

\footnote{Id., quoting “Open Source Definition,” (2000). Bruns argues that the “core principles” for nanotechnology open source must be “similar to those in the Open Source Definition.” \textit{Id.}, 13.}

\footnote{Id.}
designed around. Even the most ardent proponents of open source are uncertain about its applicability to nanotechnology, noting simply that “[t]he prominent role of software in nanotechnology research and development suggests that open source development methods might offer advantages in improving reliability, performance and accessibility.”\textsuperscript{115} Until advocates for open source can articulate a methodology for effectively incorporating open source into the development of intellectual property in nanotechnology, open source is unlikely to provide relief from the emerging patent thicket.

\section*{IV. Conclusion}

Patent thickets constitute significant challenges to growth of virtually every field of innovation. Nanotechnology is no exception. Cross-licenses and patent pools may provide effective methods of avoiding the effects of patent thickets. As long as the agreements focus on complementary (rather than substitute) patents and technologies, the agreements promote rather than hinder competition.

\textsuperscript{115} Id., at 1.
Issues of Utility in Biotech Patents

By Scott F. Gibson

The world economy is undergoing a dramatic change in which “ideas and innovations have become the most important resource, replacing land, energy and raw materials.” The change is occurring rapidly and penetrating all areas of the economy. “As much as three-quarters of the value of publicly traded companies in America comes from intangible assets, up from around 40% in the early 1980s.” Smaller, private companies, particularly start-ups, often have few assets other than their intellectual property and goodwill. Indeed, as Alan Greenspan, former Chairman of the Federal Reserve, has noted, “the economic product of the United States [is] predominantly conceptual.”

Innovators of all stripes have acknowledged that the financial viability of their companies depends on their ability to build and protect their intangible assets. As a result, companies “are seeking more patents, expanding their scope, licensing more, litigating more and overhauling their business models around intellectual property.” The increased emphasis on intellectual property – coupled with judicial decisions allowing patents in areas previously not recognized by the law – has had a tsunami-like effect on the United States Patent and Trademark Office (“PTO”), overwhelming the Office’s ability to handle patent applications. The number of patents

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1 Member, Gibson, Ferrin & Riggs, PLC, Mesa, Arizona; LLM, Biotechnology and Genomics, Sandra Day O’Connor School of Law at Arizona State University 2007 (anticipated); J.D. (cum laude), Arizona State University 1986.


3 Id.

4 Id.

5 Id.

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issued by has increased dramatically, rising from 66,000 patents in 1980 to some 175,000 patents in 2003.\textsuperscript{6} Nearly 400,000 new patent applications were filed with the PTO in 2005, and more than 900,000 applications remain unexamined, a number that continues to grow.\textsuperscript{7} Many experts believe that the increased emphasis on patents has led to a deterioration in the quality of the patents issued, as “measured by whether the invention is truly new and meets its claims.”\textsuperscript{8} Even the PTO acknowledges that some criticism is justified. A recent internal audit conducted by the PTO discloses that about 15 percent of all patents issued contain “at least one significant error,” and some 5 percent contain “at least one claim that a court would find invalid.”\textsuperscript{9}

The biotech industry is part of the emerging economy that is “primarily conceptual,” offering a virtually endless list of potential benefits to society, ranging from disease resistant crops to genetically engineered vaccines to bacteria that consume pollutants. As is the case with many “conceptual” segments of the economy, the cost of developing a commercially viable biotech product can be astronomical.\textsuperscript{10} “[M]uch like the pharmaceutical industry, biotechnology is research intensive, failure rates are high and there is a long road from research to product development.”\textsuperscript{11} Companies will be unwilling to incur the high costs of developing new biotech products unless they are able to recoup their costs and obtain a satisfactory rate of return on their


\textsuperscript{8} “Patent Sense,” The Economist, October 22, 2005.

\textsuperscript{9} Devinsky and Becker, supra note 7.


investments. Biotech companies have taken considerable steps to protect their intellectual property, which often constitutes their primary asset.

Those efforts raise significant concerns. Many critics argue that traditional protections under intellectual property law, particularly patents, raise serious questions about whether it is wise or even ethical to allow exclusionary rights to life forms or to their building blocks. Many critics fear that the increasing number of biotech patents will create a body of “anticommons,” knowledge that is “the antithesis of the traditional pool of common knowledge that all scientists freely share.”13 If that body of “anticommons” is allowed to expand, they argue, the exclusionary patent rights will deter discovery and innovation in biomedical research by increasing the cost and complexity of conducting research. Others, such as outspoken biotech critic Jeremy Rifkin, argue against biotech patents on the basis that “[t]he economic and political forces that control the genetic resources of the planet will exercise tremendous power over the future world economy, just as in the industrial age access to and control over fossil fuels and valuable metals helped determine control over world markets.”14

This paper considers the intersection between patent law and the emerging biotech industry, with an emphasis on three areas: (1) the general requirements for obtaining a biotech patent, (2) concerns about the wisdom of granting patent protection over life forms and their

12 The law provides four primary methods for protecting intellectual property and other intangible assets of a company: patents, trade secrets, trademarks, and copyrights. A patent offers the right to exclude others from practicing an invention for a period of time. Trade secrets protect information and procedures that are not publicly known. Trademarks protect company and product names and logos. Copyrights protect the product of ideas (i.e., books, software, films, etc.) but not the ideas themselves. Companies also can protect intellectual property and other intangible assets through contractual provisions such as confidentiality, nondisclosure, and licensing agreements, and through restrictive covenants with employees, including non-compete and non-solicitation agreements.


components, (3) recent developments regarding the utility requirements under patent law, and (4) concerns about negative societal impacts resulting from the patenting of biotechnology.

I. REQUIREMENTS FOR ISSUING A PATENT.

The United States Constitution authorizes Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”\(^\text{15}\) Congress first exercised this power when it passed the Patent Act of 1793; the most recent revision occurred in 1952.

Thomas Jefferson – the author of the Patent Act of 1793 – imbued the initial Patent Act with his philosophy that “ingenuity should receive a liberal encouragement.”\(^\text{16}\) That philosophy has survived to modern patent law, with the courts repeatedly recognizing the important public policy of encouraging innovation by granting inventors temporary rights to exercise a monopoly. “The overall goal of patent grants is to provide an incentive for inventors to publish the best method to practice an invention.”\(^\text{17}\) Public disclosure expands the collective knowledge of society, and helps foster additional invention and ingenuity.\(^\text{18}\) In exchange for the public disclosure, the government gives a qualifying inventor the right to exercise a monopoly and exclude others from practicing the invention in the United States for a period of time, currently 20 years from the date of application. Once the patent monopoly expires, the technology

\(^{15}\) United States Constitution, Art. 1, § 8, cl. 8.


\(^{17}\) Yali Friedman, Building Biotechnology: Starting, managing, and understanding biotechnology companies, (thinkBiotech LLC 2004), page 20.

\(^{18}\) As the Supreme Court has noted, however, “in light of the highly developed art of drafting patent claims so that they disclose as little useful information as possible – while broadening the scope of the claim as widely as possible – the argument based upon the virtue of disclosure must be warily evaluated.” Brenner v. Manson, 383 U.S. 519, 534, 86 S.Ct. 1033, 1041 (1966).
becomes part of the public domain, and later innovators may use the technology in their inventions.

The disclosure requirement also fosters innovation by allowing competitors to invent around the protected technology, thus increasing the overall knowledge in the field. By setting up the patent system as it did, Congress gave innovators sufficient time in which to recoup the investment of time and resources required to develop the invention and ensured that competitors cannot exploit the efforts of others.

An inventor must meet certain requirements to gain the right to a patent. First, the invention must cover a proper, patentable subject matter. The invention must also meet the statutory requirements of novelty and utility, and must not have been obvious to a person of ordinary skill in the art. In addition, the application must describe the manner of making and using the invention in sufficient detail to allow another person skilled in the art to make the invention. Each of these requirements is discussed below.

1. **Patentable Subject Matter**

An invention cannot be patented unless it involves a proper, patentable subject matter, i.e., a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” Though the statutory definition is broad, the courts have recognized that certain scientific advances are not “inventions,” but are instead discoveries that are not patentable. For that reason, the laws of nature, abstract ideas, and physical phenomena historically have not been patentable. Likewise, a newly discovered mineral or natural plant are

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not patentable subject matter. These discoveries are not patentable because they are “manifestations of . . . nature, free to all men and reserved exclusively to none.”

2. **Novelty**

Not surprisingly, patent rights extend only to new inventions and to new and useful improvements on existing inventions. An invention will be deemed novel unless any of the following has occurred:

- the invention was “known or used by others” in the United States before the applicant invented it;
- someone else patented or described the invention in a printed publication before the applicant invented it;
- the invention was “patented or described in a printed publication” more than one year before the applicant filed his application;
- the invention was “in public use or on sale” in the United States more than one year before the applicant filed his application;
- the inventor has abandoned the invention;

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21 *Chakrabarty*, 447 U.S. at 309.
• the applicant or his legal representatives first patented the invention or caused it to be patented in a foreign country more than a year before the U.S. application was filed;29
• the invention was disclosed in an earlier U.S. patent;”30 or
• the applicant “did not himself invent the subject matter sought to be patented.”31

3. Utility

Patent laws require that an invention be “useful” to receive protection.32 At first blush, the requirement of utility would seem to be a simple concept. Nonetheless, the definition has caused considerable debate among commentators and in the courts.

The courts first considered the concept of utility in 1817 in the case of Lowell v. Lewis,33 where Justice Story delivered the definition that guided the federal courts for nearly 150 years:

“All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral.”34

Under this definition, an invention that was harmful or immoral (e.g., “a new invention to poison people, or to promote debauchery, or to facilitate private assassination”) could not be patented.35

“But if the invention steers wide of these objections, whether it be more or less useful is a

32 “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2005).
34 Id., at 1019.
35 Id., at 1019.
circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard.”

The definition created a *de minimis* standard that allowed a patent to issue for an invention that was not “useful” to the public, as long as the invention was not harmful or immoral. The definition relied heavily on the free markets. “Because the market ultimately determined the value of the invention, an invention lacking utility would be of little value to a patentee and a limited monopoly extended to the patentee for such an invention would be of little cost to the public.”

The federal courts largely followed the *de minimis* standard until 1966, when the Supreme Court held that, to meet the requirements of § 101, an applicant must show that the claimed invention has both “significant” and “substantial” utility. The Federal Circuit Court of Appeals recently held that the requirements of “significant” and “substantial” utility apply to applications for biotech patents covering expressed sequence tags (“ESTs”). “In most other technological pursuits, the requirement that a patent be useful is secondary to criteria such as whether an invention is truly new, because most inventors do not seek protection for worthless inventions. In the arena of life patents, the assessment of an invention’s usefulness has become a crucial filter to maintain a check on patent quality.”

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36 *Lowell v. Lewis*, 15 F. Cas. at 1019.
38 *Id.*
40 For a discussion of the holding in *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005), see infra pages 24-32.
41 Stix, *supra* note 13, at 81.
4. Nonobvious Subject Matter

Under 35 U.S.C. § 103, a patent may not issue “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”42 If a person of ordinary skill in the art would combine two or more pieces of prior art to form the invention, the invention is obvious and not patentable.

5. Enablement

The final requirement is one of enablement, meaning the application must describe “the manner and process of making and using [the invention], in such full, clear, and concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.”43 The enablement requirement is part of the quid pro quo between the government and the patentee. When the written description describes the invention well enough for a person of ordinary skill in the art to make and use the invention, the body of public knowledge increases. Once the patent monopoly has ended, persons of ordinary skill in the art will be able to make and use the invention. Moreover, the enablement requirement allows innovators in most areas (though generally not in the field of biotechnology) to invent around the claimed invention.

II. CONCERNS ABOUT PROVIDING PATENTS OVER LIFE FORMS

The patent laws make intuitive sense in the context of a new process, machine, or composition of matter. They are less intuitive in the context of life or its components. As is discussed above, the law has long recognized that certain discoveries are not entitled to patent protection because they are laws of nature, minerals, abstract ideas, or other physical

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phenomena. “The patent system – both courts and patent examiners – has always wrestled with
the question of what is truly an invention (and therefore deserving of a patent) and what
constitutes a mere attempt to expropriate in unaltered form a physical law or material from the
natural world, a reason for rejecting an application.”

Historically, plants and other life forms were deemed to be non-patentable under these
principles. In 1889, the Commissioner of Patents determined that artificially bred plants were
“products of nature” that could not be patented. The applicant in *Latimer* had claimed a fiber
found in the Pinus australis, but the Commissioner rejected the claim because it would allow
“patents [to] be obtained upon the trees of the forest and the plants of the earth, which of course
would be unreasonable and impossible.” The applicant had claimed a product that “is a natural
product and can no more be the subject of a patent in its natural state when freed from its
surroundings than wheat which has been cut by a reaper or by some new method of reaping can
be patented as wheat cut by such a process.” *Latimer* led to the “‘general stand taken in these
matters’” that plants were natural products that could not be patented.

1. **Funk Bros. Seed Co. v. Kalo Inoculant Co.**

The Supreme Court first considered the patentability of life forms in 1948 when it
invalidated a patent (the “Bond Patent”) issued for a combination of bacteria on the grounds that
the combination was not an invention but rather a “work of nature.” When bacteria from the
genus Rhizobium infest the roots of leguminous plants, the plants pull nitrogen from the air and

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44 Stix, *supra* note 13, at 81
46 *Id.*, at 126.
47 *Id.*
48 *Chakrabarty*, 447 U.S. at 311, quoting Thorne, Relation of Patent Law to Natural Products, 6
“fix it in the plant for conversion to organic nitrogenous compounds.” Each of the species of bacteria does not infest all species of leguminous plants; rather, the various species of bacteria infest “well-defined groups” of the plants. Certain species of bacteria are effective only with specific species of legumes.

For many years, the strongest strains of bacteria had been selected and marketed as inoculants for leguminous seeds. Before the Bond Patent issued, the general practice was to “manufacture and sell inoculants containing only one species of root-nodule bacteria” because “the different species of the Rhizobia bacteria produced an inhibitory effect on each other when mixed in a common base, with the result that their efficiency was reduced.” Up to that time, “it had been assumed that the different species were mutually inhibitive.” As a result, a farmer with three separate crops would have to purchase three separate inoculants containing three different bacteria.

Bond discovered that certain strains of each species of bacteria did not exhibit a mutually inhibitive effect on each other. He also learned that by properly selecting and testing the strains, he could isolate the mutually non-inhibitive strains and combine them in a single product that could be used to inoculate the seeds of plants across various “cross-inoculation groups.” The Bond Patent patent sought to protect the product containing multiple species of bacteria.

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50 Id.
51 Id.
52 Id.
53 Id.
54 Id.
55 Id.
The Supreme Court invalidated the patent because Bond did not “create a state of inhibition or non-inhibition in the bacteria.” His mixture of bacteria was not an invention, but rather the work of nature.

The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metal are part of the storehouse of knowledge of all man. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.

Though Bond had discovered that certain bacteria could be mixed “without harmful effect to the properties of either,” he had done nothing more than discovered “some of the handiwork of nature,” a discovery that is not patentable.

But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of the root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

The Court held that though Bond’s discovery was “the product of skill, it certainly was not the product of invention.”

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56 Id.
57 Id.
58 Id., 68 S.Ct. at 442.
59 Id., 68 S.Ct. at 441 (emphasis added).
60 Id.
2. **Diamond v. Chakrabarty**

In the years following *Funk Bros.*, conventional wisdom held that living organisms could not be patented. That conventional wisdom changed dramatically in 1980, when the Supreme Court held that a “live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.” The Court’s decision in *Diamond v. Chakrabarty* had a wide-reaching scope, holding that Congress intended the coverage of patent law to “include anything under the sun that is made by man.”

*Chakrabarty* involved a patent application filed by a microbiologist, Ananda Chakrabarty, who asserted 36 claims related to his invention of a genetically engineered bacterium that ate crude oil. Dr. Chakrabarty’s bacterium “could break down oil slicks more efficiently than if a bioremediation specialist deployed multiple strains for the task.” Among other things, the application claimed the bacteria themselves as an invention. Following the established policy of the PTO, the patent examiner rejected the claims for the bacteria, arguing that the bacteria were “products of nature” and that living organisms could not be patented under 35 U.S.C. § 101.

The Supreme Court reversed. The Court construed § 101 broadly, noting that by its use of broad terms in § 101, “Congress plainly contemplated that that patent laws would be given wide scope.” That scope is not unlimited, however, as “[t]he laws of nature, physical phenomena,

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61 Chakrabarty, 447 U.S. at 305.
63 Id., 447 U.S. at 305.
64 Stix, supra note 13, at 78.
65 Chakrabarty, 447 U.S. at 305.
66 Id., 447 U.S. at 306.
67 Id., 447 U.S. at 308.
and abstract ideas have been held not patentable.” 68 The microorganisms were patentable subject matter, however, because they were not “a hitherto unknown natural phenomenon, but . . . a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity ‘having a distinctive name, character [and] use.’” 69 The Court held that Dr. Chakrabarty did not discover a phenomenon of nature, but instead “produced a new bacterium with markedly different characteristics from any found in nature and one having the potential utility.” 70

The government raised two arguments against the proposition that genetically engineered microorganisms were patentable subject matter under § 101. First, the government argued that the terms “manufacture” and “composition of matter” did not included living things, as reflected by the enactment of the 1930 Plant Patent Act (“PPA”) and the 1970 Plant Variety Protection Act (“PVPA”). 71 The PPA provides patent protection for certain asexually reproduced plants; the PVPA provides protection for certain sexually produced plants but specifically excludes bacteria. The government argued that if the terms “manufacture” and “composition of matter” included living things, the two Acts would have been unnecessary. 72

The Court disagreed, noting that before 1930, plants were believed to be excluded from patent protection because (1) even artificially bred plants were products of nature under patent law under Ex parte Latimer, 73 and (2) “plants were thought not amenable to the ‘written

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68 Id., 447 U.S. at 309.
70 Id., 447 U.S. at 310.
71 Id., 447 U.S. at 310-11.
72 Id., 447 U.S. at 311.
73 Id., 447 U.S. at 311. This belief arose from the decision of the patent office in Ex parte Latimer, 1889 Dec.Com.Pat. 123, which rejected a patent claim for fiber found in the needle of a pine tree.
description’ requirement of the patent law.”74 The Court held that Congress had addressed both of these concerns in enacting the PPA. In doing so, “Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human made inventions.”75

Second, the government argued that microorganisms could not be considered as patentable subject matter unless Congress specifically authorized patent protection.76 Though the Court acknowledged that Congress must establish the limits of patentability, it held that “once Congress has spoken it is ‘the province and duty of the judicial department to say what the law is.’”77 Because Congress had used broad language in enacting the patent laws, the Court found “no ambiguity” in giving that language a broad interpretation.78 “The subject-matter provisions of that patent law have been cast in broad terms to fulfill the constitution and statutory goal of promoting ‘the Progress of Science and the useful Arts’ with all that means for the social and economic benefits envisioned by [Thomas] Jefferson.”79

The Supreme Court reached its decision despite a “gruesome parade of horribles” that various amici curiae identified as possible consequences of genetic engineering.80 The Court

74 Id., 447 U.S. at 311-12.
75 Id., 447 U.S. at 313.
76 Id., 447 U.S. at 314.
77 Id., 447 U.S. at 315, quoting Marbury v. Madison, 1 Cranch 137, 177, 2 L.Ed. 60 (1803).
78 Id., 447 U.S. at 315.
79 Id. Jefferson wrote the Patent Act of 1793, which defined patentable subject matter in nearly identical terms as are used in the current statute. The broad scope of the initial statute reflected Jefferson’s belief that “ingenuity should receive a liberal encouragement.” Id., 447 U.S. at 308-09, quoting 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871).
80 Id., 447 U.S. at 316. The briefs quoted many distinguished scientists, including Nobel laureates, who suggested that “genetic research may pose a serious threat to the human race, or, at very least, that the dangers are far too substantial to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life.” Id.
rejected the suggestion that it should consider the potential hazards of genetic research in determining whether patentable subject matter under § 101 included the microorganisms. “The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks.”

III. THE AFTERMATH OF CHAKRABARTY: CONCERNS ABOUT UTILITY

By changing fundamental concepts about the extent of the patent laws, Chakrabarty laid a foundation for the biotech industry. “In the aftermath of that historic decision, bioengineering technology shed its pristine academic garb and bounded into the marketplace, where it was heralded by many analysts as a scientific godsend, the long-awaited replacement for a dying industrial order.” When interviewed after the Court’s ruling, Professor Chakrabarty, by that time a professor of microbiology at the University of Illinois Medical Center in Chicago, said that the decision would lead to more cooperation between researchers. “Traditionally, the pharmaceutical industry and the biomedical industry have been very secretive about microorganisms,” he noted. “The reason for that is they couldn’t patent their work, so they tried to protect it by hiding it.” Professor Chakrabarty predicted that the Court’s decision “will lead to a tremendous boost in both industrial and academic research.”

Others shared his enthusiasm. A spokesmanship for Genentech, Inc., a company founded on technologies of genetic engineering, enthusiastically embraced the decision, claiming that the Court’s decision had “assured this country’s technology future.” An investment analyst at E.F.  

81 Id., 447 U.S. at 317.
82 Rifkin, supra note 14, at 43.
84 Id.
85 Id.
Hutton asserted that “[w]e are sitting at the edge of a technological breakthrough that could be as important as . . . [the] discovery of fire.”

Not everyone welcomed the Court’s decision. Critics argued that the decision would lead to the commercialization of revolutionary scientific discoveries that should remain part of the common knowledge of mankind. The People’s Business Commission warned that the decision “lays the groundwork for corporations to own the processes of life in the centuries to come.” Richard N. Goldstein, a professor at the Harvard University Medical School and an outspoken critic of recombinant DNA research, argued, “It will push science more and more into the direction of a moneymaking proposition. They say that they’re going to cure this disease and that disease. But mostly they’re going to get rich.”

And get rich they did. Wall Street gobbled up the opportunities to invest in the new biotech firms. Genentech went public a few months after the Chakrabarty decision, offering one million shares at $35 per share. The price of the stock shot up to $89 per share within the first 20 minutes of trading. By the close of the first day of trading, the company had raised $36 million and achieved a market value of $532 million, even though Genentech had not yet introduced a single marketable product.

The enthusiasm toward biotechnology has not waned. Many regions, including Arizona, are staking much of their economic future on the growth and development of the industry. Biotechnology is cutting edge, it proposes solutions to disease and famine, and it offers high-

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87 Fields, supra note 83.
88 Rifkin, supra note 14.
89 Id.
90 Id.
purchasing jobs. Governments, investors, and economic developers fear that if they do not jump on the biotech bandwagon, they will be left behind.

1. **The Rush to Patent Life**

*Chakrabarty* opened the floodgates for the patenting of life, acting as authority for patenting genes, DNA fragments, stem cells, and entire organisms. In doing so, it “initiated a race to claim patent rights on genes, and genetically modified animals and plants.” The early patents on genes closely followed the “tradition of patents on chemicals,” i.e., the patent holder does not own the rights to the gene in question, but rather to an “isolated and purified” form of the gene. “Throughout the 1980s, patents on genes generally corresponded closely to foreseeable commercial products, such as therapeutic proteins or diagnostic tests for recognized genetic diseases.” In 1987, “[t]he PTO, in a complete about-face, reversed its earlier position and issued a ruling that all genetically engineered multicellular living organisms, including animals, are potentially patentable.”

In 1988, the PTO issued a patent to Harvard University for the OncoMouse, “a rodent with a gene inserted that predisposes it to cancer.” The patent on the OncoMouse raised questions about whether all types of life form are subject to proper patent subject matter. The decision to grant a patent for the OncoMouse was not well accepted in other parts of the world. In 2002, the Canadian Supreme Court rejected attempts to patent the OncoMouse under Canadian law.

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92 Stix, *supra* note 13, at 79.


94 Rifkin, *supra* note 14, at 44.

95 Stix, *supra* note 13, at 82.
In June 1991, the debate over biotech patents exploded again when the National Institutes of Health ("NIH") submitted patent applications for 337 DNA sequences that had been identified by NIH researchers working on the Human Genome Project.\(^{96}\) Shortly before that time, NIH researcher J. Craig Vetter had developed a technique for partially sequencing the expressed DNA sequences in the human brain.\(^{97}\) Using that technique, the NIH researchers had quickly learned how to identify segments of cDNA using what Vetter called expressed sequence tags ("ESTs").\(^{98}\) ESTs have no known utility of their own, but often are useful for conducting research.\(^{99}\)

Even though Vetter had not determined the function of the full-length sequences, the NIH sought patent rights for both the EST sequences and for the "full-length coding sequences of the genes from which the EST sequences had been derived and for the protein products encoded by these full-length sequences."\(^{100}\) The outcry was loud and immediate.

Critics argued that because NIH could not identify a specific biological function for the full-length sequences from which it obtained the ESTs, it was not entitled to patent protections on those sequences.\(^{101}\) NIH advanced a number of general uses for the ESTs, but the critics were not dissuaded. James Watson, one of the discoverers of the double-helix structure of DNA,

\(^{96}\) Zuhn, supra note 37, at 977.

\(^{97}\) Id.

\(^{98}\) Id. “ESTs are small pieces of DNA sequence (usually 200 to 500 nucleotides long) that are generated by sequencing either one or both ends of an expressed gene.” National Center for Biotechnology Information, “ESTs: Gene Discovery Made Easier,” located at http://www.ncbi.nlm.nih.gov/About/primer/est.html (May 4, 2006).

\(^{99}\) Researchers use ESTs to “help identify unknown genes and to map their positions within a genome.” Id. “When an EST is introduced into a sample containing a mixture of DNA, the EST may hybridize with a portion of DNA. Such binding shows that the gene corresponding to the EST was being expressed at the time of the mRNA extraction.” In Re Fisher, 421 F.3d 1365, 1367 (Fed Cir 2005).

\(^{100}\) Zuhn, supra note 37, at 977.

\(^{101}\) Id., at 979.
derided automated sequencing of ESTs as “something ‘virtually any monkey’ could do.” Watson later resigned as head of the NIH genome project, at least in part because of his concern over the patenting of ESTs. The American Society of Human Genetics argued that “[t]he anticipated utility of an EST is simply that one could be used as a research tool to identify the remainder of the coding region of the gene. . . The EST is, at best a starting point for further research and should not be patentable.” C. Thomas Caskey, the president of the Human Genome Organization, warned that “the patenting of DNA sequences having no known function could lead to increased health-care costs and restricted access to DNA-based therapies and diagnostics.”

After receiving two PTO rejections of its application, NIH abandoned its attempts to patent the ESTs; at the time, “NIH Director Harold Varmus announced that any effort to secure patent rights on DNA sequences having no known function was ‘not in the best interests of the public or science.’” NIH now takes a hostile position toward patenting ESTs and raw DNA sequences, but, as Nobel laureate Paul Berg stated, the NIH had “opened Pandora’s box” by seeking patent protection for EST sequences with no known function.

As the work on the Human Genome Project advanced, researchers began filing patents on scores of ESTs, and the PTO began granting those applications. Private sector scientists sought
to accumulate valuable intellectual property for their companies, while public sector scientists sought to keep the genetic information in the public domain. Researchers submitted applications “without really knowing what the ESTs in question did: the applicants often guessed at the biological function of the gene fragments by poking through protein and DNA databases.”

Critics described the increase in the number of EST patents as “an intellectual property ‘land grab’ over a finite number of human genes.” As of July 2002, the PTO had “granted patents on more than 20,000 genes or gene-related molecules.” Increasingly, these patents cover “not only a gene but the protein made by the gene.” By 2005, the PTO “had issued patents to corporations, universities, government agencies and nonprofit groups for nearly 20 percent of the human genome.” This number represents 4382 of the 23,688 genes contained in the gene database maintained by the National Center for Biotechnology Information; “the genes are claimed in 4270 patents within 3050 patent families.”

2. **Brenner v. Manson**

The patenting of ESTs brought into question the scope of the utility requirement in conjunction with the patenting of life forms. In 1966, the Supreme Court considered a similar question about utility requirements in the context of chemical patents.

109 AgBiotech Buzz, supra note 91.
110 Stix, supra note 13, at 80.
113 Id.
114 Stix, supra note 13, at 76.
115 Jensen and Murray, supra note 111, at 239.
Brenner v. Manson involved a patent application for “an allegedly novel process for making certain known steroids.” Citing a lack of utility, the PTO rejected the application for the chemical compound produced by the process, even after the applicant submitted a scientific article showing that “steroids of a class which included the compound in question were undergoing screening for possible tumor-inhibiting effects in mice, and that a homologue adjacent to [the] steroid had proven effective in that role.” The Board of Appeals affirmed. The Court of Customs and Patent Appeals (“CCPA”) reversed, citing Justice Story’s de minimis standard of utility: “where a claimed process produces a known product it is not necessary to show utility for the product,’ so long as the product ‘is not alleged to be detrimental to the public interest.’”

On petition for writ of certiorari, the Supreme Court reversed the decision of the CCPA. The Court noted that though “useful” is a “simple, everyday word, [it] can be pregnant with ambiguity when applied to the facts of life.” The Court declined the invitation to adopt Justice Story’s de minimis standard:

Narrowly read, [the de minimis standard] does no more than compel us to decide whether the invention in question is ‘frivolous and insignificant’ – a query no easier of application than the one built into the statute. Read more broadly, so as to allow the patenting of any invention not positively harmful to society, it places such a special meaning on the word “useful”

117 “A homologous series is a family of chemically related compounds, the composition of which varies from member to member by CH2 (one atom of carbon and two atoms of hydrogen) . . . . Chemists knowing the properties of one member of a series would in general know what to expect in adjacent members.” Id. 383 U.S. at 522 n. 3, quoting Application of Henze, 181 F.2d 196, 200-01, 37 C.C.P.A. (Pat.) 1009, 1014.
118 Brenner, 383 U.S. at 522.
119 The Board of Appeals held that “the statutory requirement of usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful.” Id.
120 Id.
121 Id.
122 Id., 383 U.S. at 529.
that we cannot accept it in the absence of evidence that Congress so intended. There are, after all, many things in this world which may not be considered “useful” but which, nevertheless are totally without a capacity for harm.\footnote{Id., 383 U.S. at 533.}

Instead, the Court held that a process patent for a chemical that “has not been developed and pointed to the degree of specific utility” creates a “monopoly of knowledge” not contemplated by the patent statutes, a monopoly that may envelop an undefined field of knowledge with no established metes and bounds.\footnote{Id.} Both the Constitution and the patent statutes contemplate that the inventor’s \textit{quid pro quo} for receiving a patent monopoly is the public benefit that comes from the disclosure of an invention with \textit{substantial utility}.\footnote{Id., 383 U.S. at 534 (emphasis added).} “Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”\footnote{Id. (emphasis added).} While the Court acknowledged that “what now seems without ‘use’ may tomorrow command the grateful attention of the public,”\footnote{Id.} the utility requirement must focus on the current known use of an invention. “[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful completion.”\footnote{Id.} Indeed, the Court held, the “patent system must be related to the world of commerce rather than to the realm of philosophy.”\footnote{Id., quoting \textit{Application of Ruschig}, 343 F.2d 965, 970, 52 C.C.P.A. (Pat.) 1238, 1245 (Rich, J.).}

3. \textit{In re Fisher}

In 1995, the PTO published new Utility Examination Guidelines that “removed some of the obstacles to EST patenting by only requiring that an applicant assert a utility that was
‘specific’ and ‘credible,’” omitting the requirement under Brenner that the utility also be “substantial.” In 1997, the PTO announced that applicants “would no longer be prevented from securing protection for an EST by the failure to specify the function of the full-length sequence from which that EST was derived.” The PTO reasoned that this approach was warranted because ESTs “were acknowledged to have utility apart from the full-length sequences from which they were derived.”

The PTO later reversed its stance. In response to the ongoing “land grab” of genetic information, the PTO issued the Eighth Edition of The Manual of Patent Examining Procedure in August 2001, in which it defined both “specific utility” and “substantial utility” to clarify the utility requirements under § 101, consistent with the principles of Brenner. The new

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131  Id.
132  Id.
133  The Manual of Patent Examining Procedure sets forth the following guidance for determining “specific utility” and “substantial utility”:

A “specific utility” is specific to the subject matter claimed. This contrasts with the general utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that a compound has “useful biological” properties, would not be sufficient to identify a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a “gene probe” or “chromosome marker” would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition.

* * *

A “substantial utility” defines a “real world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a “substantial utility” define a “real world” context of use. On the other hand, the following are examples of situations that require or constitute carrying out
Guidelines made clear that the PTO no longer would approve patents where the applicants could not articulate a “specific” and “substantial” utility for their genetic invention. Immediately afterwards, the number of patents related to DNA or RNA began dropping and has continued to drop each year since.134

Biotech companies challenged the change in policy, and ultimately Monsanto and the PTO worked together to present a test case regarding the utility requirements.135 Before the Federal Circuit issued its opinion, some commentators suggested that “Monsanto may even be hoping to lose the appeal and thereby establish a standard of utility that would keep others from obtaining patents in the area.”136

The case, In re Fisher,137 upheld the PTO’s policy and affirmed that an applicant must show a “specific and substantial utility” to receive patent protection for an EST. The Federal Circuit held that though the application asserted hypothetical uses for the ESTs, it provided no further research to identify or reasonably confirm a “real world” context of use and, therefore, do not define “substantial utilities”:

(A) Basic research such as studying the properties of the claimed product itself or the mechanism ion which the material is involved;

(B) A method for treating an unspecified disease or condition;

(C) A method for assaying or identifying a material that itself has no specific and/or substantial utility;

(D) A method for making a material that itself has no specific, substantial, and credible utility; and

(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.


134 Stix, supra note 13, at 80-81. Beginning in 1985, the number of patents involving nucleic acid, including from non-humans, increased tremendously, reaching a high of approximately 4500 patents in 2001. That number has declined in each subsequent year, “probably because of tightening requirements.” Id., page 80.


137 In Re Fisher, 421 F.3d 1365 (Fed. Cir. 2005).
data supporting those uses. As such, the application did not meet either the requirements of a “specific and substantial utility” under § 101 or the enablement requirement under § 112.138

The application, entitled “Nucleic Acid Molecules and Other Molecules Associated with Plants, contained a single claim addressing five ESTs.139 It disclosed seven different ways in which the ESTs could be used:

(1) by serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression; (3) providing a source for primers for use in the polymerase chain reaction (“PCR”) process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.140

Though the patent applicants were two individuals, Dane K. Fisher and Raghunath Lalgudi (collectively “Fisher”), Monsanto Technology, LLC (“Monsanto”) was the real party in interest.141

Consistent with the PTO’s Guidelines, the patent examiner rejected the claim based on a lack of utility, finding that “the claimed ESTs were not supported by a specific and substantial utility.”142 The disclosed uses “were not specific to the claimed ESTs, but instead were generally

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138 Id., 421 F.3d at 1367.
139 Id. The Claims reads as follows:

A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

Id. The Application disclosed 32,236 sequences; Fisher initially sought to claim 4,013 EST sequences. Zuhn, supra note 130.
140 In Re Fisher, 421 F.3d at 1368.
141 Id., 421 F.3d at 1366, n. 1.
142 Id., 421 F.3d at 1368.
applicable to any EST.” 143 The examiner also noted that ESTs did not have a substantial utility because “there was no known use for the proteins produced as final products resulting from the processes involving the claimed ESTs.” 144 She also rejected the application based on a lack of enablement under § 112, first paragraph, arguing that a person of ordinary skill in the art would not know how to use the claimed ESTs because the application “did not disclose a specific and substantial utility for them.” 145

Fisher appealed to the PTO Board of Patent Appeals and Interferences (the “Board”), which affirmed the examiner’s final rejection of the application. 146 Though Fisher advanced all seven potential uses of the ESTs on appeal, he focused on two uses: (1) use for identifying polymorphisms, and (2) use as probes or as a source for primers. 147 The Board rejected the first use because “the application failed to explain why the claimed ESTs would be useful in detecting polymorphisms in maize plants.” 148 As such, the “asserted uses for the claimed ESTs tended to the ‘insubstantial use’ end of the spectrum between a substantial and an insubstantial utility.” 149

The Board also rejected the second potential use, finding no substantial utility in “using the claimed ESTs to isolate nucleic acid molecules of other plants and organisms, which themselves had no known utility.” 150 The Board rejected the five other uses, finding no specific benefit in using the claimed ESTs in screens “because the application fails to provide any

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143 Id.
144 Id.
145 Id.
146 Id., 421 F.3d at 1369.
147 Id., 421 F.3d at 1368.
148 Id.
149 Id.
150 Id.
teaching regarding how to use the data relating to gene expression.” Analogizing to the facts in Brenner, the Board found that “‘the products claimed here lack utility, because even if used in gene expression assays, the specification does not disclose how to use SEQ ID NO:1-5 specific gene expression data.’”

Fisher filed a timely appeal to the Federal Circuit, which affirmed in a 2-1 decision. The court first rejected Fisher’s arguments that § 101 required only a minimal showing of utility, holding that none of the seven identified uses met the requirements of utility. The court noted that, under Brenner, § 101 required “‘an invention with substantial utility . . . where specific benefit exists in currently available form.'” Consequently, the court held, “to satisfy the ‘substantial’ utility requirement, asserted use must show that that claimed invention has a significant and presently available benefit to the public.”

The court also rejected the Fisher’s argument that he had disclosed a specific utility for the claimed ESTs. The PTO issued the Utility Guidelines in 2001 in part to answer questions

151 Id., 421 F.3d at 1369.
152 Id., quoting Board Decision, slip op. at 22.
153 Id., 421 F.3d at 1369.
154 Id., 421 F.3d at 1366.
155 Fisher argued that the utility threshold under § 101 was not high and that “the general commercial success of ESTs in the marketplace confirms the utility of the claimed ESTs.” Id., 421 F.3d at 1370. The government agreed that the utility threshold was not high, but argued that the application did not disclose a “single specific and substantial utility” required by Brenner and by the Utility Examination Guidelines. Id. The government argued that “Fisher’s alleged uses are so general as to be meaningless,” and that “the same generic uses could apply not only to the five claimed ESTs but also to any EST derived from any organism.” Id.

In addition, a number of amici curiae supported the government’s position that the claimed uses were “nothing more than a ‘laundry list’ of research plans, each general and speculative, none providing a specific and substantial benefit in currently available form.” Id. The amici also argued that the ESTs are “objects of further research” used to identify “what genes of unknown function are expressed during anthesis and what proteins of unknown function are encoded for by those genes.” Id. The claimed ESTs lack utility under § 101 and are not patentable “until the corresponding genes and proteins have a known function.” Id.

156 Id., 421 F.3d at 1371 (emphasis in the original), quoting Brenner, 383 U.S. at 534-35.
157 Id.
about the patentability of ESTs. The Guidelines note that “a specific utility is particular to the subject matter claimed and would not be applicable to a broad class of invention.” Further, “[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities.” When an invention is identified as a research tool, as in this case, the PTO requires that its examiners exercise particular caution to “distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.” These requirements, the court held, are consistent with the requirements established by § 101.

Fisher acknowledged that, as of the date of filing, “the underlying genes have no known functions.” As such, the court held, the claimed ESTs do nothing more than act as “research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes.” Accordingly, the claimed ESTs are nothing more than “mere ‘object[s] of use-testing,’ to wit, objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end.” The ESTs had no substantial utility because “all of Fisher’s asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could

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158 Id., 421 F.3d at 1372. Though the Guidelines are not binding on the Court, they “‘may be given judicial notice to the extent they do not conflict with the statute.’” Id., quoting Enzo Biochem v. Gen-Probe, 323 F.3d 956, 964 (Fed. Cir. 2002).

159 Id., 421 F.3d at 1372.

160 Id., quoting MPEP § 2107.01.

161 Id., quoting MPEP § 2107.01.

162 Id., 421 F.3d at 1373.

163 Id.

164 Id., quoting Brenner, 353 U.S. at 535, 86 S.Ct. 1033.
possibly achieve, but none for which they have been used in the real world."\textsuperscript{165} Further, they had no specific use because “[a]ny EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses.”\textsuperscript{166} Because the disclosed uses for the five ESTs were no different than the uses of “any EST derived from any organism,” Fisher had disclosed nothing more than general uses, not the specific uses required by § 101.\textsuperscript{167}

Fisher argued that the commercial success of EST databases supported his contention that the claimed ESTs had a specific and substantial utility. The court disagreed, noting that the “general reliance [on EST databases] does not related to the ESTs at issue in this case.”\textsuperscript{168} Fisher presented no evidence that any agricultural companies were interested in his ESTs, and “it is entirely unclear from the record whether such business entities ever will.”\textsuperscript{169} For that reason, the court held that even though commercial success may in some cases support a finding of utility, it did not do so in this case.\textsuperscript{170}

Both the government and the amici curiae argued that “allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the ‘useful Arts’ and ‘Science.’”\textsuperscript{171} The court, nonetheless, held that even if the concerns were valid, they could not be considered in determining whether Fisher’s application met the requirements for utility under § 101.\textsuperscript{172} Congress provided that if an application references “anything under the

\begin{thebibliography}{99}
\bibitem{165}Id., 421 F.3d at 1373 (emphasis in the original).
\bibitem{166}Id.
\bibitem{167}Id., 421 F.3d at 1374.
\bibitem{168}Id., 421 F.3d at 1377.
\bibitem{169}Id.
\bibitem{170}Id., 421 F.3d at 1378.
\bibitem{171}Id.
\bibitem{172}Id.
\end{thebibliography}
sun that is made by man,” it contains potential subject matter for a patent, regardless of whether reasons of public policy might argue against granting patent rights.173

The court quickly discounted Fisher’s argument that the application met the enablement requirements of § 112, noting that “the enablement requirement of § 112 incorporates the utility requirement of § 101.”174

The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.175

In his dissent, Judge Rader argued that the claimed ESTs satisfied the utility requirements of § 101, “at least as research tools in isolating and studying other molecules.”176 Unlike the chemical compounds at issue in Brenner v. Manson and In re Kirk,177 “Fisher’s claimed ESTs are beneficial to society” because, for example, they may help scientists to isolate particular genes in the maize genome.178 He analogized the ESTs to a microscope: “both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure.”179 Because “[s]cience always advances in small incremental steps,” the dissent argued, the Board improperly denied the Application on the basis that the information provided by the ESTs was too “insubstantial” to merit patent protection.180

173 Id.
174 Id.
175 Id., quoting In re Ziegler, 992 F.2d 1197, 1200-01 (Fed. Cir. 1993) (citations omitted).
176 Id., 421 F.3d at 1379 (dissent).
177 In re Kirk, 54 C.C.P.A. 1119, 376 F.2d 936 (1967).
178 In Re Fisher, 421 F.3d at 1380 (dissent) (emphasis in the original).
179 Id.
180 Id.
Though he would have reversed the decision of the PTO, Judge Rader expressed sympathy for the dilemma it faces, noting that the PTO “needs tool to reject inventions that may advance the ‘useful arts’ but not sufficiently to warrant the valuable exclusive right of a patent.” In his view, however, the utility requirement is not the appropriate method of doing so because “it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance.” Instead, he argued that such patents should be denied under the requirements of non-obviousness under 35 U.S.C. § 103.

IV. THE “TRAGEDY OF THE ANTICOMMONS”

Patents grant monopolies to inventors and, therefore, are at odds with principles of free enterprise. “By conferring monopolies in discoveries, patents necessarily increase prices and restrict use – a cost society pays to motivate invention and disclosure.” Still, the patent system has always been subject to criticism. In 1851, The Economist attacked the fairness of the patent system with arguments that reflected the conventional wisdom of the day:

The granting [of] patents inflames cupidity, excites fraud, stimulates men to run after schemes that may enable them to levy a tax on the public, begets disputes and quarrels betwixt inventors, provokes endless lawsuits . . . The principle of the law from which such consequences flow cannot be just.

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181 Id., 421 F.3d at 1381-82 (dissent).
182 Id., 421 F.3d at 1382 (dissent).
183 Id. As Judge Rader noted, the problem with this position is that the Federal Circuit already had “deprived the Patent Office of the obviousness requirement for genomic inventions” in In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995). Id.

In Deuel, the PTO cited obviousness under 35 U.S.C. § 103 as grounds for its final rejection of an application related to isolated and purified DNA and cDNA molecules encoding heparin-binding growth factors (“HBGFs”). The PTO held that by combining the teachings of one piece of prior art disclosing a heparin-binding proteine and another piece of prior art disclosing a method of cloning genes, it would have been obvious to clone a gene for HBGFs. Deuel, 51 F.3d at 1556. The Federal Circuit rejected that approached and reversed the decision of the PTO, holding that “the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have ben obvious, in the absence of other prior art that suggests the claimed DNAs.” Id., 51 F.3d at 1557.

184 Heller and Eisenberg, supra note 93, at 698.
185 “A market for ideas,” supra note 3.
Current critics argue that patents are “too easy” to obtain, and that the inventions are neither novel nor useful. Those concerns are amplified in the biotech industry. Critics argue that scientific research suffers from the issuance of the patents by creating an “anticommons” of knowledge that allows patent holders to restrict or control research by using their patents as hurdles to ongoing research.

The “tragedy of the anticommons” was first identified as a concern in biomedical research in a 1998 article in *Science* written by two professors at the University of Michigan Law School, Michael A. Heller and Rebecca S. Eisenberg.\(^\text{186}\) They analogized their concerns to the “tragedy of the commons,” which holds that scarce resources held in common are overused because “too many owners each have a privilege to use a given resource and no one has a right to exclude another.”\(^\text{187}\)

Anticommons property, they argued, is the mirror image of commons property.\(^\text{188}\) “[T]he recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an ‘anticommons’ in which people underuse scarce resources because too many owners can block each other.”\(^\text{189}\) The development of the anticommons is “an unintended and paradoxical consequence of biomedical privatization.”\(^\text{190}\) Once a body of anticommons develops in an area of biomedical research, “collecting rights into usable private property is often brutal and slow.”\(^\text{191}\)

\(^{186}\) Heller and Eisenberg, *supra* note 93, at 698.

\(^{187}\) Heller and Eisenberg, *supra* note 93, at 698.

\(^{188}\) *Id.*

\(^{189}\) *Id.*

\(^{190}\) *Id.*

\(^{191}\) *Id.*
Heller and Eisenberg argued that the government might inadvertently create an anticommons in biomedical research by allowing the patents to issue for DNA sequences, including ESTs, without requiring that the patentee to identify “a corresponding gene, protein, biological function, or potential commercial product.”\(^{192}\)

“Although a database of gene fragments is a useful resource for discovery, defining property rights around isolated gene fragments seems at the outset unlikely to track socially useful bundles of property rights in future commercial products.”\(^{193}\) They argued that if patents on individual fragments continued to be issued to different owners, future research would “require costly future transactions to bundle licenses together before a firm can have an effective right to develop these products.”\(^{194}\)

Heller and Eisenberg also warned of a second source of anticommons, the use of reach through license agreements ("RTLAs") that “give the owner of a patented invention, used in upstream stages of research, rights in subsequent downstream discoveries.”\(^{195}\) In theory, RTLAs offer advantages to both the patent holder and to researchers. Researchers who are low on cash can use an RTLA to use research tools and defer payment until their research provides financially valuable; patent holders benefit by receiving a potentially larger payment from the sale of the downstream product than they would from receiving a smaller fee paid at the time of the use.\(^{196}\) In reality, however, “RTLAs may lead to an anticommons as upstream owners stack overlapping and inconsistent claims on potential downstream products.”\(^{197}\)

\(^{192}\) Id.

\(^{193}\) Id., at 699.

\(^{194}\) Id.

\(^{195}\) Id.

\(^{196}\) Id.

\(^{197}\) Id.
“An anticommons in biomedical research may be more likely to endure than in other areas of intellectual property because of the high transaction costs of bargaining, heterogenous interests among owners, and cognitive biases of researchers.”\footnote{Id., at 701.} An anticommons would impose “cost barriers on access to medicines”\footnote{Yochai Benkler, “Commons-Based Strategies and the Problems of Patents,” 305 Science 1110, 1110 (2004).} and stifle the vast economic potential of the biotech industry. Nonetheless, the concern may be only theoretical, at least at this time. According to Skip Stiles, a consultant and the former Legislative Director for the House Committee on Science, “We don’t have any firm evidence that patents are causing problems, but there is some anecdotal evidence that the scope of biotech patents has stymied research or researchers.”\footnote{AgBiotech Buzz, supra note 91.}

Not only do broad biotech patents raise concerns about their ability to block ongoing research, they also have the potential of keeping agricultural biotech product from the developing nations that could most benefit from the technology. Critics argue that patents unfairly deprive needed biotech foods and medicines from that portion of the world’s population that most needs the benefits of the patented products.

Notwithstanding these concerns, “some academic researchers believe patent rights can be harmonized with humanitarian purposes.”\footnote{Id.} Researchers who own patent rights to biotech products can set up license agreements that allow for free use for humanitarian purposes, while still maintaining control of their intellectual property. The free humanitarian licenses allow the researchers to place the biotech products into the hands of those who most need the products, the poorest of the poor.\footnote{Id.}
V. **CONCLUSION**

The biotech industry is here to stay; the law must adapt to ensure that it keeps up with the rapidly expanding industry. Because of the high cost of developing biotech products, the issuance of patents will remain a vital portion of any biotech company’s ongoing business plan. Industry leaders, the PTO, and the courts must remain vigilant to ensure that biotech companies are allowed to protect their valuable intellectual property, while still providing for growth of the body of common knowledge arising from the new developments.
## Employee Noncompetes
### A State by State Survey

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<th>Protectable / Legitimate Interests</th>
<th>Standards</th>
<th>Exemptions</th>
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<th>Reformation Blue Pencil Red Pencil</th>
<th>Enforceable Against Discharged Employees</th>
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<td>Not overbroad in time, space, and scope; interest of individuals in gaining and pursuing a livelihood; commercial concerns in protecting legitimate business interests; public policy.</td>
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<td>Yes</td>
<td>Reformation</td>
<td>Yes, but it’s a factor to be considered.</td>
</tr>
<tr>
<td>HI</td>
<td>Yes. Haw. Rev. Stat. sec. 480-4(c)</td>
<td>Trade Secrets; Confidential Information; Customer Contacts</td>
<td>Reasonable in time, space, scope.</td>
<td>-</td>
<td>Undecided</td>
<td>Reformation</td>
<td>Undecided</td>
</tr>
<tr>
<td>ID</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Customer Contacts</td>
<td>No broader than necessary to protect the employer's legitimate business interest; reasonable as to covenantor, covenantee, and public; not contrary to public policy.</td>
<td>-</td>
<td>Yes</td>
<td>Blue Pencil</td>
<td>Yes</td>
</tr>
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</tr>
<tr>
<td>IL</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Near Permanent Customer Relationships.</td>
<td>Reasonable and necessary to protect a legitimate business interest; reasonableness measured by hardship to employee, effect on public, and reasonableness in time, space, and scope. [Legitimate business interest requirement called into question.]</td>
<td>Broadcasters; Government Contractors; Physicians</td>
<td>Yes (if employment continued for sufficient duration)</td>
<td>-</td>
<td>Yes</td>
</tr>
<tr>
<td>IN</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Goodwill; Special Training or Techniques</td>
<td>Clear and specific (not general) restraint must be reasonable in light of the legitimate interests to be protected; reasonableness is measured by totality of interrelationship of the interest, and the time, space, and scope of the restriction, judged by the needs for the restriction, the effect on the employee, and the public interest.</td>
<td>-</td>
<td>Yes</td>
<td>Blue Pencil</td>
<td>Yes</td>
</tr>
<tr>
<td>IA</td>
<td>Yes</td>
<td>Trade Secrets; Goodwill; Specialized Training</td>
<td>Whether the restriction is reasonably necessary to protect the employer’s business, unreasonably restrictive (time and space), and prejudicial to the public interest.</td>
<td>Franchisees (where franchisor does not renew)</td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes, but it’s a factor to be considered.</td>
</tr>
<tr>
<td>KS</td>
<td>Yes</td>
<td>Trade Secrets; Loss of Clients; Referral Sources; Reputation; Special Training</td>
<td>Protects a legitimate business interest; not undue burden on employee; not injurious to public welfare; reasonable in time and space.</td>
<td>Accountants (limited)</td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes</td>
</tr>
<tr>
<td>State</td>
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</tr>
<tr>
<td>KY</td>
<td>Yes</td>
<td>Confidential Business Information; Customer Lists; Competition; Employee Raiding; Investment in Training</td>
<td>Reasonable in scope and purpose; reasonableness determined by the time, space, and &quot;charter&quot; of the restriction; no undue hardship; does not interfere with public interest</td>
<td>Physicians</td>
<td>Yes (if long enough and employee resigns)</td>
<td>Reformation</td>
<td>Undecided (but it can be a factor)</td>
</tr>
<tr>
<td>LA</td>
<td>Yes. La. Rev. Stat. Ann. Sec. 23:921</td>
<td>Trade Secrets; Financial Information; Management Techniques; Extensive (Unrecouped Through Employee's Work) Training</td>
<td>No more than two years; specifies the specific geographic reach (by parishes, municipalities, or their respective parts); defines employer's business; strict compliance with statute.</td>
<td>Automobile Salesman; Real Estate Broker's Licensees (procedural requirements)</td>
<td>Yes</td>
<td>Blue Pencil, if allowed by the noncompete</td>
<td>Yes, likely.</td>
</tr>
<tr>
<td>ME</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Goodwill</td>
<td>No broader than necessary to protect the employer's legitimate business interest; reasonable as to time, space, and interests to be protected; no undue hardship to employee.</td>
<td>Broadcast Industry (presumption)</td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes, likely.</td>
</tr>
<tr>
<td>MD</td>
<td>Yes</td>
<td>Trade Secrets; Routes; Client Lists; Established Customer Relationships; Goodwill; Unique Services</td>
<td>Duration and space no broader than reasonably necessary to protect legitimate interests; no undue hardship to employee or public; ancillary to the employment.</td>
<td>-</td>
<td>Yes</td>
<td>Blue Pencil, but undecided as to whether more flexible</td>
<td>No, likely.</td>
</tr>
<tr>
<td>MA</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Goodwill</td>
<td>Narrowly tailored to protect legitimate business interest; limited in time, space, and scope; consonant with public policy; harm to employer outweighs harm to employee.</td>
<td>Broadcasters; Physicians; Nurses; Social Workers; Psychologists</td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes</td>
</tr>
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</tr>
<tr>
<td>MI</td>
<td>Yes. Mich. Comp. Laws sec. 445.774a.</td>
<td>Trade Secrets; Confidential Business Information; Goodwill</td>
<td>Must have an honest and just purpose and to protect legitimate business interests; reasonable in time, space, and scope or line of business; not injurious to the public.</td>
<td>-</td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes</td>
</tr>
<tr>
<td>MN</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Business Information; Goodwill; Prevention of Unfair Competition</td>
<td>No broader than necessary to protect the employer's legitimate business interest; does not impose unnecessary hardship on employee.</td>
<td>-</td>
<td>No</td>
<td>Reformation</td>
<td>Yes</td>
</tr>
<tr>
<td>MS</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Business Information; Goodwill; Ability to Succeed in a Competitive Market</td>
<td>Reasonableness and specificity of restriction, primarily, in time and space; hardship to employer and employee; public interest.</td>
<td>-</td>
<td>Yes (though questioned if employee terminated shortly after)</td>
<td>Reformation</td>
<td>Yes</td>
</tr>
<tr>
<td>MO</td>
<td>Yes. 28 Mo. Stat. Ann. Sec. 431.202</td>
<td>Trade Secrets; Confidential Business Information; Customer or Supplier Relationships, Goodwill, or Loyalty; Customer Lists; Protection from Unfair Competition; Stability in the Workforce</td>
<td>Reasonably necessary to protect legitimate interests; reasonable in time and space; not an unreasonable restraint on employee; purpose served; situation of the parties; limits of the restraint; specialization of the business. [Absence of legitimate business interest impacts duration, which can be no more than one year.]</td>
<td>Secretaries (limited); Clerks (limited)</td>
<td>Yes, generally.</td>
<td>Reformation</td>
<td>Yes</td>
</tr>
<tr>
<td>MT</td>
<td>Yes. Mont. Code Ann. Secs. 28-703-05</td>
<td>Likely confidential information and goodwill; may be more broad.</td>
<td>Reasonable in time or space; reasonable protection for employer; does not impose unreasonable burden on the employee or public.</td>
<td>-</td>
<td>Undecided</td>
<td>Blue Pencil, likely</td>
<td>Undecided</td>
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## Employee Noncompete

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<tr>
<td>NE</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Goodwill</td>
<td>Reasonably necessary to protect legitimate interests; not unduly harsh or oppressive to employee; not injurious to the public. Considerations include: inequality in bargaining power; risk of loss of customers; extent of participation in securing and retaining customers; good faith of employer; employee's job, training, health, education, and family needs; current employment conditions; need for employee to change his calling or residence; relation of restriction to legitimate interest being protected.</td>
<td>-</td>
<td>Yes</td>
<td>Red Pencil</td>
<td>Undecided</td>
<td></td>
</tr>
<tr>
<td>NV</td>
<td>Yes. Nev. Rev. Stat. sec. 613.200</td>
<td>Trade Secrets; Goodwill</td>
<td>Not greater than reasonably necessary to protect the business and goodwill of the employer; no undue hardship on employee. Time and space are considerations for reasonableness.</td>
<td>-</td>
<td>Yes</td>
<td>Reformation</td>
<td>Undecided</td>
<td></td>
</tr>
<tr>
<td>NH</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Business Information; Goodwill; Employee's Special Influence Over the Employer's Customers</td>
<td>Not greater than necessary to protect the employer's legitimate business interests; no undue or disproportionate hardship to employee; not injurious to public interest.</td>
<td>-</td>
<td>Yes</td>
<td>Reformation</td>
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<td>NJ</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Business Information; Goodwill in Existing Customers; Preventing Employee from Working with Customer at Lower Cost than Working through Employer</td>
<td>Protects a legitimate business interest; not undue burden on employee; not injurious to the public; not overbroad in time, space, and scope.</td>
<td>In-House Counsel; Psychologists.</td>
<td></td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>NM</td>
<td>Yes</td>
<td>Maintaining Workforce; Limitation of Competition (but not to stifle competition); Customer Relationships</td>
<td>Reasonable as applied to the employer, employee, and public; not great hardship to employee in exchange for small benefits to employer.</td>
<td></td>
<td>Yes, likely</td>
<td>Undecided</td>
<td>Undecided</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NY</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Goodwill; On-Air Persona of Broadcasters; Employee's Unique or Extraordinary Services</td>
<td>Necessary to protect legitimate business interest; reasonable in time and space; not harmful to general public; not unreasonably burdensome to the employee.</td>
<td></td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes, with exceptions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NC</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Business Information; Goodwill</td>
<td>In writing; part of an employment contract; reasonably necessary to protect legitimate business interest; reasonable in time and space; not against public policy.</td>
<td></td>
<td></td>
<td></td>
<td>Blue Pencil</td>
<td>Yes, likely.</td>
<td></td>
</tr>
<tr>
<td>ND</td>
<td>No. N.D. Cent. Code sec. 9-08-06</td>
<td>-</td>
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<tr>
<td>OH</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Customer Relationships; Prevention of the Use of Proprietary Customer Information to Solicit Customers</td>
<td>Not greater than necessary to protect the employer's legitimate business interests; no undue hardship to employee; not injurious to public interest. Considerations: absence or presence of limitations as to time and space; whether employee is sole contact with customer; employee's possession of trade secrets or confidential information; purpose of restriction (elimination of unfair competition vs. ordinary competition and whether seeks to stifle employee's inherent skill and experience); proportionality of benefit to employer as compared to the detriment to the employee; other means of support for employee; when employee's talent was developed; whether forbidden employment is merely incidental to the main employment.</td>
<td>-</td>
<td>Yes</td>
<td>Reformation</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OK</td>
<td>No</td>
<td>No. Okla Stat. tit. 15, sec. 219A</td>
<td>-</td>
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<tr>
<td>OR</td>
<td>Yes, Or. Rev. Stat. sec. 653.295</td>
<td>Trade Secrets; Confidential Business or Professional Information; Investment in Certain On-Air Broadcasters; Customer Contacts and Goodwill</td>
<td>Noncompete provided at least two weeks before employment or with bona fide advancement; employee meets minimum compensation threshold; no longer than two years; restricted in time or space; application of restriction should afford only a fair protection of the employer’s interests; must not interfere with public interest. [Qualifying garden leave clauses are enforceable.]</td>
<td>-</td>
<td>No.</td>
<td>Reformation</td>
<td>Undecided</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PA</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Goodwill; Investment in Specialized Training; Unique or Extraordinary Skills</td>
<td>Ancillary to employment relation or other transaction; reasonably necessary to protect the employer’s legitimate interests; reasonable in time and space.</td>
<td>-</td>
<td>No</td>
<td>Reformation</td>
<td>Yes, but it’s a factor to be considered.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RI</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Customer Lists; Goodwill; Special Training or Skills</td>
<td>Reasonable in light of protectable interests.</td>
<td>-</td>
<td>Undecided</td>
<td>Blue Pencil, but may allow Reformation</td>
<td>Undecided</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SC</td>
<td>Yes</td>
<td>Business and Customer Contacts; Existing Employees; Existing Payroll Deduction Accounts.</td>
<td>Necessary to protect legitimate business interest; reasonably limited in time and space; not unduly harsh and oppressive to employee's efforts to earn a living; reasonable from standpoint of public policy.</td>
<td>-</td>
<td>No</td>
<td>Reformation</td>
<td>Undecided</td>
<td></td>
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# Employee Noncompetes

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<tr>
<td>SD</td>
<td>Yes, S.D. Codified Laws sec. 53-9-8, et seq.</td>
<td>Trade Secrets; Protection from Unfair Competition; Existing Customers</td>
<td>Restriction is in the same business or profession as that carried on by employer and does not exceed two years and in a specified geographic area; reasonableness in time, space, and scope is a factor only in certain circumstances.</td>
<td>-</td>
<td>Yes</td>
<td>Reformation, likely.</td>
<td>Yes, but it's a factor to be considered.</td>
</tr>
<tr>
<td>TN</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Retention of Existing Customers; Investment in Training or Enhancing the Employee's Skill and Experience</td>
<td>Restriction must be reasonable in time and space and necessary to protect legitimate interest; public interest no adversely affected; no undue hardship to the employee.</td>
<td></td>
<td>Yes</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>TX</td>
<td>Yes, Tex. Bus. &amp; Com. Code secs. 15.50-.52</td>
<td>Trade Secrets; Confidential or Proprietary Information; Goodwill; Special Training or Knowledge Acquired During Employment;</td>
<td>Ancillary to an otherwise enforceable agreement; reasonable in time, space, and scope; does not impose a greater restraint than necessary to protect legitimate business interest. <em>On June 24, 2011, the Texas Supreme Court eliminated the requirement that the consideration given by the employer in exchange for the noncompete must give rise to the interest protected by the noncompete.</em> Physicians (in certain circumstances).</td>
<td></td>
<td>Yes</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>UT</td>
<td>Yes</td>
<td>Trade Secrets; Goodwill; Extraordinary Investment in Training or Education</td>
<td>No bad faith in the negotiations; necessary to protect legitimate business interest; reasonable in time, space, and scope; consideration of hardship.</td>
<td>-</td>
<td>Yes</td>
<td>Undecided</td>
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<td>VT</td>
<td>Yes</td>
<td>Proprietary Confidential Information; Goodwill; Relationships with Customers; Investments in Special Training</td>
<td>Necessary to protect legitimate business interest; not unnecessarily restrictive to employee; limited in time, space, and/or industry; not contrary to public policy.</td>
<td>Beauticians and Cosmetologists (by their school)</td>
<td>Yes</td>
<td>Undecided</td>
<td>Yes, but it’s a factor to be considered.</td>
</tr>
<tr>
<td>VA</td>
<td>Yes</td>
<td>Trade Secrets; Confidential Information; Knowledge of Methods of Operation; Protection from Detrimental Competition; Customer Contacts</td>
<td>No broader than necessary to protect the employer's legitimate business interest; reasonable in time, space, and scope; not unduly harsh in curtailing employee's ability to earn a living; reasonable in terms of public policy.</td>
<td>-</td>
<td>Yes</td>
<td>Red Pencil</td>
<td>Yes</td>
</tr>
<tr>
<td>WA</td>
<td>Yes</td>
<td>Customer Information and Contacts; Goodwill</td>
<td>Restriction is necessary to protect employer's business or goodwill; restriction is no greater than reasonably necessary to secure employer's business or goodwill; reasonable in time and space; injury to public does not outweigh benefit to employer.</td>
<td>Broadcasters (under certain circumstances)</td>
<td>No</td>
<td>Reformation</td>
<td>Yes, likely.</td>
</tr>
<tr>
<td>WV</td>
<td>Yes</td>
<td>Trade Secrets; Confidential or Unique Information; Customer Lists; Direct Investment in Employee's Skills; Goodwill</td>
<td>Ancillary to a lawful contract; not greater than reasonably necessary to protect legitimate business interest; reasonable in time and space; no undue hardship on employee; not injurious to public.</td>
<td>-</td>
<td>No, likely.</td>
<td>Reformation</td>
<td>Undecided</td>
</tr>
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Boston, MA 02110  
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<td>WI</td>
<td>Yes. Wis. Stat. Ann. Sec. 104.465</td>
<td>Trade Secrets; Confidential Business Information; Customer Relationships.</td>
<td>Necessary to protect legitimate business interest; reasonable in time and space; not harsh or oppressive to the employee; not contrary to public policy.</td>
<td>-</td>
<td>No, likely.</td>
<td>All or nothing. But, recent case law may suggest a judicial move toward a more tolerant approach. See Star Direct, Inc. v. Dal Pra, 767 N.W.2d 898 (Wis. 2009).</td>
<td>Yes, likely.</td>
</tr>
<tr>
<td>WY</td>
<td>Yes.</td>
<td>Trade Secrets; Confidential Information; Special Influence of Employee Over Customers to the Extent Gained During Employment</td>
<td>Restraint must be ancillary to otherwise valid agreement and fair; no greater than necessary to protect legitimate business interests; reasonable in time and space; no undue hardship on employee; employer’s need outweighs harm to employee and public; not injurious to public.</td>
<td>-</td>
<td>No</td>
<td>Reformation</td>
<td>Yes, likely.</td>
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<td></td>
<td></td>
<td>Customer lists are frequently considered trade secrets or confidential information. Some states, however, separately identify them as protectable interests.</td>
<td></td>
<td></td>
<td>Consideration for the noncompete is always a requirement. That requirement is not typically an issue when the agreement is entered into at the inception of an employment relationship.</td>
<td></td>
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<td>Reformation is also sometimes called &quot;Judicial Modification,&quot; the &quot;Rule of Reasonableness,&quot; the &quot;Reasonable Alteration Approach,&quot; or the &quot;Partial-Enforcement&quot; rule. Red Pencil is also sometimes called the &quot;All or Nothing&quot; rule.</td>
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Planning ahead key for both sides of non-competes
by Russell Beck
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Love them or hate them, non-competes are a fact of business in all states but California, Oklahoma and North Dakota.

Whether your employee left and you need to enforce a non-compete, or you are hiring an employee subject to a non-compete, proper advance planning can help prevent a winnable case from turning into a losing case.

In the May issue of New England In-House, you were advised about the need to ensure your agreements are both current and provide the maximum protections available — consistent with your corporate culture (“Taking your non-compete from good to great”). That is just the starting point.

While there are variations on the theme, a typical non-compete dispute has a predictable pattern. An employee leaves and joins a competitor, arguably in violation of a non-compete. The former employer quickly sends a letter demanding that the employee immediately quit his job. Sometimes the letter says that the new employer must terminate the employee.

The employee and/or new employer respond by disputing the violation or by proposing limits to the scope of the employee’s prospective duties.

If the parties are unable to reach an agreement, the former employer files a lawsuit and asks for an immediate injunction prohibiting the employee from moving forward with the job. A hearing is held a few days later. The employee and new employer scramble to file an opposition. The court conducts a hearing and issues its decision.

From start to finish, all that happens in a matter of weeks. And, although the cases generally linger afterward, for all intents and purposes they are won and lost at the injunction stage. Accordingly, winning at that stage is critically important.

When these issues arise, they are frequently without advance notice and quick action is imperative. Indeed, undue delay on the part of the former employer can kill an otherwise strong case.

Quick action means little time to investigate or prepare — contrary to the type of thorough investigation and preparation that would ordinarily be done in advance of most other lawsuits.

So knowing what to do ahead of time is critically important.

Whether you’re on the side enforcing the agreement or on the other side, there are steps you can take to enhance your chances of success. They are divided below by which side you find yourself on.

Enforcing restrictive covenants

The following steps should be taken (or at least considered) in connection with enforcing restrictive covenants. (Not all steps will apply to all situations.)

Conduct an exit interview.
Remind employee to leave all company property and information.

- Trade secrets
- Documents (electronic and physical)
- Works in progress
- Nothing on home computer
- PDA/smart phones/cell phones
- Laptops
- Badges/access cards
- Obtain written certification of compliance

Confirm compliance with all existing obligations.

- Fiduciary duties
- Invention assignments
- Confidentiality
- Non-compete

Remind employee of all agreements and continuing obligations.

- Invention assignments
- Confidentiality
- Non-compete
- Non-solicitation
- No-hire/anti-raiding

Provide all reminders and agreements in writing.

- Written acknowledgement of receipt
- Written promise to comply

Ask for identity of new employer.

- If undecided, ask employee for a commitment to provide an update upon a decision being made
- What is the new title?
- What does the position entail?
- Is there overlap with existing technologies and/or customers?

Turn off all access.

- E-mail
- Voice-mail
- Passwords
- Physical ID/access cards

Review all computers and servers through which trade secrets and other confidential information could be taken. Look for improper use and new or odd patterns of usage. This may require retaining a computer forensics specialist.

- E-mail
- Social media
- USB/thumb drives
- External hard drives and disk burners
- Downloaded and uploaded files
- Deleted/altered/copied files
- FTP sites
- Websites
Send a cease and desist letter if there is, or is likely to be, a breach of obligations.

Consider whether to file a lawsuit and possible causes of action (below). If the decision is to sue, the lawsuit should be commenced promptly. Delay can be fatal.

- Breach of contract
- Breach of fiduciary duty
- Misappropriation of trade secrets
- Inevitable disclosure
- Conversion
- Computer Fraud and Abuse Act
- Corporate raiding
- Tortious interference
- Unfair competition (G.L.c. 93A)

Consider whether to sue both the former employee and the new employer, or only the former employee.

Anticipate defenses and counterclaims (see below) and factor into decision of whether to sue.

- Marshal evidence to respond
- Identify witnesses (fact witnesses, expert witnesses)

Line up a bonding company.

Criminal complaint?

**Defending against restrictive covenants**

The following steps should be taken (or at least considered) in connection with defending against an action to enforce restrictive covenants. (Like the steps for enforcing restrictive covenants, some steps may not be applicable in all situations.)

*Return all company equipment, documents and information. Take nothing. (See above.)*

*Review all restrictive covenants for the nature of obligations.*

Review possible defenses.

**Basic requirements.**

- Limited in time, space, scope
- Legitimate business interests: trade secrets, confidential information, goodwill

**Lack of consideration.**

- Timing of when executed
- Changes in position
- Duration of employment

**Lack of irreparable injury/balancing of harms.**

*Former and new employer are not competitors.*

- Overlap in competition is de minimis

*Delay/moot*

*Equity/fairness.*

- Circumstances at signing
- Stealth agreement
- Circumstances at termination
• Extraordinary hardship
• Compensation/low-level employee
• Contract of adhesion
• Unclean hands

Selective/inconsistent enforcement
Employer breach
Employer change: successor/assign
Ambiguity
Novation
Antitrust

Marshal evidence in support of any potentially-applicable defenses.

Plan how to respond during an exit interview.
• Acknowledge the enforceability of the agreement?
• Disclose the identity of the new employer?
• Disclose the nature of the new position?

At the earliest possible time — preferably before the new job is accepted — determine how the restrictions will be handled, and if appropriate, document it.
• What are the implications of the restrictive covenant?
• Can the duties of the new job be narrowed to avoid violating the restrictions?
• If not, can the new job duties be narrowed to limit the harm, or likelihood of harm, to the former employer?

Who will pay for the defense costs?
• What if a conflict of interest arises between employee and new employer?

Wait to be sued or go on offense with a declaratory judgment action?

Potential counterclaims?
• Invasion of privacy
• Wage Act
• Wiretap Act
• Stored Communications Act
• Unfair Competition (G.L.c. 93A)

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Taking your non-compete agreement from good to great
by Stephen Riden
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If your company is like many others, it has been using the same non-compete agreement for years with little or no changes.

So far, there haven’t been any major problems and it seems to cover the bases: departing employees are not permitted to compete against your company for a specified period of time within an appropriate geographic area.

Figuring it’s best to leave well enough alone, why make any changes?

As it turns out, lots of companies believe that their non-compete agreements provide better protection than they actually do and don’t discover that there’s a problem until it’s too late.

All too often, an employer that finds itself needing to enforce its non-compete agreement will send a demand letter or file a lawsuit and, unfortunately, only after testing the application of its agreement in the context of a dispute, discovers that its agreement is not designed to handle specific situations, or worse, that the agreement is wholly unenforceable.

But you’re a savvy advisor, so your company’s non-compete agreement is good and it will hold up in court. The question remains, how can you turn your good non-compete agreement into a great non-compete agreement?

There are several provisions that might be missing from your standard form agreement — provisions that will provide your company a better shot of having its interests protected to the fullest extent possible when an employee leaves to join a competitor.

So, to help improve your company’s chance of obtaining the best possible results, you can add a few simple clauses to your standard form agreement right now.

Some considerations

Non-competes, like all contracts, must be supported by consideration, so if you are making changes to any existing agreements with employees, make sure that consideration — which in some New England states is satisfied by continued employment — is provided in exchange for the modified non-compete.

For purposes of this discussion, we will assume that your non-compete has all of the basic provisions necessary for an enforceable agreement:

First, that it has a reasonable term — typically, a one-year limitation against working for a competitor is permissible.

Second, we’ll assume that your non-compete specifies a geographic reach that is reasonably tied to your company’s legitimate business interests (i.e., most often the protection of trade secrets, other confidential information, and goodwill).

Third, we’ll also assume that the scope of the proscribed activities described in your non-compete is
reasonably related to your company’s legitimate business interests; e.g., a prohibition against
performing work for a competitor that is similar to the work the employee is currently performing for
your company is reasonable, while a restriction against working for any company — competitor or not
— is unreasonable.

The elements above are, of course, just the basics. Here are some provisions that will help move a
good non-compete agreement along the path to becoming a great:

Tolling provision. Say an employee leaves your company but neglects to disclose that they are leaving
to work for a competitor in violation of their non-compete agreement. This is not an uncommon
scenario. What happens if that breach only comes to light two months later? Assuming that the non-
compete agreement has a one-year duration, that would mean the effective duration would be
reduced to the 10 remaining months.

However, a clause that extends the duration of the non-compete period for the amount of time that
passes before the employer learns that its former employee is engaged in prohibited activity provides
additional protection.

The same clause could also toll the non-compete period for the time it reasonably takes the employer
to obtain injunctive relief to halt further impermissible competition. In both of these circumstances,
the tolling stops the clock for activities beyond the employer’s control and helps to ensure that the
employer obtains the full benefit of its non-compete agreement.

It is important to note that, in some states, such a tolling provision can create ambiguities, which
militate against its use, while in others, it may suffice to limit its reach, as a court may construe an
excessive tolling period as unreasonable.

Assignment/successor-in-interest clause. Some Massachusetts trial courts have ruled that non-
compete agreements are not assignable without the employee’s consent and that a non-compete
cannot be enforced by a successor company. In order to have the best chance of overcoming the
effect of these rulings, your non-compete agreement should contain a provision that expressly
provides that the agreement will be binding upon assignment or sale, and enforceable by your
company’s assignees and successors.

Change of position/responsibilities. When an employee’s position or set of responsibilities within a
company changes, the employee’s non-compete agreement may thereby be vitiated. A provision that
specifies that the parties anticipate that the employee’s position and/or responsibilities within the
company may change during his or her employment, and that the same non-compete will govern in
any such circumstances, will provide a persuasive defense in the event the non-compete is challenged
in court on these grounds.

Choice of law/forum selection. As with any agreement, it is in the interest of the parties to a non-
compete to designate the governing law in the event there is a dispute and to select a forum where
those disputes will be resolved. The choice of law provision is especially critical in non-compete
agreements, as there is significant variation among the states as to their enforcement, ranging from
Massachusetts, where non-compete agreements are routinely enforced, to California, where non-
compete clauses are generally invalid.

Disclosure obligation. If it is the case that all problems are problems of imagination, it is also the case
that many problems can be solved with effective communication. Productive communication between
an employer and its former employee is encouraged by a provision that requires an employee to (1)
show any new employer a copy of the non-compete agreement and (2) notify the former employer of
any offers for employment that may violate the non-compete agreement.

Acknowledgment of consideration and irreparable harm. Among the first lines of defense for any
employee who is defending against a claim for violation of a non-compete is to argue that the
agreement is not supported by proper consideration, the non-compete is not protecting legitimate
business interests, and that, in any event, the former employer is not irreparably harmed by the
employee’s competitive activity.
One way to head these arguments off is to incorporate the employee’s own acknowledgment in your non-compete agreement that the agreement is, in fact, supported by valid consideration, the company has specific business interests at stake (generally, trade secrets, confidential information, and goodwill), and that the company would be irreparably harmed in the event the employee violates the terms of the agreement. Having straightforward language to this effect in a non-compete agreement can provide a neat quote for a motion for preliminary injunction seeking to enforce that agreement.

Supplement with backup agreements. So long as you’re considering the protection provided by your company’s non-compete agreement, now is also a good time to assess whether your company is availing itself of the protections provided by the array of restrictive covenants available to it, including (1) nonsolicitation agreements, which prohibit the solicitation of the company’s customers, (2) no-raid or antipiracy agreements, which bar departing employees from soliciting the company’s other employees to go work for the new employer, and (3) confidentiality agreements, which restrict an employee’s use of the company’s confidential information and trade secrets.

Even with the addition of all of these provisions to your company’s non-compete agreement, there is no guarantee of success in the courtroom in the event your company finds itself in the position of enforcing its non-compete. However, the time that you or your outside counsel devotes to making these changes will be time well spent if your company ever needs to enforce its non-compete agreement with a departing employee.

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