December 1980 was a watermark for American university technology transfer. The events of that month changed expectations about the commercialization of academic discoveries and set in motion new institutional policies and cultural changes that are still ongoing and unresolved. On December 2, 1980, the United States Patent and Trademark Office (USPTO) issued a patent to Stanford University entitled *Process for Producing Biologically Functional Chimeras* (#4237224). The patent covered the recombinant DNA (rDNA) technique developed by Dr. Stanley Cohen of Stanford University, California and Dr. Herbert Boyer of the University of California, San Francisco. At the time it was unusual for patents to be issued to a university discovery under research funded by the federal government. Indeed, the practice was for any intellectual property right to revert back to the federal government with each university able to petition the federal funding agency for permission to patent – an inefficient and cumbersome policy. But all this changed with the passage of the Bayh-Dole Act on December 12, 1980 (P.L. 96-517),¹ which granted universities ownership of intellectual property from federally funded research and obligated them to engage in practices to promote commercialization. The congressional testimony in support of the change was motivated by the perceived lack of American competitiveness and a desire to produce greater return from the significant public funding that had contributed to the prominence of American research universities. At the same time, American universities were searching for new revenue streams and ways to demonstrate their relevance.

The Cohen-Boyer commercialization program proved to be the ideal example to motivate the new technology transfer regime made possible by the passage of Bayh-Dole. By the time the Cohen-Boyer patent(s)² expired in 1997, Stanford University had received over $255 million in licensing revenues based on over $35 billion in product sales. Precisely how the Stanford University Patenting and Licensing Office was able to achieve this high rate of return is an interesting story in itself (Feldman, Colianni and Liu, 2008). The granting of 469 non-exclusive licenses created a flurry of activity but moreover conferred an advantage on startup companies that suddenly had legitimacy and a tradable asset when they signed up for the license. Certainly the widely adopted licensing program and the buzz it created helped launch the U.S. biotech industry (Feldman and Yoon, 2011).
But one major implication for American universities was the idea that there was significant revenue to be made from technology transfer. The Society of University Patent Administrators, founded in 1974 to address the concern that inventions funded by the U.S. government were not being commercialized effectively had achieved its mission. The Society changed its name to the Association of University Technology Managers (AUTM) and broadened its mission to promote technology transfer by providing a professional association for the new function. From the initial founding membership of 11 institutions, AUTM has grown into an international organization.

Over the ensuing 35 years absolutely every American Research University and even many undergraduate institutions and community colleges have created offices of technology licensing and transfer. Academics have changed their behavior to accept technology licensing (Bercovitz and Feldman, 2008). Scholars debate the desirability of these changes. For some, this new environment is key to promoting innovation and technological change and the hallmark of greater partnerships with industry and government (Etzkowitz, Leydesdorff and Geuna, 1999). To others, the emphasis on commercialization, intellectual property protection and greater engagement with industry erodes academic values, threatens the intellectual commons, and dilutes the mission of universities away from their core activities (Slaughter and Leslie, 1997). However, putting these important debates aside, this chapter will review the American experience in technology transfer by examining court cases involving university intellectual property as an interpretative lens. This litigation highlights contentious issues around technology transfer. Our analysis reveals that universities that have been more successful at technology transfer, have been at it longer, and have experienced a big hit have greater involvement with litigation. These court cases are shaping the unfolding relationships between universities, faculty members and commercial interests.

**American technology transfer through the lens of litigation**

As technology transfer has grown and become more prevalent, court cases have begun to reflect relational tensions between universities and industry, government, and other universities. There is a clear and ongoing debate over whether universities should, or even will be able to continue to legally maintain their sole status as educational organizations given their engagement with profit making activities.

Court cases affecting technology transfer at universities were found through an online keyword search of The Chronicle of Higher Education in June 2014. Articles were found from The Chronicle’s website as early as 1970. Cases were found that began as early as 1988, and some were still ongoing at the time of the search. Forty-nine court cases were discovered using keywords: lawsuit, technology transfer, university, spinout, start-up, court case, and patent. The most influential cases identified are summarized in Table 3.2. The discussion follows major themes identified in reviewing the court cases.
While there is great interest in realizing public benefit for university research the fact that universities receive licensing revenues, which they then distribute to faculty inventors fuels this debate. Lawsuits questioning the appropriateness of revenue generating activities for non-profit educational entities have become more common over time. Such cases target the tax-exempt status of universities and research exceptions provided because of their educational purpose. The tactics used by some universities in technology transfer have raised question as to whether the university is aggressive for the sake of protecting knowledge, or for the sake of protecting monetary interests.

Court cases affect technology transfer by underscoring the diligence needed by universities if they are to compete for rights with companies that often have much larger budgets to litigate sometimes decade-long lawsuits. Cases disputing the language of contracts underscore a need for universities to employ professional technology officers who have the knowledge to protect the rights of universities and their faculties. Recent cases also illustrate the impact of contractual relationships dictated by technology commercialization on university technology transfer. Broken or misunderstood contracts and stringent intellectual property policies can easily alienate universities from industry and government agencies. Court cases not specifically involving a university can even affect their ability to transfer technology. Friend-of-the-court briefs issued by universities show their awareness of such possible impacts.

March-in rights

A trend exists in technology transfer court cases involving issues of intent of the Bayh-Dole Act. Several cases have involved the petitioning of Bayh-Dole “march-in” rights by plaintiffs or defendants. If petitioned, the right allows the federal agency that funded research leading to an invention to require the invention owner grant a license to the petitioner, even if the owner has already issued an exclusive license to another entity. Four conditions involving a necessity for the public good must be met in order to invoke these rights, though (35 U.S.C. § 203).

CellPro, Inc. brought a petition for the National Institutes of Health (NIH) to invoke its march-in rights after Johns Hopkins University, Baxter Healthcare Corporation and Becton Dickinson and Company brought suit against the company in 1994 claiming patent infringement. The plaintiffs argued CellPro’s device, Ceprate, infringed on patents owned by Johns Hopkins that were exclusively licensed to Becton Dickinson, who then sold the license to Baxter. The patents covered a technique that isolates stem cells CellPro was using to treat cancer patients whose bodies were harmed by extensive radiation treatments (Blumenstyk, 1997a). The case was the result of a failed license negotiation between the parties (Blumenstyk, 1997b). CellPro argued the patents were invalid and an initial jury agreed, but a judge for the U.S. District Court for the District of Delaware overturned the verdict. The case went through another jury trial, which found that CellPro had willfully infringed and ordered the defendant to pay treble damages (Dunbar, 2001).
In 1997, CellPro petitioned National Institutes of Health (NIH), the invention’s funding agency, to require Johns Hopkins to sell CellPro a license to the patent after a judge ordered a future injunction of sales of Ceprate. NIH denied the petition a week after CellPro was ordered to pay treble damages (Blumenstyk, 1997b), stating that Baxter and Johns Hopkins were taking reasonable steps to apply the patents toward the same technique, so there was no public health need that would be cause for CellPro to have a license to them (NIH, Office of the Director 1997). The case concluded in 1998 when the U.S. Court of Appeals for the Federal Circuit upheld the jury’s decision (Johns Hopkins University et al. v. CellPro, Inc., 1998). CellPro announced in 2008 it would file for bankruptcy as a result of losing the case (Blumenstyk, 1998).

A group of patients suffering from Fabry disease brought a class action lawsuit against Mount Sinai School of Medicine and Genzyme Corporation in March 2011, accusing the defendants of negligence and violating the Bayh-Dole Act when they refused to break an exclusive licensing agreement and allow other companies to produce a medication of which Genzyme had a shortage. The drug, Fabrazyme, eased and lengthened the lives of patients who suffer from Fabry disease and was being rationed at an ineffective level to the patients due to a shortage that began two years prior. The patients sought damages from the companies for withholding a federally funded invention from the public. The suit was brought after a petition to NIH requesting it use its march-in rights was denied in December 2010. The petitioners called for NIH, who funded the drug’s research, to demand the license be extended to other companies for manufacturing. NIH denied the request stating extension of the license would not solve the shortage problem (NIH, Office of the Director, 2010). The group re-petitioned NIH to march-in in 2011 and included a request in the petition for NIH to more clearly delineate conditions under which it would invoke its march-in rights (Blumenstyk, 2011b). NIH closed the second Fabry march-in case in February 2013 without ruling on the petition after the Fabrazyme shortage ended (Carik, et al. v. U.S. DHHS, 2013). A related case began in 2012 when another group of patients sued the U.S. Department of Health and Human Services, Mount Sinai, and other federal agencies over the shortage (Carik, et al. v. U.S. DHHS, 2013). The lawsuit was dismissed in 2013 by the U.S. District Court for the District of Columbia then dismissed again on appeal in 2014 by the U.S. Court of Appeals for the Federal Circuit (Carik, et al. v. U.S. DHHS, et al. 2014).

**Challenges to tax-exempt status**

Court cases involving technology transfer are one by-product of the expansion of the role of universities to include technology transfer and commercialization. The reach, strength, and efficacy of this expanded role have been questioned in several court cases since the early 2000s. A group of property owners challenged the tax-exempt status of several Princeton University buildings in 2011, claiming the buildings made money for the university rather than serving an educational purpose. The same group also questioned Princeton’s overall tax-exempt status
because of the hundreds of millions of dollars the university receives in royalties from a patent on the anticancer drug Alimta. It then distributes these royalties to faculty members – an action the property owners also view as a business activity for the school (Blumenstyk, 2013c). A New Jersey Tax Court Judge denied Princeton’s motion to dismiss the case in June of 2013 (Offredo, 2013). As of February 2014 a court date had not been set, and the case was being settled out of court (Rappa, 2014). The outcome of this case could signal other citizens to bring similar suits against other research universities if the plaintiffs succeed in their challenge of Princeton’s tax-exempt status based on the university’s royalty profits and their subsequent distribution.

Assignment of rights

The United States Supreme Court agreed to hear a major case, the Board of Trustees of the Leland Stanford Junior University et al. v. Roche Molecular Systems Inc. et al. after it went through several rounds of appeals. In 2011 the Supreme Court decided through the case how patent rights were to be assigned when contractual agreements overlapped or contradicted. Stanford brought suit against Roche Molecular Systems in 2005 accusing the company of patent infringement on a device used to test for HIV (Huq, Goldberg, and Meagher, 2009; Kelderman, 2011). Roche held that it owned the patent in question, as well. The dispute arose because the Stanford researcher who developed the technology, Mark Holodniy, signed an agreement to assign rights of any future inventions to Stanford, and then also signed a Visitor Confidentiality Agreement at a company later acquired by Roche that assigned discovery rights to the company. The Supreme Court ruled the rights belonged to Roche because the Visitor Confidentiality Agreement was an immediate agreement while the Stanford agreement was only a promise to assign rights in the future (Huq, Goldberg, and Meagher, 2009). The major implication of this case for universities, outlined by the majority opinion, was that the Bayh-Dole Act did not automatically give them rights to the patented discoveries of their scientists; therefore, the wording of assignment agreements should be carefully articulated (Kelderman, 2011). Many universities and research institutions reached out to the Supreme Court arguing for a ruling in favor of Stanford, aware of the impact a verdict for Roche might have on their ability to argue patent rights (Blumenstyk, 2011a).

11th Amendment immunity

Universities have sought to downplay their economic activity as defendants in several technology transfer cases of the last decade. Some public universities have attempted to avoid lawsuits by claiming immunity from lawsuits under the 11th Amendment of the U.S. Constitution because of their legal status as government organizations. The 11th Amendment grants States and their agencies immunity from federal lawsuits initiated by citizens of another state. The University of Missouri claimed immunity under the 11th Amendment in a 2003 patent dispute
case brought by Vas-Cath, Inc. Vas-Cath and Missouri both argued their own scientists were the first to invent a catheter used for dialysis, but the USPTO gave the patent rights to the university. When Vas-Cath appealed this decision to the U.S. District Court for the Western District of Missouri, Western Division, the university claimed immunity. The district court granted immunity in 2005 and dismissed the case (Vas-Cath, Inc. v. Curators of the University of Missouri, et al., 2005). When Vas-Cath appealed this decision, the U.S. Court of Appeals for the Federal Circuit held that Missouri could not claim immunity and remanded the case (Vas-Cath, Inc. v. Curators of the University of Missouri, et al., 2007a). The appeals court held the university waived its constitutional immunity when it participated in a federal administrative forum by asking the USPTO to hold an interference proceeding over the disputed patent and dismissed the appeal on that basis (Blumenstyk, 2007c). The case was ultimately dismissed by the Court of Appeals of the Federal Circuit in 2008 (Vas-Cath, Inc. v. Curators of the University of Missouri, et al., 2008) after the district court, upon remand, found Vas-Cath failed to state a claim under the rules of civil procedure (Vas-Cath, Inc. v. Curators of the University of Missouri, et al., 2007b).

Eleventh Amendment immunity was also claimed in *The Regents of the University of New Mexico v. Galen D. Knight and Terence J. Scallen*. The University of New Mexico filed suit against two scientists, Knight and Scallen, who developed a cancer treatment while at the university. Though the scientists signed over rights to the treatment in 1991, they refused to update the university’s patent record in 1996. The university subsequently brought suit against the scientists and won the case, but the defendants were allowed to make counterclaims when they alleged the university had stolen their rights (Engber, 2004). The university claimed 11th Amendment immunity when subjected to the counterclaims, and the U.S. District Court for the District of New Mexico granted the immunity. On appeal the U.S. Court of Appeals for the Federal Circuit remanded the case, stating the district court incorrectly granted immunity to the university because the university had waived 11th Amendment immunity when it filed a lawsuit in federal court. On remand the district court dismissed Knight and Scallen’s counterclaims. The scientists once again appealed, but in 2004 the U.S. Court of Appeals for the Federal Circuit affirmed the lower courts decision (The Regents of the University of New Mexico v. Knight, et al., 2004). These two cases outline the confusion that can arise over patent filing issues when inventors file for similar patents at the same time. Such cases may have been influential in the creation and passage of the new first-to-file patent law.

**Experimental use exception**

Another trend in technology transfer litigation is university defenses based on special treatment rights because of their educational legal status. A case brought against Duke University depicts such a defense based on a legal exception. When former Duke professor John M.J. Madey brought suit against the university for patent infringement in 1997, Duke argued it had not infringed due to an
experimental use exception. This exception states that scientists can use patented inventions without a license if their research does not involve a business purpose (Blumenstyk, 2003). A disagreement between Madey and Duke over the operation of a research lab resulted in Duke removing Madey from his position as Principal Investigator. Following his removal Madey resigned from Duke entirely. When Duke continued to use Madey’s patented technologies in his former lab at the university, Madey sued for infringement. In 2001, the U.S. District Court for the Middle District of North Carolina granted Duke this exception and partial summary judgment. The district court held Duke had not infringed because the patented technologies were used “solely for research, academic, or experimental purposes” in line with Dukes technology transfer policies, and because Madey had not proven any commercial intent on the part of Duke (Madey v. Duke, 2001).

Madey appealed the decision to the U.S. Court of Appeals for the Federal Circuit who found the district court incorrectly applied the experimental use exception and remanded the case. The Court of Appeals stated the district court focused too heavily on Duke’s status as a non-profit when evaluating the merit of the experimental use exception, “suppressing the fact that Duke’s acts appear to be in accordance with any reasonable interpretation of Duke’s legitimate business objectives,” and ordered the District Court to apply a more narrow understanding of the exception on remand (Madey v. Duke, 2002). The U.S. Supreme Court declined to hear Duke’s appeal to evaluate the Court of Appeals finding, which kept the Court of Appeals’ narrower definition of experimental use intact. Like the Stanford case, many universities petitioned the Supreme Court on behalf of Duke, fearing the implication of such a finding for technology commercialization at private universities (Blumenstyk, 2003). As the case progressed Duke attempted a “government license” defense, stating it had a right to use the patented materials because it was using them for the government. Duke also argued that because the materials were from government-financed research the government had a license to them under Bayh-Dole. The district court denied this defense in a 2006 motion for summary judgment, stating a university could not raise such a defense on behalf of the government, unless it was “for the government with its authorization and consent,” which Duke had not proven (Madey v. Duke, 2006). Duke settled with Madey in August 2006. Terms of the settlement included returning Madey’s lab equipment (Gallagher, 2009).

**Doctrine of equivalents**

The Supreme Court ruling in Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD. (a/k/a SMC Corporation) and SMC Pneumatics, Inc. (2008), however, affirmed universities’ ability to protect patents from copycat inventors through the doctrine of equivalents. The doctrine of equivalents maintains that a patent holder may sue a competitor over a rival invention even if the competitor’s discovery is not an exact copy. Festo sued SMC Corporation in 1988 for damages and infringement on two patents for technologies used in rods used to move goods (Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD, et al., 1993).
Festo acknowledged the infringement was not literal, stating SMC Corporation’s device infringed under the doctrine of equivalents. A jury trial found SMC guilty in 1994. The U.S. Court of Appeals for the Federal Circuit upheld the decision, but the U.S. Supreme Court later took the case and remanded it to the Court of Appeals (Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD, et al., 2007). Upon rehearing, the Court of Appeals for the Federal Circuit held because the patent had been amended and made narrower before it was issued, the doctrine of equivalents did not apply and therefore SMC Corporation had not infringed (Blumenstyk, 2002c). The Supreme Court again heard the case and remanded in 2002, maintaining three exceptions existed that would allow the doctrine of equivalents to apply to an amended patent: the “equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question” (Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD, et al., 2002). The U.S. Court of Appeals for the Federal Circuit subsequently remanded the case to the district court in 2003 (Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD, et al., 2003), where a jury trial found SMC Corporation guilty of infringement based on the doctrine of equivalents. In 2005, however, a judge for the U.S. District Court of the District of Massachusetts vacated the jury’s decision holding SMC Corporation’s equivalent patent would have been foreseeable to Festo professionals, so the infringement claim was not valid (Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD, et al., 2005). The U.S. Court of Appeals for the Federal Circuit affirmed the district court’s decision in 2007 (Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD, et al., 2007) and in 2008 the Supreme Court declined to review the Appeals Court’s decision, ending the 20-year long dispute (Festo Corporation v. Shoketsu Kinzoku Kabushiki Co., LTD, et al., 2008).

Inventor rights

Dr. Renee L. Kaswan sued the University of Georgia (UGA) Research Foundation over the Foundation’s handling of a patent and license to a discovery she made that is used for Restasis eye drops. Dr. Kaswan was in the process of obtaining the patents herself when Allergan, Inc., the company the patent was licensed to, received FDA approval for the drug. The university decided not to transfer the rights to Dr. Kaswan because of the FDA approval and to let Allergan take the drug to market. Dr. Kaswan subsequently sued the Foundation and tried to have the decision invalidated when she discovered it had been made without her input. A Georgia Superior Court judge held in 2007 that the university did not have to consult with Dr. Kaswan about decisions regarding the patent. This ruling meant control of inventions patented through universities would be given entirely to the universities technology transfer managers in the Court’s jurisdiction, making the inventor’s desires legally irrelevant (Blumenstyk, 2008b). The seven-year dispute ended in a
2010 settlement in which UGA paid Kaswan $20.2 million (Shearer, 2010). Though this case did not set precedent, it could be persuasive in other courts.

**Related precedents**

Cases that do not involve universities can still have an impact on their ability to transfer technology and capitalize on its commercialization. In *MedImmune Inc. v. Genentech Inc.* the U.S. Supreme Court decided a patent’s validity could be challenged in court by an entity that had agreed to license it and was already paying royalties. After licensing a patent from Genentech and paying royalties on the patent, MedImmune tried to have Genentech’s patent invalidated in court (Blumenstyk, 2007b). The U.S. District Court for the Central District of California dismissed the case stating MedImmune did not have standing to sue. The district court based its decision on a U.S. Court of Appeals for the Federal Circuit precedent that stated, “a patent licensee in good standing could not establish a case or controversy under the Federal Constitution’s Article III with regard to the patent’s validity, enforceability, or scope.” In 2007, though, the Supreme Court overturned the precedent and remanded the case, ordering it be decided on its merits. The Supreme Court held that a licensee has standing to sue without first having to break their patent license (*MedImmune, Inc. v. Genentech, Inc. et al.*, 2008a). Several universities issued friend-of-the-court briefs arguing against such a verdict, fearing that it would prompt more companies to challenge universities’ patents, and ultimately weaken the Bayh-Dole Act (Blumenstyk, 2007b). The case settled in 2008 (*MedImmune, Inc. v. Genentech, Inc. et al.*, 2008a).

Universities may be drawn into court cases because of their relationship to the companies that license their technology. An example of this was seen in *AsymmetRx, Inc. v. Biocare Medical, LLC*. AsymmetRx sued Biocare Medical for patent infringement in 2007. When the United States District Court for the District of Massachusetts ruled in favor of Biocare in 2008 AsymmetRx appealed to the U.S. Court of Appeals for the Federal Circuit. Without resolving the merits of the case, the Appeals Court vacated the decision of the lower court and remanded. It held that AsymmetRx did not have standing to sue Biocare Medical for infringement on a discovery it licensed from Harvard University without naming Harvard a party to the suit (*AsymmetRx, Inc. v. Biocare Medical, LLC*, 2009). The Appeals Court stated Harvard could, however, bring suit against Biocare Medical without naming AsymmetRx a party. The discrepancy was due to the language of the licensing agreement (Huq, Goldberg, and Meagher, 2009). The court held that Harvard had not granted AsymmetRx all substantial rights, which would have allowed the company to sue independently (*AsymmetRx, Inc. v. Biocare Medical, LLC*, 2009). Harvard later joined AsymmetRx in arbitration against Biocare Medical (*AsymmetRx, Inc., et al. v. Biocare Medical, LLC*, 2010).

Universities were indirectly involved in two other cases found through The Chronicle search. Research Corporation Technologies (RCT) sued several companies, including Microsoft in 2001, for patent infringement. The University of Rochester became involved in the case because it owned the invention RCT
commercialized and licensed to other companies (Blumenstyk, 2006a). The University of Utah was indirectly involved in *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al.* (2013). The plaintiff claimed three gene patents used to detect certain cancers that were owned by the university and licensed to Myriad Genetics were invalid (Blumenstyk, 2013b). The U.S. Supreme Court ruled in favor of the plaintiffs in 2013, holding “A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated” (Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al., 2013).

**Patent infringement and license disputes**

Court cases involving allegations of patent infringement and/or fraud constitute the majority of cases affecting technology transfer and appear the earliest out of the cases found from The Chronicle search. Universities regularly make such claims in suits against companies and/or individuals. Companies and/or individuals also make such claims against universities, though this trend is to be less common. Most patent infringement cases are concluded without the broad implications on technology transfer of the cases outlined previously. Still, the large number of cases universities have been involved in, and the monetary and temporal costs of them, has implications for universities and their ability to effectively commercialize technology.

**Major cases**

The rulings of some patent infringement and patent validity cases carry broad implications and are outlined in Table 3.2. In 2002, Ariad Pharmaceuticals, Inc., the Massachusetts Institute of Technology, the Whitehead Institute for Biomedical Research and Harvard College sued Eli Lilly and Company for patent infringement. The biomedical patent under question was owned by Harvard and the Whitehead Institute and exclusively licensed to Ariad (Blumenstyk, 2010c). A jury found Eli Lilly guilty of infringement in 2006, but in 2010 the U.S. Court of Appeals of the Federal Circuit reversed the verdict and declared Ariad’s patent invalid because it did not fulfill the written description requirement (Ariad Pharmaceuticals et al. v. Eli Lilly and Company, 2010) and therefore was too broad (Blumenstyk, 2010c). According to USPTO, “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention” (USPTO, 2014a). The written description requirement has been the subject of much recent debate. Both parties of the Ariad v. Lilly case proffered different interpretations of the requirement. Ariad claimed the district court erred when it interpreted the written requirement being separate from the enablement requirement, but the Court of Appeals affirmed the distinction in Lilly’s favor (Ariad Pharmaceuticals et al. v. Eli Lilly and Company, 2010). The enablement requirement states a patent claim must describe how to make and use
the technology to be patented (USPTO, 2014b). The overturned decision was a great upset to the plaintiffs and many others who believed the narrow understanding of the written description requirement used in the court’s decision could make it more difficult for universities to patent basic research (Blumenstyk, 2010c).

Patent validity is often brought into question in patent infringement cases as part of a defense. WARF endured considerable criticism during the 2000s because of its strict policies regarding the use of its patents on stem cell lines. The criticism was due to the fact that five of the 21 stem cells lines scientists could conduct research on during the George W. Bush Administration were patented to WARF. WARF aggressively protected its right to the patents, causing many organizations to criticize the Foundation and claim they impeded research progression (Blumenstyk, 2006c). Consumer Watchdog (formerly the Foundation for Taxpayer and Consumer Rights) challenged the patents’ validity in court in 2006 by requesting inter parties reexamination of the patent (Consumer Watchdog v. Wisconsin Alumni Research Foundation, 2014). The organization argued the patents should not have been granted because the discoveries were too broad to be patent eligible (Blumenstyk, 2006c). The Patent Trial and Appeal Board disagreed with Consumer Watchdog, though, and affirmed the validity of WARF’s patents. In 2014 and after several prior rounds of appeals (Basken, 2013a), the U.S. Court of Appeals for the Federal Circuit dismissed Consumer Watchdog’s appeal of the Board’s decision. The Court of Appeals held Consumer Watchdog ineligible to sue because the organization could not establish an injury in fact since it was not involved in stem cell research or commerce and was not a competitor of either WARF or WARF’s licensee (Consumer Watchdog v. Wisconsin Alumni Research Foundation, 2014). Whether the Court of Appeals would have upheld the patent is unknown, as the case was dismissed before trial.

The Regents of the University of California filed a lawsuit against Genentech Inc. in 1990 for patent infringement on a discovery used in the company’s human-growth hormone drug Protropin (Van Der Werf and Blumenstyk, 1999). Genentech countered arguing the patent was invalid. Though the jury trial held the patent was valid, it deadlocked over the case in June of 1999. A new trial was scheduled to begin in 2000 (Blumenstyk, 1999a), but the two parties reached a $200 million settlement in 1999 before the new trial began. The university had spent approximately $20 to $25 million on the case (Van Der Werf and Blumenstyk, 1999). Besides the enormous litigation costs, the case is illustrative of the longevity of some technology transfer disputes. The dispute began in 1978 when a Genentech scientist stole DNA from the university. Genentech acknowledged the theft and paid $2 million to the university in compensation in 1979, but many believe the DNA was used to invent Protropin. Genentech and the University of California stated the settlement was not an admission of guilt of patent infringement or guilt of the use of the stolen DNA for Protropin by Genentech (Van Der Werf and Blumenstyk, 1999).
Other litigation against universities

Onconome Inc. filed a lawsuit in 2009 against a researcher, Robert H. Getzenberg and the university that employed him during the time Onconome funded over $13 million of Getzenberg’s research. The company accused the defendants of fraud and breach of contract and sought damages including money the company spent on licenses to commercialize Getzenberg’s technology (Onconome, Inc. v. University of Pittsburgh et al., 2009; Blumenstyk, 2009b). Eli Lilly and the University of California have traded roles in several legal disputes. In 1993, Eli Lilly filed suit claiming the university breached an exclusive license contract when it invited other companies to seek licenses for the same patent (Blumenstyk, 1993). In 2003 several companies, including Biogen Idec, Genentech, and Genzyme, sued Columbia University accusing the university of seeking a patent for a technique the university already had an expired patent for, in an attempt to continue receiving royalties. The case resulted in several settlements. Though Columbia was able to keep its patent, it agreed not to enforce it against the companies (Blumenstyk, 2004c; Blumenstyk, 2005b).

Other litigation brought by universities

Most litigation is seen in cases where the university accuses a company, organization, or other university of patent infringement. These cases can take years to conclude, some lasting well over a decade. The longevity brings enormous litigation costs. University of Colorado Health Sciences Center v. Wyeth Pharmaceuticals (2004) lasted over 11 years. It began in 1993 when the Center brought suit against American Cyanamid (later acquired by Wyeth) for patent infringement. The university eventually won the case and $58 million in damages (Blumenstyk, 2004b).

Universities sometimes sue individuals directly over technology transfer disputes. In West Virginia University v. Kurt L. VanVoorhies, the university won rights to an invention VanVoorhies started working on when he was a graduate student at the university. VanVoorhies argued the university should not have rights to the invention because it was not complete until after he left the university. In a similar case, the University of New Mexico eventually dropped a lawsuit against former researcher Jonathan S. Nimitz for rights to discoveries Nimitz made after he left the university. The discoveries were variations on a compound he invented at the university (Blumenstyk, 2002b).

The University of Alabama at Huntsville sued Milton Harris for patent infringement after he made money from an invention he patented and spun-out while at the university. The university won the case. Harris paid damages and the university agreed not to continue with the patent claim (Burd, 2006). St. Johns University began a lawsuit against a former professor and graduate student, claiming they formed a company that profited from research they conducted while at the university without granting the university the monetary compensation it was owed (Blumenstyk, 2010d). WARF has also been involved in several lawsuits
against companies: a 2001 license dispute lawsuit against Geron Corporation (Blumenstyk, 2006c); a 2003 patent infringement lawsuit against Sony and Toshiba (Blumenstyk, 2004a); and a 2006 patent infringement case against Arkopharma, LLC (Blumenstyk, 2006b). These types of court cases are not only an occurrence of the past decade. The University of Pennsylvania and University of Houston System filed lawsuits against an emeritus faculty member over patent infringement and former faculty member over failure to alert of an invention, respectively, almost 25 years ago (Grassmuck, 1990).

Other patent validity cases

Microsoft used a patent validity defense in 2003 when the University of California accused it of infringing on a web-browser technology patent. The USPTO affirmed the validity of the patents after Microsoft appealed the district court’s decision awarding the university $521 million. The USPTO later reopened the investigation and the case was eventually settled in 2007 (Foster, 2007; Read, 2007). Pfizer Inc. raised the same defense when it was sued by the University of Rochester for patent infringement, but won the case. The U.S. Court of Appeals for the Federal Circuit affirmed the decision, and the U.S. Supreme Court declined to hear another appeal from Rochester (Blumenstyk, 2004d). In another case, the University of Minnesota and two of its researchers brought suit against Glaxo Wellcome claiming patent infringement. A patent validity defense was used and the case settled out of court (Blumenstyk, 1999b).

Litigation settlements

Most patent infringement cases brought by universities against companies ended in out-of-court settlements or orders to pay damages and/or future royalties. The University of Texas sued Research in Motion and settled for $1.8 million in 2005. Georgetown University sued Digene Corporation for patent-infringement and settled for $7.5 million with continued royalty payments in 2005 (Mangan, 2005). Emory University settled a six-year long dispute with GlaxoSmithKline and Shire Pharmaceuticals Group in 2002 over the rights to three anti-AIDS drugs. Emory received a monetary settlement and each party obtained licenses to the others’ patents. The settlement also finalized the ending of a dispute over another patent that began in a lawsuit against GlaxoSmithKline’s predecessor Glaxo Wellcome, even though the suit settled in 1999 (Borrego, 2002). Marvell Technology Group was found guilty of willful infringement on a patent owned by Carnegie Mellon University and ordered to pay $1.54 billion in damages to the university (DeSantis, 2014). Approximately seven other similar patent infringement or licensing dispute cases were found through the Chronicle search. These include: suits initiated by Cornell University and the Massachusetts Institute of Technology against separate defendants in 2002 (Blumenstyk, 2002a); a suit filed by the Washington Research Foundation against three cellphone manufacturers for patent infringement on Bluetooth technology in 2006 (Blumenstyk, 2007a); a suit Northeastern University
and Jarg Corporation filed against Google in 2007 (Huckabee, 2007); a suit filed by Iowa State University against several companies in the early 1990s concerning technology used in facsimile machines (J.L.N., 1992); and a suit the University of Michigan brought against Learjet Corporation (Grassmuck, 1990).

Unintended consequences of litigation

Lawsuits involving technology transfer disputes can have surprising consequences. Micron Technology imposed a hiring ban on the University of Illinois-Champaign’s students and suspended other activities with the university after the university brought suit against Micron for patent infringement. The university responded by asking the judge in the case for an injunction based on coercion, but the judge denied the request (Blumenstyk, 2013a). The University of Kansas sued NIH and Millennium Pharmaceuticals to add two inventors from the university to a patent. The patent only had a scientist from Millennium listed as inventor at the time. The university won the case in 2012 and added its scientists to the patent (Biemiller, 2012), thereby likely gaining more control over the patent, its licensing, and revenues. It is possible though, that filing suit against NIH may have harmed its important relationship with the funding organization (Blumenstyk, 2008c).

Other court cases

Some legal disputes over inventions arise when researchers change jobs and move to a new company or university. Florida State University accused American BioScience of stealing the inventions of a university researcher by hiring one of the researcher’s postdoctoral students. Though a lower court ruled in favor of Florida State, the U.S. Court of Appeals for the Federal Circuit overturned the ruling and ordered the patents on inventions of the postdoctoral student be assigned to American BioScience. The company did, however, pay to settle claims that it stole trade secrets (“Despite Ruling”, 2003).

Court cases show universities strongly assert their rights to inventions. One case resulted in a three and a half year prison sentence for the defendant, Petr Taborsky, in 1993 after he refused to turn over a patent to the University of South Florida on a discovery he made there as a student (Nicklin, 1993). Also in the early 1990s, the University of Minnesota sued a current professor, a former professor and three companies owned by the defendants and their families in an effort to recover alleged lost royalties and “diverted research-contract income” (Blumenstyk, 1992). A 2003 suit the Purdue Research Foundation and Cook Biotech brought against Stephen Badylak and ACell Inc. raised concerns about Purdue’s actions. The plaintiffs accused former Purdue scientist Stephen F. Badylak of stealing research data from the university and helping a collaborator invent and patent a technology that became the basis for the ACell Inc. ACell is a competitor of a company, Cook Biotech, which Purdue had an ownership stake in. The case against Badylak was dismissed before it reached trial. ACell claimed the accusations were false, and the U.S. Court of
Appeals for the Federal Circuit sided with the defendant in 2006, holding ACell not guilty (Blumenstyk, 2007e).

**University technology transfer litigation best practices**

Universities are interested in safeguarding their economic interests. The commonly seen seven figure royalties licenses brought to universities have certainly increased their interest in economic self-preservation and prosperity. The court cases found through a search of The Chronicle of Higher Education illustrate a dilemma universities face. Universities must delicately balance the public interest with their own interest in insured longevity. The array of court cases impacting technology transfer and the recurring themes of the disputes highlight a lack of solidarity among universities with regard to how to best approach technology transfer litigation.

More proactively, university technology transfer offices (TTOs) have tried self-governance. Eleven universities collaborated in 2006 to produce a set of suggested guidelines, or best practices, for universities facing or considering technology transfer litigation. The guidelines are outlined in the white paper “In the Public Interest: Nine Points to Consider in Licensing University Technology” (Blumenstyk, 2007d) and were endorsed by the Association of University Technology Managers (AUTM) (AUTM, 2014). They include suggestions for limiting lawsuits to those only absolutely necessary, avoiding licensing to patent trolls (companies which aggregate patents for the purpose of future litigation), offering fewer exclusive licenses, and taking special concern over the language of contracts (Blumenstyk, 2007d). As of July 2014 over 100 universities and

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**Figure 3.1** Cumulative number of technology transfer programs founded by year
institutions had endorsed the principles (AUTM, 2014). In 2013, however, AUTM began to reexamine its stance against patent aggregators as some argue aspects of aggregation may actually bring commercialization to more technologies (Basken, 2013b).

**Relationship of litigation to university operations**

Certainly litigation appears to have some relationship to university operations. The Wisconsin Alumni Research Foundation (WARF), founded in 1925 is the oldest university TTO in the United States and in 1968 was the first university to own the rights to patents of federally financed inventions. WARF frequently litigates and has a large enough endowment to bring lawsuits against any organization it feels may be infringing on its rights (Blumenstyk, 2006c). Of the 49 cases that were the subject of articles in *The Chronicle of Higher Education*, WARF was involved in four.

Several important trends in technology transfer licensing revenue, program age, and legal dispute involvement at American universities can be observed through data from AUTM’s annual voluntary licensing survey. The majority of TTOs at universities were established after the Bayh-Dole Act. Figure 3.1 outlines the trend in program start dates. The year 1985 witnessed the most activity with the initiation of 15 programs. Office establishment tapered off by the early 2000s.

University license revenue has generally trended upwards, as shown in Figure 3.2. A sharp decline in total revenue occurred from 2008 to 2009, which may be attributed to the global recession. Total annual revenue and maximum annual revenue tend to follow the same trajectory, meaning the years with the highest

![Figure 3.2 License revenue by year](image-url)
maximum annual revenues tend to have proportionally high total annual revenues. The highest total revenue occurred in 2008, the same year the highest maximum revenue was attained. Northwestern University achieved the highest revenue in 2008, likely due to the December 2007 sale of a portion of its rights to the drug Lyrica (Blumenstyk, 2010a). Similarly, another unusually high total revenue occurred in 2005, due to the license revenue Emory University received for its sale of its future rights to two anti-AIDS drugs (Blumenstyk, 2005a).

A comparison of technology transfer program start dates, court cases, license revenue, and technology blockbusters provides a perspective on technology transfer trends in the U.S. University technology blockbusters, or “big hits,” are defined as those technologies that bring in licensing or other revenues much higher than the average license revenues attained by the particular university. Such blockbusters have the potential to inflate universities’ total revenue. Big hits were identified through a search of articles in the Chronicle of Higher Education. Because AUTM includes revenues from lawsuit settlements and equity sales in its overall license revenue category, such “blockbuster” settlements were included in the results. For example, Northwestern University’s sale of equity in a startup company is an example of such a big hit that is a one time event.

Table 3.1 Revenue, blockbuster, legal dispute and program age correlations

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Of the 23 universities with cumulative license revenue greater than $200 million:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>had at least one blockbuster</td>
<td>52.17%</td>
<td>12</td>
</tr>
<tr>
<td>were involved in at least one legal dispute</td>
<td>60.87%</td>
<td>14</td>
</tr>
<tr>
<td>had technology transfer offices/programs created before 1980</td>
<td>60.87%</td>
<td>14</td>
</tr>
<tr>
<td>Of the 26 universities with at least one blockbuster:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>were involved in at least one legal dispute</td>
<td>46.15%</td>
<td>12</td>
</tr>
<tr>
<td>had cumulative license revenue greater than $200 million</td>
<td>46.15%</td>
<td>12</td>
</tr>
<tr>
<td>had technology transfer offices/programs created before 1980</td>
<td>38.46%</td>
<td>10</td>
</tr>
<tr>
<td>Of the 35 universities involved in at least one legal dispute:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>had at least one blockbuster</td>
<td>34.29%</td>
<td>12</td>
</tr>
<tr>
<td>had cumulative license revenue greater than $200 million</td>
<td>40.00%</td>
<td>14</td>
</tr>
<tr>
<td>had technology transfer offices/programs created before 1980</td>
<td>45.71%</td>
<td>16</td>
</tr>
<tr>
<td>Of the 30 universities with technology transfer offices/programs created before 1980:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>had at least one blockbuster</td>
<td>33.33%</td>
<td>10</td>
</tr>
<tr>
<td>were involved in at least one legal dispute</td>
<td>53.33%</td>
<td>16</td>
</tr>
<tr>
<td>had cumulative license revenue greater than $200 million</td>
<td>46.67%</td>
<td></td>
</tr>
</tbody>
</table>

Our findings indicated that of the 23 AUTM member universities with cumulative license revenue greater than $200 million, 52.17% of the universities had at least one blockbuster, 60.87% were involved in at least one court case, and 60.87% established TTOs or programs before 1980. These results depict a correlation between higher technology transfer licensing revenue, office or program age, blockbuster revenue earnings, and court case involvement. They suggest that the older and more successful a TTO is (when judged by cumulative revenue), the more likely that office will be to engage in a technology transfer legal dispute, and the more likely that office is to have attained its higher cumulative revenue due to one blockbuster license or settlement. Table 3.1 outlines the relationship between these variables.

These general trends can mask the fact that most universities net a loss in their technology transfer activities. A simple calculation of net revenue that subtracts total FTEs costs and total new patent filing costs found that of the 228 universities in the AUTM database for the years 1991 to 2012, where data was available, only 24.94 percent of the universities saw a net profit in any given year, with 76.02 percent incurring a loss in any given year. The universities that received the highest net profits out of the data for any given year were those described previously as the more litigious with the most blockbusters. The University of California System was found to have had some of the largest profits, as well as some of the largest losses in various years. Other than the California System, though, no university with one the highest net profits also had one of the largest net losses.

Table 3.2 Court cases

<table>
<thead>
<tr>
<th>Case</th>
<th>Issue</th>
<th>Date Initiated</th>
<th>Date of Final Adjudication or Appeal (Jurisdiction)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case</td>
<td>Issue</td>
<td>Date Initiated</td>
<td>Date of Final Adjudication or Appeal (Jurisdiction)</td>
<td>Reference</td>
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<tr>
<td>Estate of Lewis, et. al. v. Princeton University and Borough of Princeton</td>
<td>Tax-exempt status</td>
<td>April 2011</td>
<td>Ongoing (Tax Court of New Jersey)</td>
<td>Blumenstyk, 2013c; Mulvaney, 2014; Rappa, 2014</td>
</tr>
</tbody>
</table>

Table 3.2 continued
### Table 3.2 continued

<table>
<thead>
<tr>
<th>Case</th>
<th>Issue</th>
<th>Date Initiated</th>
<th>Date of Final Adjudication or Appeal (Jurisdiction)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case</td>
<td>Issue</td>
<td>Date Initiated</td>
<td>Date of Final Adjudication or Appeal (Jurisdiction)</td>
<td>Reference</td>
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<tr>
<td>----------------------------------------------------------------------</td>
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</tr>
<tr>
<td>The Regents of the University of New Mexico v. Galen D. Knight and Terence J. Scallen</td>
<td>11th Amendment immunity</td>
<td>May 21, 1999</td>
<td>November 4, 2004 (U.S. Court of Appeals, Federal Circuit)</td>
<td>Engber, 2004; The Regents of the University of New Mexico v. Knight, et al., 2003; The Regents of the University of New Mexico v. Knight, et al., 2004</td>
</tr>
</tbody>
</table>

Source: Compiled by the authors from sources in the Reference column of Table 3.2.
Conclusion

Data findings question the effectiveness of the United States model of university technology transfer and the way success in such a model is measured. Though many universities have been able to capitalize on the available monetary gains of active participation in technology commercialization, success has more often than not brought with it financial losses in terms of legal fees and licensing costs. Furthermore, blockbuster inventions are not the norm. As our findings and previous articles (Breznitz and Feldman, 2012; Feldman et al., 2002) indicate, most university technology transfer programs net a loss.

An overview of U.S. university technology transfer from a legal perspective, in conjunction with available data, outlines the ongoing debate over the merit of federal legislation like Bayh-Dole and other initiatives meant to promote university technology transfer. Several authors view Bayh-Dole critically, arguing the Act has had a detrimental effect (Sampat 2006; So et. al. 2008). Others continue to espouse its economic and innovation benefits. The overwhelming majority of universities incurring a loss from technology transfer activities lend credence to the idea that the current U.S. system needs revision. The costs of litigation concurrent with earning large profits bolster the argument that universities should carefully consider their strengths and weaknesses before devoted large numbers of resources to technology transfer. Still, the publicized profits gained by universities from blockbuster inventions or settlements may make pursuing commercialization at least monetarily worth its risk. But monetary risk does not address the issue of whether universities have stepped beyond their bounds of education and public service to behaving more like profit centered corporations. The arguments in favor and against this expanded role are unlikely to be resolved easily.

Technology licensing in the U.S. despite its problems most certainly will continue and evolve. Litigation is useful as a lens for understanding how the system is evolving, as future court cases are likely to determine the organizational configuration. The early gold rush that prevailed after the passage of Bayh-Dole is being tempered and technology transfer is beginning to look more like a routine function and an outlet for the greater public good.

Notes

1 For a summary of the Bayh-Dole Act, see www.autm.net/Bayh_Dole_Act1.htm.
2 The original patent application was split into three patents.

References


