MONETIZE VS. INCENTIVIZE: CONTRACTING FOR HEALTH CARE INNOVATION

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INTRODUCTION

Innovation is driven to a remarkable extent by principles of contracting.1 Rather than rejecting formal legal entanglements in a fast-

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paced innovation environment, parties who thrive through intellectual property creation and expansion are embracing the certainty of contracts as a means of capturing their investment.\(^2\) This is nowhere more evident than in the health care industry, where innovation is highly valued and capturing investment is required to compete.\(^3\) In this industry, the new world of technology-driven innovation and the old world of strict formal legal documents unite in the hopes of capturing the process, technology, or system that will prove to be the competitive advantage.

This relationship between contract and innovation is the source of extensive academic discussion.\(^4\) Contracts are recognized today as the best means for interaction among parties without an established relationship but, even more so, for minimizing the uncertainties that are the very nature of innovation.\(^5\) Contract law consistently evolves to accommodate the needs of firms; this has implications not only for the firms, but the individuals the firms target as the “inputs of innovation.”\(^6\)

The health care industry presents a particularly unique innovation environment in which to consider the use of contracts to drive innovation by employees. As intellectual property rights are increasingly valued as assets to monetize,\(^7\) the contracts developed for creation of these assets

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2. Erin O’Hara O’Connor & Christopher R. Drahozal, The Essential Role of Courts for Supporting Innovation, 92 Tex. L. Rev. 2177, 2178 (2014) (stating that “parties to innovative contracts and those operating in innovative environments rely much more heavily on lawyers and contract documents than do their counterparts in non-innovative environments”).

3. See infra Part II.

4. See infra Part I.

5. Gilson, Sabel & Scott, Novel Contractual Forms, supra note 1, at 180-81 (summarizing the high levels of uncertainty and resulting contractual response to cascading innovations following the exogenous shock of “the information revolution”).

6. Lobel, supra note 1, at 790 (describing the “inputs of innovation” as “skills, experience, know-how, professional relationships, creativity, and entrepreneurial energies” and noting that these are now “subject to control and propertization”). See generally Larry A. DiMatteo, Strategic Contracting: Contract Law as a Source of Competitive Advantage, 47 Am. Bus. L.J. 727, 772-79 (2010) (discussing contracting for innovation and contracts as governance structures). See also infra Part I.A.

7. Baldia, supra note 1, at 20-21 (stating that “[f]irms can no longer afford to ignore potential return on R&D investment from internally developed, but unused, IP. Rather, they must actively exchange such IP with third parties better situated to develop and
must incentivize employees who are drivers of innovation.\footnote{But see Mark A. Lemley, \textit{IP in a World Without Scarcity}, 90 N.Y.U. L. Rev. 460, 492 (2015) (asserting that it is possible that “IP theory is wrong about what motivates people to create”).} This article examines the current health care industry’s strategic contracting regime of invention assignment agreements designed to promote innovation through human capital and posits whether the regime incentivizes innovation.

Understanding innovation and, in particular, what motivates innovation in the health care sector, is increasingly important.\footnote{See infra Part IV.} A major development utilized by firms to promote innovation is to capture knowledge of employees at all levels. Capturing knowledge and asserting rights to employee-created ideas is a trend increasingly recognized by legal scholars.\footnote{See, e.g., Andres Sawicki, \textit{Buying Teams}, 38 Seattle U. L. Rev. 651, 665 (2015) (discussing the use of invention assignment agreements by start-up firms); Lobel, \textit{supra} note 1, at 790 (stating that “[t]he new cognitive property has emerged under the radar, commodifying intellectual intangibles that have traditionally been kept outside of the scope of intellectual property”).} For example, firms in the United States employing engineers and scientists require these employees or agents, nearly universally, to assign their inventions to their employer.\footnote{Parker Howell, \textit{Whose Invention Is It Anyway? Employee Invention-Assignment Agreements and Their Limits}, 8 Wash J.L. Tech. & Arts 79, 80 (2012) (discussing intellectual property right assignments in America).} Such assignments reflect the beliefs that innovation should come from all employees at all times and that the organization “owns” any such innovation produced by their employees.\footnote{Julian Birkinshaw, Cyril Bouquet, & J.L. Barsoux, \textit{The 5 Myths of Innovation}, 52 MIT Sloan Mgmt. Rev. 43, 43 (2011) (stating that “the new imperative is to view innovation as an all the time, everywhere capability”). But see Baldia, \textit{supra} note 1, at 20 (distinguishing between “open access innovation” (OAI) which promotes free access and use of IP and “open business innovation” (OBI), in which the outputs are privately controlled and managed).} That same phenomenon is now occurring in the medical field, as the proportion of physicians employed by hospital systems increases to respond to the difficult provider market.\footnote{See infra Part II.} As the health care industry undergoes the exogenous shock of new regulations and technological changes as part of the information revolution, is it responding in a way that will promote innovation? A key question for health care providers in remaining competitive in an increasingly challenging market is how to maximize knowledge ownership, in particular, the potential for “human capital.”\footnote{Lobel, \textit{supra} note 1, at 790 (introducing the “growing field of human capital law”).} In the health care industry this issue combines commercialize it through various models, . . . which can lead to increased technology development.”).
intellectual property — primarily patent law — the Bayh-Dole Act,\textsuperscript{15} common law, and contract law, with some important underlying employment considerations.\textsuperscript{16}

This article examines contracting for innovation in the context of a highly regulated industry. Part I presents the two prevailing theories concerning the consequences of contracting for innovation in a dynamic marketplace: taming uncertainty or constraining human capital. Part II surveys the health care industry and the changes in incentives for innovation, including the Affordable Care Act.\textsuperscript{17} Part III then explores intellectual property created by agents and employees, and changes in patent law stemming from the passage of the Leahy-Smith America Invents Act.\textsuperscript{18} Part III highlights the Bayh-Dole Act’s crucial role in transforming innovation in research and teaching hospitals and discusses the renewed importance of invention assignment agreements and contract law following the U.S. Supreme Court’s decision in \textit{Stanford v. Roche}.\textsuperscript{19}

Part IV further examines contracting for human capital in the context of research and teaching hospitals. Are effective assignment agreements vital in protecting innovation and containing health care costs? Do such agreements strike the best balance in motivating innovation or does the current trend value short-term monetization of intellectual property over long-term innovation? This article concludes with a cautionary note regarding the use of assignment agreements to promote innovation by employees and agents whose primary responsibility is delivering health care and a proposal for limiting the practice to promote physician engagement in the process of innovation. In a quickly evolving industry, strategies motivated more by monetizing intellectual property assets over collaborative engagement with innovators may prove to limit the strategic advantages of contracting for innovation.

\textit{See also} Norman D. Bishara & David Orozco, \textit{Using the Resource-Based Theory to Determine Covenant Not to Compete Legitimacy}, 87 Ind. L.J. 979, 982 (2012) (constructing employee-employer contracting as a “knowledge ownership dispute”).


\textsuperscript{16} Lobel, supra note 1, 790 (describing human capital law at the “intersections of IP law, contract and employment law, and antitrust law”).


\textsuperscript{19} Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., 131 S. Ct. 2188 (2011).
I. CONTRACTING FOR INNOVATION AND COLLABORATION

Innovation is a process rather than a singular outcome, product, or event.\textsuperscript{20} As the process is continuous in the most advanced innovation environments, the structures to support innovation must be similarly evolving and flexible.\textsuperscript{21} Contracts are the tool that best matches the process necessary for innovation.\textsuperscript{22} When parties focus on strategic networking to create efficiencies in innovation, contracts evolve.\textsuperscript{23} The result may be the promotion of interaction between the parties, thereby permitting extensive collaboration.\textsuperscript{24} However, in the context of agent-or-employee–created innovation, evolving contract law may undermine the balance developed by intellectual property law.\textsuperscript{25} This section examines the promise of contract law in innovation and the emerging problem presented by contracting for knowledge ownership.

A. The Promise: Taming Uncertainty Through Contract

At the firm level, uncertainty is now the goal of innovation rather than the bane.\textsuperscript{26} Legal theorists, who seek to understand the information age economy and its priority on constant innovation, note that the stability achieved through vertical integration in the industrial-age economy is no

\textsuperscript{20} Although there is not singular agreement around how best to characterize innovation. See, e.g., Keith Sawyer, The Collaborative Nature of Innovation, 30 WASH. U. J.L. & Pol’y 293, 296-97 (2009) (explaining that “I define ‘innovation’ as the emergence of a viable product or service that has an impact on the world, in contrast to ‘creativity,’ which I define as the generation of new, useful, and nonobvious ideas”); Brett Frischmann, Innovation and Institutions, 24 Vt. L. Rev. 347, 357 (2000) (stating that “[a]n innovation is a pure public good that can be directly consumed or used as an input into the production of another good”).

\textsuperscript{21} See Gilson, Sabel & Scott, Vertical Disintegration, supra note 1, at 441 (stating that due to “the profusion of new technological possibilities...innovations cascaded, often leading to improvement cycles that became self-perpetuating”).

\textsuperscript{22} See DiMatteo, supra note 6, at 735 (stating that “[c]ontract is the most flexible, strategic tool that the law offers to the business community”).

\textsuperscript{23} See Mark A. Lemley, Contracting Around Liability Rules, 100 CALIF. L. REV. 463, 470-83 (2012) (discussing that parties can use contract law to avoid inefficient liability rules).

\textsuperscript{24} See Peter Lee, Social Innovation, 92 WASH. U. L. REV. 1, 66-67 (2015) (arguing for a more holistic approach to innovation that accounts for the “deeply communal” nature of the innovation process).

\textsuperscript{25} See, e.g., Lobel, supra note 1, at 799-800 (describing the abstract-concrete and idea-expression distinctions as “the heart of the bargain struck in IP”).

\textsuperscript{26} Gilson, Sabel & Scott, Vertical Disintegration, supra note 1, at 441-42. See also Lemley, supra note 8, at 465 (“We need a post-scarcity economics, one that accepts rather than resists the new opportunities technology will offer us. Developing that economics is the great task of the twenty-first century.”).
longer the goal of innovative firms.\textsuperscript{27} Innovative firms value the uncertainty that is a natural consequence of pushing past incumbent technology and systems to consider the next disruptive technology that will reshape the market.\textsuperscript{28} There are multiple theories on the basis of “the information revolution,”\textsuperscript{29} but the key developments are perhaps best summed up by “globalization, technology, and entrepreneurship.”\textsuperscript{30} Whereas in the industrial-age economy assets of interest were the machines or other tangible property, in the information age economy, assets of interest are intangible assets, such as patent rights and other intellectual property.\textsuperscript{31}

Observing contracting in this environment, legal theorists note that a firm’s move toward embracing constant uncertainty likewise changed the private governance structures created through contract.\textsuperscript{32} In an innovative environment, collaborative conditions and sharing of information leads to efficient “flow between the firm’s internal innovation process and an external environment populated by clients, suppliers, competitors, government and private research institutions, or other businesses.”\textsuperscript{33} As Gilson, Sabel, & Scott note in their work on contracting for innovation, the firms create contracts to promote this flow of information based on unknown and unknowable terms.\textsuperscript{34} The lack of certain specific contract terms does not hinder parties from developing the necessary governance structure to create contracts that permit information flow that promote

\textsuperscript{27} Gilson, Sabel & Scott, \textit{Vertical Disintegration}, supra note 1, at 442 (explaining that “[i]n the heyday of vertical integration, incumbency was the goal, allowing firms to see over the horizon of technical development and providing, through economies of scale, the means to realize the possibilities they saw. Now incumbency is seen as a burden, proficiency with current technologies obstructing the view of future directions.”).

\textsuperscript{28} \textit{Id.} at 442. \textit{See also} Baldia, supra note 1, at 20 (stating that “[f]undamentally, [open business innovation] allows firms to build and rely on global networks or eco-systems of innovation to intake new ideas, develop new products and services, leverage new and existing IP core to such products and services, and keep pace with R&D in competitive global markets”).

\textsuperscript{29} Gilson, Sabel & Scott, \textit{Novel Contractual Forms}, supra note 1, at 180; Gilson, Sabel & Scott, \textit{Vertical Disintegration}, supra note 1, at 441-42.


\textsuperscript{31} Sawicki, supra note 10, at 683.

\textsuperscript{32} DiMatteo, supra note 6, at 775.

\textsuperscript{33} Baldia, supra note 1, at 15 (dubbed the “innovation ecosystems”).

\textsuperscript{34} Gilson, Sabel & Scott, \textit{Vertical Disintegration}, supra note 1, at 473. \textit{See also id.} at 452 (explaining that “when the level of uncertainty is high, contracts will be incomplete because it simply costs too much (or may be impossible) for contracting parties to foresee and then describe appropriately the contractual outcomes for all (or even most) of the possible future states of the world that might materialize”).
constant innovation;\textsuperscript{35} rather the uncertainty of specific terms is just a part of the uncertainty embraced in innovation environments. The parties create a governance system through contract that allows for a "rich braiding of formal and informal terms that deters opportunism during the collaborative/learning phase of the contract."\textsuperscript{36}

The important goal of such "braided" contracts is the promotion of the collaborative environment that is necessary for innovation to enhance efficiency and to offer market advantages.\textsuperscript{37} The nature of innovation today is "a highly interactive, multi-disciplinary process that involves cooperation among a growing and diverse network of organizations and individuals across national borders."\textsuperscript{38} Rather than focus on definitive rights — what contract law and other legal provisions brought to the industrial–age firms — the innovation required in the information–age economy focuses on contracts that allow sustained interactions for collaboration.\textsuperscript{39}

B. The Problem: Constraining Human Capital

The promise of contracting for innovation at the firm level looks very different from the agent or employee viewpoint. Legal scholars viewing contracting in the information age at the employee/agent level offer a different perspective on the means by which firms create sustained interactions for collaboration: constraint of human capital. From this perspective, firms have not embraced uncertainty necessarily; instead, they have limited uncertainty by placing greater restraints on employees. It would be a vast overstatement to suggest that the use of contracts to constrain human capital is a new development given the evolution of the law concerning employee-inventor to emphasize the collaborative nature of invention.\textsuperscript{40} Nonetheless, the expanding web of "regulatory and contractual

\begin{footnotes}
\footnote{35. \textit{Id.} at 458.}
\footnote{36. \textit{Id.} at 473.}
\footnote{37. DiMatteo, \textit{supra} note 6, at 773 (stating that "[a] strategic contract balances the need to minimize the uncertainties inherent in innovation, while providing the flexibility so as not to inhibit the creative process").}
\footnote{38. Baldia, \textit{supra} note 1, at 15.}
\footnote{39. Lee, \textit{supra} note 24, at 70.}

If a judge could not see an inventive man as part of the working class, the judge vastly increased the employee’s chances of becoming an entrepreneur if he was not one already. Once judges began to see inventive employees as employees first and inventors second, it became much harder for the employee to capitalize on his ideas.

\textit{Id.} at 1198.
controls on human property has prompted some to raise an alarm about the propertization of employees’ knowledge.\(^{41}\)

A well-drafted contract can bind employees’ knowledge and ideas in ways that intellectual property regulation cannot.\(^{42}\) Across industries, many firms now routinely utilize assignment agreements to gain control over intellectual property that is otherwise controlled by individual inventors.\(^{43}\)

Given the flexibility of contract law, the scope of the innovation assignment often is all-encompassing. Not only do such agreements cover employees who are not hired to invent,\(^{44}\) but they define innovations broadly. For example, Google employees sign an assignment agreement for “inventions” which is defined to include “inventions, designs, developments, ideas, concepts, techniques, devices, discoveries, formulae, processes, improvements, writings, records, original works of authorship, trademarks, trade secrets, all related know-how, and any other intellectual

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41. Lobel, supra note 1, at 790 (defining these controls as “postemployment restrictions, including noncompetition contracts, nonsolicitation, nonpoaching, and antidealing agreements; collusive do-not-hire talent cartels; pre-invention assignment agreements of patents, copyright, as well as nonpatentable and noncopyrightable ideas; and nondisclosure agreements, trade secret laws, and economic–espionage prosecution against former insiders”).

42. Id.; see also Norman D. Bishara & David Orozco, Using the Resource-Based Theory to Determine Covenant not to Compete Legitimacy, 87 IND. L.J. 979, 981-82 (2012) (showing how “the employer is attempting to use contractual means to reach beyond the normal default bounds of the employment relationship and exert control over the postemployment mobility choices and human capital value of the individual, and to do so in direct contravention of the employee’s expressed desire for freedom of employment mobility”); Sawicki, supra note 10, at 651 (questioning the prevailing explanation of acquisition of start-ups in Silicon Valley as evidence of the “cooperative norms” and instead noting that “[l]arge technology firms cannot acquire . . . patent rights by simply hiring the start-up’s engineers; instead they must buy the start-up itself”).

43. Lobel, supra note 1, at 803 (stating that “[t]he explicit subversion of the lines drawn in patent and copyright law in the drafting of assignment agreements is increasingly standard”). But see Lemley, supra note 8, at 465 (discussing the idea that IP is governmental control of market entry and market prices that subvert the free market). See generally Cynthia Estlund, Something Old, Something New: Governing the Workplace by Contract Again, 28 COMP. LUB. L. & POL’Y J. 351, 364 (2007) (noting how “[a]t first blush, the notion of privately contracting over public policy (and arguably around it) might seem in tension with some basic tenets of democratic governance. Private parties, unsatisfied with the laws and mechanisms supplied by public law, are writing their own private labor and employment laws. Of course, public law and regulatory mechanisms have long coexisted with contractual mechanisms for private ordering, and in effect with private governance mechanisms.”).

44. Sawicki, supra note 10, at 665 (stating that “[j]oint invention by more than one person is possible; corporate invention, however, is not”).

45. DiMatteo, supra note 6, at 735 (noting that flexibility in contract law is a means for firms to maintain competitive advantages).

46. Lobel, supra note 1, at 799 (stating that courts allow the inclusion of work done at home).
property, whether or not patentable or registerable under patent, copyright, or similar laws. The assignment not only of employees’ inventions and designs but also of their ideas and concepts moves well beyond the type of creations protected by intellectual property law and into a “cognitive property thicket.”

The all-encompassing scope is not limited to content coverage but also applies to time frame. The assignment agreements may require employees to give control of even their future ideas and innovation to their employer, significantly restricting the future mobility and opportunity of employees.

Firms create inherent conflicts with their employees through such all-encompassing assignment agreements. As Professor Katherine Stone noted in describing the “New Psychological Contract” of the American workforce, the problem of ownership of human capital is the crux of the divide between firms and their agents. Fundamentally, employees assume that the skills and knowledge they acquire on a particular job ‘belong’ to them in the sense that they take these with them when they depart. Employers, on the other hand, believe that if they have imparted valuable skills or knowledge to their employees, they should ‘own’ that human capital, in the sense of being able to ensure that it is utilized on their firm’s behalf.

47. Id. at 803.


49. Lobel, supra note 1, at 791 (discussing that employment restrictions limit hiring of talent and of sparking innovation).

50. Sawicki, supra note 10, at 666 (explaining that “[i]nvention assignment agreements are often not limited to inventions for which patent applications are filed during the course of employment; instead, they reach any inventions produced while the employee is at the firm”); accord Lobel, supra note 1, at 799 (noting the “common practice of requiring employees to forfeit all future innovation . . . effectively restricting them from later pursuing independent career paths, notwithstanding the fact that they were not hired to invent”).

51. Lobel, supra note 1, at 799 (noting the restriction regardless of the nature of the future employment).


Although courts have limited the impact of traditional covenants not to compete to protect employees’ pursuits of trade and to promote interests in mobility, and, in some cases, states do not enforce such agreements, neither is true for innovation assignment agreements. In California, where covenants not to compete are unenforceable, assignment agreements are enforced. Even assignment agreements that extend into the future, such as the one signed by a research scientist that gave his employer the right to any inventions developed within one year after the employment relationship had terminated, are enforced in some states. The South Carolina Supreme Court upheld a verdict for the employer because assignment agreements, “do not operate in restraint of the employee’s trade but merely vest ownership of an invention with the entity which ought to have it.”

Professor Lobel emphasizes the ubiquitous nature of such assignment agreements by noting that assignment agreements may not only apply to future inventions, but also “reach back to an employee’s past” and arise that the expectations with respect to human capital differ between employees and employers.


55. CAL. BUS. & PROF. CODE ANN. § 16600 (2015) (stating that non-compete agreements cannot be enforced). *See also* Gomulkiewicz, supra note 54, at 264–65. California’s strong rule against the enforceability of non-competes has been replicated in Hawaii, North Dakota, Montana, and Oklahoma although the courts in Montana and Oklahoma have interpreted their statutes to permit the enforcement of non-competes in certain circumstances. Although not going as far as California, Colorado and Oregon limit enforcement of non-competes to managers and professional workers. *Id.* at 265.

56. CAL. LABOR CODE § 2870(a) (2014) (stating that the provision would be against public policy). *See also* Sawicki, supra note 10, at 665 (discussing some limitations “unless the invention relates to the employer’s business or results from the employee’s work for the employer”).

57. Milliken & Co. v. Morin, 731 S.E.2d 288, 288 (S.C. 2012) (holding that the agreement is enforceable because it is not too broad); *see also* Lobel, supra note 1, at 819–20 (discussing Milliken).


59. Lobel, supra note 1, at 814 (referencing the case of Brown v. Alcatel USA, Inc., No. 05-02-01678-CV, 2004 WL 1434521, at *3 (Tex. App. June 28, 2004), which involves Evan Brown, who conceived of an invention before working for Alcatel, based on years of his own computer programming experiences that began while he was in college).
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not only through individual contract but through institutional policy “such as a company handbook or an employee manual.”60 This leads him to conclude:

Business competitors do not desire to hire individuals obligated under such a clause because the work product of such employees may not accrue to the new employer’s benefit. At best, employers that hire inventive employees obligated under such agreements will under-utilize the employees’ inventive skills so as not to develop conflicts with prior trailer clauses.61

II. HEALTH CARE INNOVATION INCENTIVES

Innovation through collaboration is crucial to the health care industry as it undergoes a 21st century transformation. Although regulation is certainly a factor in this industry, the challenges that necessitate this transformation are the same factors that led to the information revolution in many industries: “globalization, technology, and entrepreneurship.”62 In this section the health care industry is highlighted because it is an industry that is attempting to innovate through integration and consolidation and specifically by employing assignment agreements, as utilized by other industries, for strategic contracting. The practice raises the question: does this promote collaboration for advancing innovation or constrain human capital in a way that limits innovation to the detriment of not only the health care industry but also the economy and well-being of the United States?

A. Snapshot of the Health Care Industry

The impact of the health care industry on the economy of the United States is impressive. In 2014, aggregate spending on health care in the country represented $3.0 trillion dollars, or 17.5 percent of gross domestic product (GDP).63 This is the highest percentage of GDP health care spending in the world.64 The Health and Human Services Department

60. Lobel, supra note 1, at 815.
61. Id. at 820.
62. DiMatteo, supra note 6, at 734.
63. CEN

expects that the health care share of GDP will continue its growth and reach 20.1 percent by 2025.\textsuperscript{65} The spending is distributed 32.1 percent to hospital care, 19.9 percent to physician/clinical services, 9.8 percent to pharmaceuticals, 22.7 percent to home health care, nursing care, or other personal health care, and 15.4 percent to administrative and other health care spending.\textsuperscript{66} Although there was a slowdown in growth of health care spending attributed to the recession years, with the growth of per-capita health care spending stabilizing at around 3 percent between 2009 and 2012 in contrast to 5.3 percent growth seen only five years prior, these slowdowns may be misleading given the continued growth in health care spending over time.\textsuperscript{67} Even with the slowdown from the recession, national health expenditures continue to see growth, with 2014 healthcare spending showing a moderate increase of 4.3 percent from the previous year.\textsuperscript{68} A major factor in long-term health care spending growth is innovation in technology for new treatments and procedures and diffusion of existing technology.\textsuperscript{69}

The health care industry was not always such a robust and dominant part of the U.S. economy. In 1929, it was a mere 3.5 percent of GDP.\textsuperscript{70} By 1960 it had risen to 5.1 percent, a third of which was primarily for treatment of World War II veterans.\textsuperscript{71} A period of rapid growth began after 1966 with the introduction of Medicare and Medicaid.\textsuperscript{72} Costs tripled
between 1970 and 1997. In 1980, expenditures comprised 7.9 percent of GDP; by 1997, they were 13.5 percent.\footnote{Caplow, supra note 70, at 152.}

Beginning in 1929, concurrent with the onset of the Great Depression, a combination of three factors created a powerful force in the American health care system: privatized health care insurance.\footnote{See Charles D. Weller, “Free Choice” as a Restraint of Trade in American Health Care Delivery and Insurance, 69 IOWA L. REV. 1351, 1360–1362 (1984) (discussing the forces that caused a rapid rise in the development of health insurance plans).} First, due to the lack of support of health insurance by the American Medical Association, many people, particularly the poor, had little to no access to care.\footnote{Id. at 1362.} Second, hospitals faced financial peril as a result of the Great Depression and were forced to find new ways to finance their services.\footnote{The American Medical Association’s resistance to group health insurance eventually resulted in its conviction for violating the Sherman Antitrust Act, 15 U.S.C. § 3 (1982).} Third, Baylor University Hospital in Dallas, in order to raise revenue, offered a single hospital health insurance plan to school teachers in the area.\footnote{See Am. Med. Ass’n v. United States, 317 U.S. 519 (1943) (holding the American Medical Association liable under the Sherman Antitrust Act for restraining trade).} Baylor’s plan was quickly replicated throughout the struggling hospital industry in the United States and by 1933 a number of innovative plans were offered by hospitals and related organizations.\footnote{Weller, supra note 74, at 1361.}

Private health insurance expanded following World War II and throughout the Post-War period with accelerating cost increases for health care services.\footnote{Id. at 1361.} Despite these increases, attempts in both the legislative and executive branches of government to pass major health care reform were met with little success. The changes in Medicare, Medicaid, and the passage of the Health Insurance Portability and Accountability Act (HIPAA) during this time are examples of measured responses taken to aged and is financed by federal payroll taxes; Social Security Amendments of 1965, Pub. L. No. 89-97, § 102, 79 Stat. 286, 291–332 (1965) (current version at 42 U.S.C. §§ 1395–1395yy (2012)). The Medicaid Act provides matching federal funds for state medical assistance to the indigent; Social Security Amendments of 1965, Pub. L. No. 89-97, § 121, 79 Stat. 286, 343–52 (1965) (current version at 42 U.S.C. §§ 1396-1396v (2012)).

\begin{itemize}
  \item 73. Caplow, supra note 70, at 152.
  \item 76. Weller, supra note 74, at 1361.
  \item 77. Id. at 1361.
  \item 78. Weller, supra note 74, at 1363. Although not necessarily embraced by all. See id. at 1364 (stating that “[t]hese developments, however, were understandably threatening to the hospital and medical professions. They were particularly threatening to a profession built on a model of the individual solo practitioner in a period of scientific, social, and economic dislocation.”).
  \item 79. Crimm, supra note 72, at 15 (explaining that “[a]s hospital and health care insurance coverage reached more people, demand for health care accelerated”).
\end{itemize}
address significant health care cost issues. The Patient Protection and Affordable Care Act of 2010 (ACA) is the most significant attempt at reforming the U.S. health care system since the passage of Social Security and Medicare. Some of the key effects of this law are the: (1) primary individual mandate; (2) fundamental changes to the employee and health benefit plan market; (3) establishment of state health insurance exchanges; and (4) extension of Medicaid coverage.

B. Hospital Consolidation Prompted by Innovation Costs

Just as hospitals needed to transform their relationship to financing patient care during the Great Depression, now hospitals must adjust to the changing health care landscape and increased costs of providing care, particularly the costs associated with technology such as innovations in new treatments and procedures. A number of researchers who have examined the growth in health care spending in the United States conclude that it is the increased use and diffusion of innovation in treatments and procedures that drive cost. The rate of use of sophisticated medical


82. See Sarah Rosenbaum, Realigning the Social Order: The Patient Protection and Affordable Care Act and the U.S. Health Insurance System, 7 J. HEALTH & BIOMED. L. 1, 4 (2011) (noting that “contentiousness seems to be a basic ingredient of social welfare legislation”).

83. Id. at 11-16 (stating that “the heart of the law is an individual mandate that requires ‘applicable’ individuals to maintain ‘minimum essential health coverage’ or face certain financial penalties”).

84. Id. (referring to these provisions as the “four pillars” of the ACA). It is beyond the scope of this chapter to discuss the ACA in depth. Rather, this chapter adopts an agnostic approach to the law, characterizing its major changes to health care law as part of the historical evolution of health care in the United States that offers opportunities as well as challenges for those in the health care industry. For a discussion of the “bitter reception” of the ACA and the political aspects of its passage and implementation. See id. at 4–10.

85. Chandra, supra note 64, at 284–85.

procedures in the United States outpaces the rate of use in all other countries.\textsuperscript{87}

Such pervasive use of innovation in health care is associated with procedures of all kinds. For example, proton beam accelerators are used to treat prostate cancer patients and were projected to double in number between 2010 and 2014.\textsuperscript{88} The cost of installation for each accelerator, however, is hundreds of millions of dollars.\textsuperscript{89} Even for technology that costs less for each item, such as cardiac stents to treat heart disease, if the use of the technology becomes the norm for a large number of patients, the impact on the cost of health care spending is significant. In the 1990s, the typical treatment for blockage in arteries was angioplasty, a balloon threaded into the artery and then expanded at the site of the blockage.\textsuperscript{90} Later, cardiologists routinely utilized stents or multiple stents to widen narrow arteries.\textsuperscript{91} During the mid-2000s, several research trials questioned the benefits of cardiac stents in the treatment of the most common type of heart disease. This led to a decline in the use of cardiac stents that impacted health care spending in both Medicare and the private insurance market, and contributed to an overall decline in health care spending around 2004.\textsuperscript{92}

Innovation in treatment and procedures and, more generally, the use of technology and technical equipment impacts the cost of health care overall. In response to the increased costs of providing care, as well as the decline in hospital use, hospitals are consolidating at a rapid pace.\textsuperscript{93} This consolidation, in turn, may result in increasing consumer health care costs all the more.\textsuperscript{94} Therefore, innovation in health care has the potential for broad patient benefits but also negative cost impact. The implications for


\textsuperscript{88} Chandra, \textit{supra} note 64, at 286.

\textsuperscript{89} Id.

\textsuperscript{90} Id. at 279.

\textsuperscript{91} Id.

\textsuperscript{92} Id.

\textsuperscript{93} David M. Cutler & Fiona Scott Morton, \textit{Hospitals, Market Share and Consolidation}, 310 J. Am. Med. Ass’n 1964 (2013). The authors note that many factors contribute to the consolidation trend, including the decline in hospital use. Between 1981 and 2011, hospital use as measured by inpatient days at short term acute hospitals declined by 33 percent despite the increase in population overall and the aging of the population. Coincident with the decline in number of days in hospitals, 15 percent of hospitals closed. Id. at 1965.

\textsuperscript{94} Id.
innovation in the changing health care landscape require the industry to pursue innovation not just with an eye toward monetizing intellectual property, but also toward transforming the industry to improve each hospital’s value chain.\textsuperscript{95}

The hospital mergers that have become commonplace over the past decade not only reflect trends in innovation\textsuperscript{96} but, in an effort to improve value chains, the mergers establish new employment relationships between hospitals and the physicians and health care practitioners who work there. With the implementation of the ACA, industry experts anticipate that consolidation will increase.\textsuperscript{97} Because the industry is seeing both horizontal consolidation and vertical consolidation,\textsuperscript{98} there are important consequences to employment relationships in the health care industry. Moreover, many health systems now engage hospital employees in the process of innovation through academic medical centers.\textsuperscript{99} Often, hospitals now consist of a system built around one or more academic medical centers with community or short term acute centers supporting the academic medical center.\textsuperscript{100}

Horizontal consolidation, or hospitals merging or acquiring other hospitals, typically results in hospitals becoming part of a health system. From 2007 to 2012, 432 hospital mergers and acquisitions were announced involving 835 hospitals, were announced.\textsuperscript{101} Sixty percent of hospitals are now part of health systems, which is an increase of seven percent in a decade.\textsuperscript{102} In theory, the consolidation should result in cost savings for a hospital, but empirical studies show mixed results.\textsuperscript{103} Often times, a larger hospital system with a flagship academic medical center has the market power to increase prices for medical procedures and hospital stays and, thus, fails to incorporate the full integration of the system that would lead to lower health care costs for consumers.\textsuperscript{104}


\textsuperscript{96} Birkinshaw, supra note 12, at 43.

\textsuperscript{97} Cutler & Morton, supra note 93, at 1965.

\textsuperscript{98} Id.

\textsuperscript{99} See infra Part IV (discussing ways in which hospitals attempt to claim physician innovation).

\textsuperscript{100} Cutler & Morton, supra note 93, at 1964.


\textsuperscript{102} Cutler & Morton, supra note 93, at 1965.

\textsuperscript{103} Id. at 1967.

\textsuperscript{104} Id. (noting that “flagship academic medical centers offering perceived higher
Vertical consolidation within the health care industry has led to a marked increase in hospital ownership of physician practices. Data from the Medical Group Management Association (MGMA) surveys showed that the percentage of physicians working in practices owned by a hospital or integrated delivery system increased from 24 percent in 2004 to 40 percent in 2011.\(^\text{105}\) Although the American Medical Association takes issue with data suggesting that close to 60 percent of physicians are now employed by hospitals,\(^\text{106}\) there is no dispute that the trend is toward fewer physician-owned practices and more physicians employed by hospitals than ever before.\(^\text{107}\) Just as in other industries that adopt an “everybody innovates” approach,\(^\text{108}\) many hospitals hope that their newly acquired physician employees are the source of future innovation in health care that will offset the decrease in government payments under the ACA.\(^\text{109}\) For example, a 2012 survey by the American College of Cardiology showed that the percentage of cardiologists employed by hospitals rose from 11 percent in 2007 to 35 percent in 2012.\(^\text{110}\) Quality care often yield enormous market power...a patient who has a serious illness and also is well insured will seek out these hospitals with little regard for price”).


\(^{107}\) Id. (citing a report by the American Hospital Association which stated that the number of physicians employed by community hospitals increased by 32 percent between 2000 and 2012. It also cited a survey conducted by Accenture which concluded that only 36 percent of physicians would work at independent practices by the end of 2013.). See also Abby Goodnough, New Law’s Demands on Doctors Have Many Seeking a Network, N.Y. Times, at A1 (Mar. 3, 2014), available at http://www.nytimes.com/2014/03/03/us/new-laws-demands-on-doctors-have-many-seeking-a-network.html?_r=0 [https://PERMA.CC/HZ29-SSM6].

\(^{108}\) Birkinshaw, supra note 12, at 43.


III. PROTECTING THE INVESTMENT IN HEALTH CARE INNOVATION

The Bayh-Dole Act is known as “innovation’s golden goose.” Prior to the Act, the patent laws of the United States, designed with an individual inventor in mind, did not address the issue of the ownership of inventions that were created as part of employment. Indeed, the U.S. Constitution provides that protecting inventors is the best way to promote progress in science and useful arts. Despite changes in the patent laws over time, the individual inventor, whether Henry Ford or Bill Gates, remains an important part of the American identity. The administration of patent law also impacted this cultural perception.

A. Statutory Protections

The most significant patent law reform in more than 50 years is the Leahy-Smith America Invents Act (AIA). The AIA changed the United States from a “first-to-invent” country to a “first-to-file” country, thereby

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115. U.S. CONST. art. I § 8 (stating that “Congress shall have power . . . 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”).
116. Kamprath, supra note 113, at 190 (noting that “[o]ur society has long recognized the intensely personal nature of an invention and the importance of providing stimulation and encouragement to inventors”).
117. Fisk, supra note 40, at 1198 (discussing the change in “cultural perception of invention from inventor-hero to Bell Labs” came about slowly, in part, because of the “Patent Office’s bureaucratic insistence on the existence of an individual inventor no doubt influenced the way that employers and employees perceived who had been the inventor in fact”).
aligning U.S. patent law with most other patent systems throughout the world. This change was widely discussed and aroused controversy in the intellectual property community because it is perceived to favor larger corporations and well-financed entities over the individual inventor. The end of the cultural primacy of the individual inventor in innovation seems complete. The concern with the change to “first-to-file” is that corporations will quickly file patent applications to out-race the individual inventor.

The change to a first-to-file system, taken in context with reduced filing fees for small and micro entities, represents Congress’ attempt to strike a balance that would protect intellectual property assets that are increasingly important to the domestic economy, while creating more opportunities in the global economy. However, if Steve Jobs is correct that it is not money that is required for innovation but rather well-managed people “who get it,” proper incentives and motivation to invent might still be lacking.

The Bayh-Dole Act is a prime example of statutory changes that can spark interest in the investment and commercialization of technology. In the 1970s, there was growing concern that the era of American inventiveness, propelled by necessity during World War II, was over. Production and investment in technology by U.S. corporations fell behind other countries,

(2) the claimed invention was described . . . under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

Id.

121. Ashworth, supra note 118, at 395.
122. See, e.g., Kamprath, supra note 113, at note 5 (noting “[t]his system favors those entities that can dedicate fiscal resources and personnel solely to creating patent application as fast as possible. Competing against large corporations and universities, America may well see the death of the individual inventor”).
123. Fisk, supra note 40, at 1198 (discussing the transformation from inventing as a singular act to a collaborative task).
126. Ashworth, supra note 118, at 395.
most notably Japan. In 1980, Senators Bob Dole and Birch Bayh drafted the University and Small Business Procedures Act (commonly known as the Bayh-Dole Act) to “promote the utilization of inventions arising from federally supported research,” “promote collaboration between commercial and non-profit organizations,” and “ensure that the Government maintains sufficient rights in any supported inventions.”

To achieve its goals, the Bayh-Dole Act focused on federal funding agreements and the patentable products derived from research conducted under those funding agreements. Universities and academic medical centers that participate in federally funded research were given incentives to collaborate with businesses and become involved in monetizing intellectual property to the financial benefit of the institutions. The institutions retained royalties derived from federally-funded research as long as any royalties were “utilized for the support of scientific research or education.” The Act does not grant the research institution complete rights to patentable products but, instead, establishes a hierarchical system that determines what entity or person has the right to retain title in the inventions produced from federal funding.

The first opportunity to retain title to federally-funded inventions developed by small businesses or not-for-profits belongs to those federal contractor organizations themselves. If the federal contractor chooses not to retain title to the inventions, the federal government is next in line to take title to the inventions. If the federal government also passes on the opportunity to retain title to inventions produced from the federal funding agreement, the individual employee-inventor working for the federal contractor has the right to sole title.

If the federal contractor retains the rights to an invention, it commits to several key obligations including: reporting all “subject inventions,”

129. Id.
130. Stanford, 131 S. Ct. at 2192-2193.
133. Stanford, 131 S. Ct. at 2193. See also Stephen T. Black, Psst! Wanna Buy a Bridge? IP Transfers of Non–Existential Property, 31 Ga. St. U.L. REV. 523, 531 (explaining that “[t]he Bayh-Dole Act was designed to free up federally funded research so that it could be more readily moved into the marketplace. The Act reinforced the concept that the inventor owns the patent, regardless of what funds or resources the inventor used in reducing the patent to practice or in researching the underlying science.”).
135. See id.
136. See id. at § 203.
137. Id. at § 201(e) (stating “[t]he term ‘subject invention’ means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement . . .”).
taking reasonable efforts to commercialize the invention through patenting or licensing, and granting the federal government a license to the subject invention.\textsuperscript{138}

Medical researchers and the biotech industry are among those that laud the Bayh-Dole Act for its achievements in advancing biomedical research. One National Institute of Health (NIH) Report from 2001 stated: “Federally funded biomedical research, aided by the economic incentives of Bayh-Dole, has created the scientific capital of knowledge that fuels medical and biotechnology development.”\textsuperscript{139} Indeed, federal contractor start-up companies created the entire biotechnology industry.\textsuperscript{140} Although there are a few notable exceptions,\textsuperscript{141} monetizing the inventions has proven to be a bigger challenge for the federal contractors involved in the federally-funded research, including academic medical centers. Technology transfer activity, such as invention disclosures, patent applications, patent issuances, and licenses, increased steadily following passage of the Act;\textsuperscript{142} however, the activity, more often than not, is a financial drain on academic centers rather than income generating.\textsuperscript{143} In 2006, 52 percent of U.S. institutions spent more on technology transfer than the income generated from the activity.\textsuperscript{144}

The difficulty with bringing patentable products to market and monetizing research to the financial benefit of the institution is not a failure of academic medical centers or universities uniquely. Research studies reveal that the difficulty with innovation is not the “good idea” but moving the idea through the process to revenue generation.\textsuperscript{145} Effective restrictive covenants in contracts that the health care industry now utilizes extensively

\textsuperscript{138} Tresemer, supra note 128, at 357–58.
\textsuperscript{140} Vicki Loise & Ashley J. Stevens, The Bayh-Dole Act Turns 30, 30 SCI. TRANSL. MED. 52, 52 (2010).
\textsuperscript{141} Richard Perez-Pena, Patenting Their Discoveries Does not Pay Off for Most Universities, a Study Says, N.Y. TIMES (Nov. 20, 2013), at A18, available at http://www.nytimes.com/2013/11/21/education/patenting-their-discoveries-does-not-pay-off-for-most-universities-a-study-says.html [HTTPS://PERMA.CC/ZX5X-PD3T] (noting that Columbia University received $790 million in revenue from patents involving inserting DNA into cells and New York University received more than $1 billion for a patent that led to an autoimmune drug).
\textsuperscript{142} Jay P. Kesan, Economic Rationales for the Patent System in Current Context, 22 GEO. MASON L. REV. 897, 905 (2015) (noting that “following the passage of the Bayh-Dole Act, universities did not necessarily produce more or better research, but began patenting and licensing at far greater rates”).
\textsuperscript{143} Loise, supra note 140, at 52.
\textsuperscript{144} Id.
\textsuperscript{145} Birkinshaw, supra note 12, at 44 (referring to the “eureka myth” that a single moment of insight is required to create innovation).
to secure intellectual property may help protect that “good idea” but little else.\textsuperscript{146} These restrictive covenants alone cannot motivate innovation as a process.\textsuperscript{147}

B. \textit{Stanford v. Roche} Interprets the Bayh-Dole Act

A recent U.S. Supreme Court decision challenged long-held interpretations of the Bayh-Dole Act and federal contractors’ ability to secure intellectual property. Many commentators view the decision as tipping the delicate balance in the system of incentives created by the Bayh-Dole Act for federal contractors and private industry.\textsuperscript{148} In \textit{Stanford v. Roche}, the Court held that the Bayh-Dole Act does not automatically grant title in intellectual property to federal contractors nor does it give federal contractors the right to take title to such property unilaterally.\textsuperscript{149} The invention at issue in the case was Roche’s HIV test kits that are used widely in hospitals and medical clinics around the world.\textsuperscript{150} The facts of the case provide an interesting example of the process of commercializing technology in the health care industry.

The HIV test kits marketed by Roche began development at a small California research company, Cetus. Previously, Cetus had developed a Nobel Prize winning technique, polymerase chain reaction, known as PCR.\textsuperscript{151} Using this technique, Cetus sought methods for quantifying blood-borne levels of HIV, the virus that causes AIDS. In 1988, Cetus started collaborating with researchers at Stanford University to test the efficacy of new AIDS drugs.\textsuperscript{152} Dr. Mark Holodniy worked as a researcher at Stanford. When he began working there he signed an employment contract that included a “Copyright and Patent Agreement.” Under the terms of that agreement, Holodniy agreed to assign to Stanford his “right, title and interest

\begin{footnotes}
\item[146] Lemley, supra note 8, at 504 (stating that “[t]he IP laws were created in a world of scarcity. They sought to take ideas that were public goods - things that by their nature were not scarce - and artificially make them scarce by designating them as owned by someone.”).
\item[147] Birkinshaw, supra note 12, at 44.
\item[148] See, e.g., Ted Hagelin, The Unintended Consequences of Stanford v. Roche, 39 AIPLA Q. J. 335, 336 (2011) (noting that (under the Stanford decision) employee-inventor could defeat an employer’s expectancy contract interest in an invention... by filing a patent application in his or her own name and assigning the patent application to a third party. This gaping loophole in patent law could put tens of billions of dollars of patent ownership rights at risk); Takenaka, supra note 114, at 288 (discussing how “[e]ven though basic policies and objectives were expressly set out in the Bayh-Dole Act, they played no role in [the Court’s] interpretation”).
\item[149] Stanford, 131 S. Ct. at 2190.
\item[150] Id. at 2192.
\item[151] Id.
\item[152] Id.
\end{footnotes}
in” inventions created while employed there.\textsuperscript{153}

Holodniy became interested in using the PCR technique to quantify HIV levels in patient blood samples. To learn more about PCR, he was permitted to conduct research at Cetus after signing a “Visitor’s Confidentiality Agreement.”\textsuperscript{154} The agreement stated that Holodniy “will assign and do[es] hereby assign” to Cetus his “right, title and interest in each of the ideas, inventions and improvements” made as a result of having access to Cetus.\textsuperscript{155} Holodniy’s work with Cetus is an example of the collaboration between business and academic medical center research that the Bayh-Dole Act encouraged.

Holodniy conducted research at Cetus for nine months and, during that time, devised a PCR-based procedure for quantifying the amount of HIV in a blood sample. He returned to Stanford to test the HIV measurement technique with his colleagues. Stanford eventually obtained three patents related to the HIV measurement process after securing written assignment of rights from all Stanford employees involved in the research, including Holodniy.\textsuperscript{156} Holodniy’s Copyright and Patent Agreement with Stanford signed at the time of his employment required that he assign his rights in any intellectual property to Stanford.

In 1991, Roche Molecular Systems purchased all of Cetus’ PCR-related assets, including the intellectual property rights that Cetus obtained through agreements, such as the one signed by Holodniy. After testing, Roche commercialized the HIV quantification technique by selling HIV test kits.\textsuperscript{157} In 2005, Stanford filed suit against Roche contending that the HIV test kits violated the patents Stanford had obtained on the HIV measurement process.\textsuperscript{158} Roche responded that it was co-owner of the HIV measurement process because the Visitor Confidentiality Agreement signed by Holodniy assigned his rights to the process to Cetus and later Roche when it purchased the assignment of rights. Stanford, however, asserted that Holodniy had no rights to assign through the Visitor Confidentiality Agreement because Stanford had superior rights over Holodniy as a federal contractor.\textsuperscript{159} Stanford reasoned that, because Holodniy’s research was, in part, federally funded through an NIH grant, it was subject to the Bayh-Dole Act.

\textsuperscript{153} Id.
\textsuperscript{154} Id.
\textsuperscript{155} Id.
\textsuperscript{156} Id.
\textsuperscript{157} Id.
\textsuperscript{158} Id. at 2194.
\textsuperscript{159} See Lobel \textit{supra} note 1, at 816 (noting that “[i]n the backdrop of the new cognitive property, it should not be surprising that the dispute over invention ownership in this case was between two institutions, Cetus and Stanford, while the inventor had long been stripped of any claims to his invention”).
the Act, Stanford believed that it had superior ownership rights, as first in line to acquire title, over the inventor himself who is last in line under the Bayh-Dole Act.\textsuperscript{160}

Justice Roberts, writing on behalf of the Court, took exception to the idea that the inventor was the last in line to claim any rights to his own invention, believing such an interpretation of the Bayh-Dole Act turned patent law on its head.\textsuperscript{161} The Court began its opinion by noting that, “[s]ince 1790, the patent law has operated on the premise that rights in an invention belong to the inventor.”\textsuperscript{162} The Bayh-Dole Act, the Court concluded, did not violate that basic premise of patent law.\textsuperscript{163} Congress was obligated to state its intention to change the fundamental rights of the inventor under patent law expressly if that, indeed, was its intention when creating the Bayh-Dole Act.\textsuperscript{164} Instead of moving the inventor to the back of the line in priority to rights in an invention,\textsuperscript{165} the Bayh-Dole Act, the Court determined, focused on rights between the federal contractor and the federal government only after the federal contractor obtained sole rights to the invention from the inventor.\textsuperscript{166}

The Copyright and Patent Agreement that Holodniy signed upon his employment with Stanford University provided that he would assign rights to Stanford for inventions created during his employment there.\textsuperscript{167} Before Stanford filed patent applications for the HIV measurement technique, it had obtained Holodniy’s assignment of rights as well as the assignment from others involved in the research.\textsuperscript{168} However, the Visitor Confidentiality Agreement that Holodniy signed before beginning work at Cetus happened

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\item \textsuperscript{160} Stanford, 131 S. Ct. at 2192.
\item \textsuperscript{161} Id. at 2199. See also Lobel, supra note 1, at 816 (characterizing Stanford v. Roche as a dispute based on the wording of two competing agreements and noting the “key issue in the case was the interpretation of the phrase ‘do hereby assign,’ which is commonly used in employment pre-invention assignment agreements”).
\item \textsuperscript{162} Stanford, 131 S. Ct. at 2192.
\item \textsuperscript{163} Id. at 2199.
\item \textsuperscript{164} Id. at 2195 (explaining that in the past, Congress has excluded inventors from patent rights, including certain contracts dealing with nuclear material and atomic energy. “Congress provided that title to such inventions ‘shall be vested in, and be the property of, the [Atomic Energy] Commission.’”).
\item \textsuperscript{165} Id. at 2194 (the District Court held that “the Bayh-Dole Act ‘provides that the individual inventor may obtain title’ to a federally funded invention ‘only after the government and the contracting party have declined to do so’”).
\item \textsuperscript{166} Id. at 2198 (“The Bayh-Dole Act expressly confers on contractors the right to challenge a Government-imposed impediment to retaining title to a subject invention . . . [T]here is no need to protect inventor or third-party rights, because the only rights at issue are those of the contractor and the Government.”).
\item \textsuperscript{167} Id at 2192 (the Copyright and Patent Agreement provided that Holodniy agreed to assign “right, title and interest in” inventions created while employed there).
\item \textsuperscript{168} Id. at 2194.
\end{enumerate}
\end{footnotesize}
before Stanford obtained its assignment of rights. Therefore, the assignment of rights that Cetus obtained occurred while Holodniy retained full rights in his research. In that way, Cetus received a full assignment of rights to the patentable technology while Stanford had a future promise to assign rights. The Court held that the Bayh-Dole Act did not change inventors’ rights under patent law nor did it change principles of contract law. Stanford failed to obtain the proper assignment of rights and its status as a federal contractor did not provide superior rights in the research.

Stanford v. Roche, in some respects, simply reinforced the importance of careful contracting to secure fully the employee assignment agreement in federally funded research. The Court noted that NIH guidelines made it clear to federal contractors that not all aspects of intellectual property are controlled under the Bayh-Dole Act. In essence, federally funded research is on an equal footing with innovation provided by employees to any organization and monetizing that innovation requires careful assignment agreements.

Another perspective on Stanford v. Roche is one that goes well beyond contracts. The ruling underscores the law’s recognition that innovation by employees is unique.

169. Id. at 2192 (the Visitor Confidentiality Agreement provided that Holodniy “will assign and do[es] hereby assign” to Cetus his ‘right, title and interest in each of the ideas, inventions and improvements’ made as a result of having access to Cetus).

170. Id. at 2199 (“With an effective assignment, those inventions—if federally funded—become ‘subject inventions’ under the Act, and the statute as a practical matter works pretty much the way Stanford says it should.”).


172. Stanford, 131 S. Ct. at 2199 (“In guidance documents made available to contractors, NIH has made clear that ‘[b]y law, an inventor has initial ownership of an invention’ and that contractors should therefore ‘have in place employee agreements requiring an inventor to “assign” or give ownership of an invention to the organization upon acceptance of Federal funds.’”).

173. Takenaka, supra note 114, at 285 (“[M]any federal funded inventions will fall outside of the Bayh-Dole Act if contractors fail to execute written assignments with inventors.”).

174. See, e.g., Black, supra note 133, at 530 (noting that “a]bsent the tinkering of the Supreme Court in Stanford, Roche would have lost, by application of the doctrine of ‘he who was first in time was first in right’”).

175. Id. at 531 (“In the U.S. IP system, we accord first rights to an inventor, even if the person is employed by an entity that provides him or her with the means to invent.”). But see, e.g., Fisk, supra note 40, at 1198 (tracing the change in the employee-inventor system to favor employer rights).
innovation as just another duty of employment. The concept that employers own what employees produce is clear. The Court conceded that “[n]o one would claim that an autoworker who builds a car while working in a factory owns that car.” The Court saw an important distinction when the employee is creating a patentable invention for a federal contractor, however. The right of inventors to their inventions is “one of the fundamental precepts of patent law,” according to the Court, and the Bayh-Dole Act did not change that. This perspective is important in the context of innovation in health care assignment agreements but the decision has provided impetus for ever expanding assignment agreements to secure intellectual property rights for firms, including health care systems.

IV. INNOVATION ENCUMBERED BY CONTRACT LAW

A. Hospital Systems Claim Rights to Physician Innovation

Whereas the guiding belief of intellectual property rights is that “encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors,” contract law is the means for businesses to gain control of intellectual property. Invention assignment agreements are not the only — or necessarily the most ubiquitous — post-employment restrictions utilized across industries as the value of intellectual property assets increase.

Although common law default rules permit, in some cases, an employer to obtain a “shop right” or a non-exclusive license to use the inventions of an employee, these common law rules are state-law based and are poorly defined generally. This uncertainty underscores the value to employers of assignment contracts. Well-created assignment agreements include a broad scope in both content and time frame. As the facts of Stanford v. Roche illuminate, however, pre-invention agreements do not guarantee employer

176. Stanford, 131 S. Ct. at 2196.
177. Id. (“But, as noted, patent law has always been different: We have rejected the idea that mere employment is sufficient to vest title to an employee’s invention in the employer.”).
178. Id. at 2198 (“It would be noteworthy enough for Congress to supplant one of the fundamental precepts of patent law and deprive inventors of rights in their own inventions. To do so under such unusual terms would be truly surprising.”).
180. Lobel, supra note 1, at 813 (“The real devil is in contract law.”).
181. Howell, supra note 11, at 86 (characterizing the doctrine of “shop right” as “disorderly”).
182. See supra Part I.B (discussing the theory of constrained human capital resulting from contracts for innovation).
ownership of an invention given the fundamental precepts of patent law granting unique status to inventors and the collaborative nature of research in the medical field. To date, few cases address the enforceability of these agreements in the health system setting. However, as assignment agreements become more ubiquitous in these organizations, particularly as hospitals consolidate to form ever larger health care systems with a focus on innovation, these assignment agreements will receive closer scrutiny.

In a recent case, Grocela v. General Hospital Corp., Dr. Grocela challenged the Intellectual Property Policy (Policy) of his employer, Massachusetts General Hospital (MGH) as “an unreasonable, oppressive and unduly harsh restraint on trade.” Under the Policy, and as a condition of his biennial application for reappointment as a clinical staff physician with a surgical specialty in urology, Grocela, and all staff physicians, certified that the ownership and disposition of inventions and other intellectual property created during the time of appointment to the professional staff were determined by the Policy. The Policy granted ownership rights to MGH of all staff inventions “that arise out of or relate to the clinical, research, educational or other activities of the Inventor.”

Importantly, Grocela’s assignment agreement was not a separately negotiated contract or even signed as part of the hiring process. Instead, the assignment agreement was part of MGH’s intellectual property policies to which physicians were bound as part of the biennial reappointment process. The state courts repeatedly have found that health care systems’ intellectual property policies, including broad assignment agreements, bind

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183. See supra Part III.B (discussing the facts of Stanford v. Roche).
184. See Bob Herman, A Public-Private Enterprise: Why Intellectual Property is a Mainstay of Academic Hospitals, BECKER’S HOSP. CFO (June 28, 2013), http://www.beckershospitalreview.com/finance/a-public-private-enterprise-why-intellectual-property-is-a-mainstay-at-academic-hospitals.html (noting that “[m]ost medical centers that are affiliated with universities have a technology transfer or commercialization office, and according to the Association of University Technology Managers, there are several dozen academic medical centers and health systems with such an office”).
186. Id. at *3.
187. Id. at *1.
188. Id. Cf. Lobel, supra note 1, at 810 (describing Google’s assignment agreement defining “inventions”).
190. Id.; see also Brown v. Alcatel USA, Inc., No. 05-02-01678-CV, 2004 WL 1434521, at *2 (Tex. App. June 28, 2004) (deeming an assignment agreement signed as a condition of employment was enforceable because “the continued employment and payment of salary, which would not have occurred but for Brown signing the employment agreement, was [the employer’s] performance under the unilateral contract”).
individual health care providers, such as physicians. The courts held that inclusion of assignment agreements in general policy documents meant “the individual expressly agreed to be bound.”

The Research Ventures and Licensing Department at MGH administered the Policy concerning invention ownership. This department received disclosures about inventions created by staff physicians and, after determining ownership of the invention, decided whether to pursue patents or partners to market the invention. The department could decide to return ownership rights to the inventor and forego the opportunity to patent or market the invention. Grocela participated in this process during his employment with MGH, disclosing at least nine inventions. Three of the inventions disclosed by Grocela to MGH later reverted back to ownership by Grocela when, at his request, MGH assigned its interests back to him.

In 2011, Grocela entered into an agreement to partner with Grindstone Medical to raise investment capital to develop and market his inventions and any future inventions not owned by MGH. In 2012, Grocela created the “voice box invention” outside of the hospital, on his own time and at his own expense. Although the voice box invention “utilizes or incorporates knowledge” that he gained as a physician at MGH, as stated in the Policy, Grocela objected to being restricted from creating his own business around an invention concerning voice phonating by virtue of his work as a surgeon with a specialty in urology.

Grocela argued before the Massachusetts court that MGH’s ownership of inventions under its Policy should be limited to inventions related to his specialty of urology. To read the Policy broadly to extend to all inventions whether connected to the work he is employed to perform or not, he reasoned, “bars [him] from ordinary competition and thus is contrary to public interest, which favors a person’s right to carry on a trade freely.”

The court rejected Grocela’s claim, finding instead that he was aware

194. Id.
195. Id. at *2.
196. Id.
197. Id.
198. Id.
199. Id. at *3.
that his employer contemplated the discovery of inventions as part of his employment. Therefore, even if the inventions were created outside of employment, they were within the scope of his employment.\textsuperscript{200} The court found that the hospital had a compelling interest in promoting the free sharing of staff inventions to benefit the patient population served by MGH.\textsuperscript{201} What the court does not address, or seem to understand is a concern for individual employees, was that Grocela was not hired to invent or research, but to treat patients.\textsuperscript{202}

Grocela, the court reasoned, received adequate compensation for discoveries because “[a]s a member of the staff, he reaps the benefit of the clinical resources, office space, access to doctor-patient relationships and professional prestige available to a physician who practices at one of this country’s major teaching hospitals.”\textsuperscript{203} But is that adequate incentive for innovation generated, not from work in the physician’s practice area, and for which Grocela benefitted the hospital by serving patients within his specialty?\textsuperscript{204}

Courts generally interpret assignment agreement disputes in favor of employers.\textsuperscript{205} State statutes carve out some exceptions to the enforcement of assignment agreements, particularly in instances, such as the case in Grocela, where the invention takes place outside the place of employment and without employer resources.\textsuperscript{206} Statutes in seven states create limitations to invention assignment clauses.\textsuperscript{207} These statutes are generally modeled after

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\item \textsuperscript{200} Id. at *4 (citing National Dev. Co. v. Gray, 316 Mass. 240, 247 (1944)).
\item \textsuperscript{201} Id. at *5.
\item \textsuperscript{202} See Lobel, supra note 1, at 799 (discussing how “[e]ven more generally, the sense of wrong may come from the common practice of requiring employees to forfeit all future innovation through assignment agreements, effectively restricting them from later pursuing independent career paths, notwithstanding the fact that they were not hired to invent”). Cf. Birkinshaw, supra note 12, at 43 (advocating for an approach that firm innovation should involve all employees) with Stone, supra note 52, at 525 (identifying the tension between employees and employers as a fundamental different view of who “owns” knowledge acquired at work).
\item \textsuperscript{203} Grocela, 2012 Mass. Super. LEXIS 206, at *5.
\item \textsuperscript{204} See, e.g., Brown v. Alcatel USA, Inc., No. 05-02-01678-CV, 2004 WL 143521, at 2 (Tex. App. June 28, 2004) (holding that a unilateral contract “becomes enforceable if the party seeking to enforce the contract has performed, conferring even a remote benefit on the other party”).
\item \textsuperscript{205} Robert P. Merges, The Law and Economics of Employee Inventions, 13 HARV. J. L. & TECH 1, 8 (1999).
\item \textsuperscript{206} Howell, supra note 7, at 81. In the Grocela case, however, the Massachusetts court did not follow this standard. 2012 Mass. Super. LEXIS 206.
\item \textsuperscript{207} See N.C. GEN. STAT. ANN. §§ 66–57.1, 66–57.2 (West 2012); CAL. LAB. CODE §§ 2870–72 (West 2011); WASH REV. CODE §§ 49.44.140–150 (West 2008); KAN. STAT. ANN. § 44–130 (West 2008); DEL. CODE ANN. 19 § 805 (West 2006); MINN. STAT. ANN. § 181.78 (West 2006); 765 ILL. COMP. STAT. ANN. 1060/2 (West 2001) (indicating various examples of such limitations).
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Minnesota’s law. They do not confer specific rights on employees but limit the enforcement of the contract if such a contract attempts to bind employees beyond statute limitations. Generally, statutes modeled after Minnesota’s law prohibit employers from requiring invention assignment agreements unrelated to the employee’s work or the employer’s business. However, as seen in Grocela, the courts interpret this provision broadly. In that case the fact that an invention related to medical intervention was related to the hospital’s business even though it was not related to Grocela’s area of specialty and practice.

Statutes in two states – Utah and Nevada – take the pro-employer approach. In Utah, the statute permits employers to acquire rights to employees’ later inventions through invention assignment agreements, even if the invention is created outside of work on the employee’s own time. Nevada, however, eliminates the need for assignment agreements altogether. Employer ownership of inventions created while employed is the default status. The statute, passed by the state legislature in 2001, provides: “Except as otherwise provided by express written agreement, an employer is the sole owner of any patentable invention or trade secret developed by his employee during the course of the employment that relates directly to work performed during the course of the employment.”

Nevada’s approach is controversial. It represents the opposite of the basic premise of patent law that the Stanford v. Roche Court found so compelling: “rights to an invention belong to the inventor.” Undoubtedly, Nevada’s approach eases employers’ transaction costs of securing rights in employees’ inventions, but to what extent does it incentivize employees, the individuals employers rely on to create?

The facts of the Grocela case suggest that Grocela was more motivated to market and distribute his inventions than MGH. MGH assigned the rights of his earlier disclosed inventions to Grocela and he created a partnership to

208. Howell, supra note 7, at 89.
210. Howell, supra note 7, at 89.
212. Howell, supra note 7, at 89.
215. See Mary LaFrance, Nevada’s Employee Inventions Statute: Novel, Nonobvious, and Patently Wrong, 3 Nev. L.J. 88, 88 (2002) (stating that “Nevada has become the only state that allows ownership of patentable inventions to be transferred from one party to another in the complete absence of an assignment agreement, and without any form of actual notice to the transferor”).
216. Stanford, 131 S. Ct. at 2192.
further the inventions to market.\textsuperscript{217} Although MGH’s Policy adequately protected its rights in employees’ inventions, the system may not adequately promote innovation and provide incentives to physicians to innovate.\textsuperscript{218}

As one scholar notes, patent rights are more focused on invention than the factors that lead to true innovation: “implementation, replication, and extension of new technologies.”\textsuperscript{219} The patent system relies on market-forces to move an invention from idea to innovation.\textsuperscript{220}

\textbf{A. Protecting the Process of Innovation}

A lack of clear incentive to innovate when the need for innovation is so great, particularly in the health care industry, should prompt legislatures to explore other approaches.\textsuperscript{221} In the same way that the AIA changed United States patent law from a “first to invent” country to a “first to file” country in order to align with most other patent systems around the world,\textsuperscript{222} it is important to consider how other industrialized countries approach the issue of the ownership of intellectual property created by employees. Japan and Germany provide two examples of legal approaches to invention assignment agreements that differ from the United States’ state-based contract law system.\textsuperscript{223}

Japan, unlike the United States, has a uniform approach to assignment agreements through a law that covers both private and public employers.\textsuperscript{224} Japan’s law restricts pre-invention assignment agreements so that they only apply to inventions that result from the employee’s duties and relate to the employer’s business.\textsuperscript{225} Furthermore, the employer only obtains a non-

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\item \textsuperscript{217} Grocela, 2012 Mass. Super. LEXIS 206, at *2 (describing an employer-employee transaction where invention rights were returned to the inventor in exchange for future royalties from sales).
\item \textsuperscript{218} See Sawicki, supra note 10, at 683 (predicting the spread of talent-driven hires focused on the acquisition of intellectual property rights to industries focused on technology development).
\item \textsuperscript{219} Lee, supra note 24, at 34-35.
\item \textsuperscript{220} Id. at 35.
\item \textsuperscript{221} But see Lemley, supra note 8, at 492–94 (discussing whether IP theory is wrong about what motivates people to create).
\item \textsuperscript{222} See supra notes 118–124 and text accompanying.
\item \textsuperscript{223} A thorough comparison of Japanese and German law regarding invention assignment agreements is beyond the scope of this chapter but a brief overview offers a perspective on the issue of motivating innovation.
\item \textsuperscript{224} Vai Io Lo, Employee Inventions and Works for Hire in Japan: A Comparative Study Against the U.S., Chinese and German Systems, 16 TEMP. INT’L & COMP. L.J. 279, 291 (2002).
\item \textsuperscript{225} Henrik D. Parker, Reform for Rights of Employed Inventors, 57 S. CAL. L. REV. 603, 616 (1984).
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exclusive license on the patent.\footnote{Lo, supra note 224, at 282.} The employee may elect to assign the rights to obtain the patent to an employer and may choose to grant an employer an exclusive license to the invention, but the employer must pay reasonable compensation to receive this assignment of rights.\footnote{Id.} Reasonable compensation is based on two factors: profit the employer will derive from the invention and the contribution the employee has made to the completion of the invention.\footnote{Id. at 284.}

German patent law includes fundamental ownership rules that are substantially similar to the ownership rules in U.S. patent law.\footnote{Id. at 284.} The major difference, however, is that Germany supplemented its patent law with the Employee Invention Act (EIA) to balance the tension between patent law and labor and employment law.\footnote{Id. at 284.} Pursuant to the EIA, employers obtain ownership in inventions made by employee-inventors, but protect the employees’ rights to reasonable compensation.\footnote{Id. at 284.} The compensation is a share of the value of the invention in addition to salary.\footnote{Id.} In practice, some commentators note, due to the lack of definition or agreement to “reasonable compensation,” many employee-inventors are left without a clear avenue for enforcing their rights.\footnote{Id. at 43–44.} Also, this compulsory license mechanism of the EIA eliminates freedom of contract between the employee and employer with regard to invention assignments.\footnote{Id.} Nonetheless, it is useful to consider the role of compensation related to the value of the invention, or the profit the employer could earn from the invention, to motivate employees to innovate. Similar compensation or reward systems exist in other countries

\begin{itemize}
  \item 226. Lo, supra note 224, at 282.
  \item 227. Id.
  \item 229. See generally Takenaka, supra note 114, at 310 (discussing German laws pertaining to invention ownership).
  \item 230. Id. at 284.
  \item 231. Id.
  \item 232. Merges, supra note 205, at 43.
  \item 233. Id. at 43–44.
  \item 234. Id.
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that grant a significant number of patents.\textsuperscript{235}

If \textit{Stanford v. Roche} created uncertainty related to the Bayh-Dole Act’s role in intellectual property development and ownership, it also created an opportunity to consider what legislative changes could better motivate innovation, particularly in the health care industry. One global perspective is that innovation may require a compensation system for employee-inventors as is common for employee-inventors in Japan and Germany.\textsuperscript{236} Of course, there are examples of United States employers that have instituted a compensation incentive to innovation. The University of California system and other academic systems offer employee-inventors royalty-sharing plans.\textsuperscript{237} A system that extends the royalty sharing with other employee incentives could offer the motivation necessary to advance innovation, particularly for the new health care environment of major hospital systems built around an academic medical center. However, not all innovation experts agree.\textsuperscript{238}

Research in behavioral economics suggests that motivation for innovation decreases if large incentives are offered.\textsuperscript{239} Rather than focus on external rewards such as compensation to motivate innovation, the better motivator is recognition.\textsuperscript{240} However, assignment agreements do not permit innovators to “participate in the process” of developing intellectual property.\textsuperscript{241} The facts of \textit{Grocela} documented that Dr. Grocela turned over inventions only to wait to see if the hospital system developed them in any way. On three different instances, he requested the hospital return his rights to allow further development.\textsuperscript{242} Innovation is a process that does not end with the “good idea.”

If health care systems want their health care providers to innovate, the systems must stop emphasizing the contracting for knowledge ownership that these broad assignment agreements represent. Instead, rather than contracting for knowledge ownership, the systems must think about

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\item \textsuperscript{235} See \textit{Lobel}, \textit{supra} note 1, at note 148 (noting that “Germany, the United Kingdom, France, and Finland all require fair compensation to the employee for any assigned invention” and that “China and Japan similarly guarantee employee-inventors a reward for assigned work”).
\item \textsuperscript{236} See \textit{supra} notes 225–228 and text accompanying.
\item \textsuperscript{237} Kamprath, \textit{supra} note 113, at 196 (noting that “[c]ompulsory royalty sharing plans may appear to be fairer to the employee-inventor, but they suffer from some of the same problems as other employer-defined compensation systems: the employer totally controls the system and the employee-inventor has no recourse if left out in the cold”).
\item \textsuperscript{238} See, \textit{e.g.}, Birkinshaw, \textit{supra} note 12, at 48 (stating “Myth # 4. Pay is Paramount”).
\item \textsuperscript{239} \textit{Id}.
\item \textsuperscript{240} \textit{Id}. (noting that recognition and engagement such as participating in presenting ideas to senior management are better rewards for ideas than pay).
\item \textsuperscript{241} See \textit{supra} notes 122–123 and text accompanying.
\item \textsuperscript{242} \textit{Grocela}, 2012 Mass. Super. LEXIS 206, at *2.
\end{itemize}
knowledge as Nobel Laureate Elinor Ostrom encouraged — as “a shared resource, a complex ecosystem that is a commons...”

Not only does this relieve the tension that Katherine Stone identified which is caused by violation of the psychological contract, but it also encourages participation in the true nature of innovation: the process. Legislatures must recognize assignment agreements as restrictive covenants with long-term implications not only on employee mobility but also innovation and courts must interpret assignment agreements narrowly to achieve the mutually beneficial result of knowledge as a shared resource rather than an owned resource.

Practically then, assignment agreements with health care providers who are not hired to research or invent but rather to provide patient care, should be negotiated contracts and not a unilateral contract embedded in intellectual property policies. Giving innovative employees the opportunity to negotiate their part in the process results in more motivation to invent and more emphasis on the on-going nature of innovation. Negotiating assignment agreements allows implicitly for recognition of the innovative work of employees and this negotiation, in and of itself, provides greater incentive for the provider to innovate. Innovative employees may require monetary reward or compensation as part of negotiated assignment agreement, which, in turn, increases the short-term cost of innovation for the health care system. However, it also provides greater incentive for that provider to participate in the process of negotiating, which suggests better long-term financial results for the system.

In addition to negotiated agreements, legislatures should narrow the scope of assignment agreements similar to the trend of narrowing application of covenants not to compete and other restrictive covenants that unreasonably bind employees’ mobility. The expanding scope of assignment agreements to include ideas and concepts prior to employment as well as hold-over clauses for future inventions bind not only employee mobility but creative mental processes. Firms certainly contribute to the development of ideas through learning on the job but that contribution cannot negatively impact the innovation process itself well into the future. Firms have a right to reduce uncertainty through contract but they do not have a right to stifle innovation that benefits society as a whole.

244. Stone, supra note 52, at 525; see also supra notes 52–53 and text accompanying (discussing this concept).
245. See supra notes 189–192 and text accompanying (providing relevant case law).
246. See Lemley, supra note 8, at 492–94 (concurring with this assessment).
247. See generally Bishara, supra note 14, at 288–90 (discussing restrictive covenants impacting mobility). See also supra notes 54–55 and text accompanying (discussing restrictive covenants and their potential implications).
CONCLUSION

Who owns knowledge? This article traced the growing trend to contract against uncertainty in the information age so that firms may more effectively collaborate. However, it outlined that such strategic contracting is binding employees in broad assignment agreements that allow firms to own human capital of employees not hired to invent — in other words, knowledge itself. This growing practice in health care systems has a uniquely detrimental impact on the health of patients in the system but also the United States economy because health care spending involves increasing percentage of GDP.

The impact of consolidation in the health care industry results in hospital systems focused on monetizing innovation rather than incentivizing innovation and the Supreme Court’s interpretation of the Bayh-Dole Act only encouraged a greater need for broad assignment agreements. As health care systems claim ownership of health care provider ideas, the process of innovation is turned on its head. This article argues that incentive to innovate is encouraged by negotiated assignment agreements that recognize the health care provider’s part in the process of innovation. It further encouraged courts and legislatures to narrow the permitted scope of such agreements to the knowledge providers acquire directly though their work responsibilities limited to the time of employment.