Industry, universities, and intellectual property

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Abstract

Recent decades have seen increased links between university and industry scientific discovery. This paper describes changes to intellectual property rights as they relate to industry-university ties, with a focus on the field of biotechnology. The paper proceeds in two parts: I first outline major court cases and legislation that changed university and/or biotechnology patenting and then explore the effects of those changes on scientific knowledge production.

Introduction

Longstanding views on the production of scientific knowledge distinguished ideas created in the private sector from those in academia. In introducing the term "Pasteur's quadrant" to refer to use-inspired (or translational) basic research, Stokes (1997) reframed the traditional classification of research as either purely for scientific interest or purely for commercial gain.[1] The dual use of knowledge thus allows for a single discovery to contribute to both scientific inquiry and commercial applications (Murray and Stern, 2007).

With legislative changes geared towards increasing US competitiveness and the growth of fields such as biotechnology, industries and universities have in fact become more closely tied over the past few decades. Industry-university links now take several forms: start-ups by researchers from academia; joint R&D collaborations by firms and academic scientists; or consulting work by faculty (Debackere and Veugelers, 2005).

In their review on university research and public-private interactions, Foray and Lissoni (2010) note

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[1] Research purely for scientific interest falls into "Bohr's quadrant" (pure basic) and research purely for commercial gain falls into "Edison's quadrant" (pure applied).

two tensions inherent in the growing ties between industry and academia: (1) an individual-level trade-off for scientists between basic research and commercializing academic inventions, and (2) a system-level trade-off between industry's need for clear intellectual property rights (IPR) versus the cumulative nature of science, which depends on accessibility to academic research. While knowledge in the private sector is generally protected by patents, knowledge in academia has typically been characterized by publication and disclosure (Murray, 2007).

This paper covers changes to IPR as they relate to industry-university ties, with a focus on the field of biotechnology. The paper is divided into two parts: Part 1 details the major court cases and legislation that reframed university and/or biotechnology patenting. Part 2 looks at impacts of these changing IPR on scientific knowledge production, outlining evidence on both the individual- and system-level trade-offs that come with increased industry-university scientific collaboration.

Part 1: Key court cases and legislation

The Patent Act of 1790 is the first US patent statute. According to its Section 101, claimed inventions must meet the definition of patentable subject matter: "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[2] The development of biotechnology required rethinking of patent law; several important court cases and legislation relevant to university and/or biotechnology patenting are discussed below.

1.1 Diamond v. Chakrabarty (1980)

In 1972, microbiologist Ananda Chakrabarty filed a patent on a genetically engineered bacterium to treat oil spills. The patent examiner rejected his claim on the grounds that (1) microorganisms are "products of nature" and (2) living things are not patentable.[3] The USPTO Board of Appeals affirmed the examiner's decision, but the United States Court of Customs and Patent Appeals reversed, with the case then reaching the Supreme Court (Robinson and Medlock, 2005).

The Supreme Court heard *Diamond v. Chakrabarty* in 1980, ruling that genetically engineered microorganisms are patent eligible under Section 101 of the Patent Act. In a five-to-four decision, the Court concluded that a patent may be obtained on "anything under the sun that is made by man."[4] Chakrabarty had produced a new bacterium "with markedly different characteristics from any found in nature and one having the potential for significant utility"; as such, his invention was patent eligible.[5]

[2] 35 U.S.C §101.
[3] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[4] Ibid.
[5] Ibid.

Diamond v. Chakrabarty, in conjunction with the Bayh-Dole Act described below, allowed for the issuance of thousands of new patents and stimulated growth in the emerging biotechnology industry (Robinson and Medlock, 2005).

1.2 Bayh-Dole Act (1980)

The Patent and Trademark Laws Amendment, more commonly known as the Bayh-Dole Act, changed university incentives to patent by allowing universities to own the patents that arise from federal research grants and the discretion to issue exclusive licenses. Lawmakers believed this change to patent law would motivate private investors to support university discoveries after government sponsorship ended, improve the translation of those university discoveries into new commercial products and industries, and increase US competitiveness (Rai and Eisenberg, 2003).[6]

Following the Bayh-Dole Act, the number of US patents awarded to university inventors annually increased from 500 in 1982 to 3255 by 2006 (Lach and Schankerman, 2008). What is less clear is whether this rise in patent activity should be attributed to the Bayh-Dole Act or to simultaneous progress in the biotechnology and software fields (Foray and Lissoni, 2010). Part 2 details several empirical studies evaluating the impacts of the Bayh-Dole Act on university patenting.

1.3 Madey v. Duke (2002)

Anyone who uses a patented invention without authorization may be liable for patent infringement, except in the case of experimental use. The experimental use doctrine in patent law provides protection from infringement claims for those who use patented inventions solely for non-commercial experimental purposes, such as testing whether an invention works as claimed or scientific inquiry (Cai, 2004).[7] In *Madey v. Duke University*, Professor John M. J. Madey sued his former employer Duke for patent infringement on equipment in his laboratory that he invented and patented, and that Duke continued to use after his departure from the university.[8] Reversing a district court decision that Madey had failed to prove Duke's use of his equipment was not experimental, the Federal Circuit held: (1) The experimental use defense must be proven by the defendant; (2) the district court's definition of the experimental use defense was "overly broad"; and (3) the district court overly weighted Duke's nonprofit status (Cai, 2004).

The Federal Circuit determined that irrespective of an entity's commercial status, an alleged infringement does not meet the experimental use defense if it is (1) "in furtherance of the alleged infringer's legitimate business"; and (2) "not solely for amusement, to satisfy idle curiosity, or for

[6]The Stevenson-Wydler Technology Innovation Act (1980) preceded the Bayh-Dole Act and enacted similar provisions for scientists working in federal laboratories, including at the National Institutes of Health.

[7]The experimental use doctrine is also referred to as the experimental use exemption or the research exemption.

[8]Madey v. Duke University, 307 F.3d 1351 (2002).

strictly philosophical inquiry".[9] While research universities often conduct research projects with no commercial application, these projects still "further the institution's legitimate business objectives, including educating and enlightening students and faculties participating in these projects."[10] The ruling thus narrowed the experimental use doctrine and prevented its use as a defense for universities in patent infringement cases (Saunders, 2003).

1.4 Stanford v. Roche (2011)

Supreme Court case *Stanford v. Roche* upheld that title to inventions belongs to inventors, even under Bayh-Dole when the inventor is a researcher at a federally funded lab. Prior to the passage of the Bayh-Dole Act, patents resulting from federally funded research were owned by the United States.

The case involved patents Stanford held on an assay to measure the effectiveness of AIDS therapies. It was developed using polymerase chain reaction (PCR) technology created by scientists at Cetus, subsequently bought by Roche. A Stanford research fellow had spent time at Cetus in order to learn how to use PCR and then returned to Stanford where he developed the assay. The research fellow had signed agreements with both Cetus and Stanford assigning his rights and title to any inventions to those institutions while working there. When Stanford attempted to license the patents and Roche refused to take a license, Stanford sued Roche for patent infringement. The Supreme Court ultimately ruled that the Bayh-Dole Act does not vest initial title to patents from federally funded research to universities. As such, Stanford's claim to the patent was invalidated by Roche's claim to it (Hagelin, 2011).

1.5 America Invents Act (2011)

Signed into law on September 16, 2011 by President Barack Obama, the Leahy-Smith America Invents Act (AIA) changed the US patent system from a first-to-invent (FTI) system to a first-inventor-to-file (FITF) system (with a grace period). In doing so, the US patent system became more similar to the European system.

The FTI system prior to the AIA awarded patents to the first person to invent something, rather than the first to file a patent application. Under the AIA's FITF system, if another person discloses an invention first, e.g. in a scientific publication, then no one else may patent it. Inventors who describe an invention first in a publication have 12 months to file their patent application. The AIA also provides 6 months from the publication of a patent application *by others* for inventors to submit prior art—such as scientific journal articles—that the patent examiner should consider.

[9] Ibid.
[10] Ibid.

Previously, this period was only 3 months. As such, the new law creates a hybrid "first to file or publish" rule (Austin, 2012). Nonetheless, because the European Patent Office does not allow such a grace period for the first to publish, scientists wanting to protect their inventions in Europe and other places in the world would still need to file their patents first. Finally, the AIA also allows for a 9-month period after a patent is granted in which other parties may request a post-grant review, making patent challenges easier and cheaper to file (Austin, 2012; Sherkow and Scott, 2015).

1.6 Association for Molecular Pathology v. Myriad Genetics, Inc. (2013)

Are human genes patentable? This was the question before the Supreme Court in the 2013 case *Association for Molecular Pathology v. Myriad Genetics, Inc.* For roughly three decades beforehand, US courts had expanded the scope of patentable subject matter; this expansion coincided with growth in the field of biotechnology. Gene patents were issued under recognition of the time and resources necessary for processes such as the isolation of genes. But as the technology to isolate and sequence DNA became simpler and less expensive, concerns grew regarding the potential negative consequences of these patents (Ghosh, 2017).

In *Myriad*, patients, physicians, and advocacy groups challenged a research laboratory's patents for isolating deoxyribonucleic acid (DNA) in genes and creating composite DNA (cDNA).[11] In particular, Myriad Genetics had patented the BRCA1 and BRCA2 gene mutations that predispose individuals to breast and ovarian cancer, and these patents underlay its commercial genetic test. Critics objected to Myriad's restrictions on the use of its genes in research and to the high price of the Myriad genetic test, even when advances in sequencing technology had decreased costs substantially (Kesselheim et al., 2013).

A unanimous Court ruled that "naturally occurring" DNA segments such as the BRCA1 and BRCA2 gene mutations are not patent eligible, even if isolated from the surrounding chromosome; cDNA was patent eligible because it was not naturally occurring. With *Myriad*, the Court invalidated thousands of gene patents that had been issued previously (National Library of Medicine, 2019); genes are not patentable because they are "products of nature."[12]

Part 2: Impacts on scientific knowledge production

The court cases and legislation described above, combined with increased industry-university links, have altered the process of scientific discovery and the ownership rights to those discoveries. Below I describe some of the extant literature investigating resulting impacts on scientific knowledge production, with a focus on two trade-offs: (1) an individual-level trade-off for scientists between basic

[11] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[12] Ibid.

research and commercializing their inventions and (2) a system-level trade-off between industry's need for IPR versus the cumulative nature of science which emphasizes free sharing of discoveries.

2.1 Individual-level trade-off for scientists

I outline four key papers evaluating effects of the Bayh-Dole Act on the rate and direction of university patenting. Henderson et al. (1998) construct measures of patent "importance" and "generality" to explore the change in quality of university patents surrounding the act. They find that the relative importance and generality of university patents fell simultaneously as the overall number of university patents rose. Before the mid-1980s, university patents were more highly cited (i.e. more important) and more general than a random sample of all patents, but that difference disappeared over time. The authors suggest an observed increase in university patenting between 1965 and 1988 thus reflects an increased "propensity to patent" rather than an increase in important inventions.

Thursby and Thursby (2002) investigate whether the growth in technology transfer through university licensing reflects a change in the nature of university research. They develop a model to understand the extent to which licensing growth is due to the productivity of observable inputs or to changes in the propensity of faculty and administrators to license. They use data from two surveys: (1) a survey of US universities and their technology transfer activities and (2) a survey of businesses that licensed university inventions. Although they cannot reject the hypothesis that faculty research has shifted, their results suggest that such shifts in research direction are less important than other factors, including the propensity to patent and license. While academic research did not shift from basic to applied, an increase in patenting efforts resulted in even minor inventions being patented.

Mowery and Sampat (2005), however, suggest the Bayh-Dole Act had minimal effects. They note that the increase in aggregate university patent propensity found by Henderson et al. is a continuation of a trend beginning prior to the act. They show that universities increased their share of patenting from less than 0.3 percent in 1963 to nearly 4 percent by 1999, but the growth rate in patenting share begins accelerating before 1980. Mowery and Sampat also note that lobbying by research universities aided in the passage of the Bayh-Dole Act, and thus the act is "as much an effect as a cause of expanded patenting and licensing by US universities during the post-1960 period" (p. 119). In summary, they write that the act appears "neither necessary nor sufficient" for the growth in university patenting (p. 125). Further, increased university patenting does not necessarily mean that university research is actually being commercialized into products.

Looking at individual incentives for scientific production, Lach and Schankerman (2008) evaluate how cash flow rights from university inventions (i.e. the share of license royalties received by academic inventors) affect the licensing income generated by universities. Under Bayh-Dole, royalty income from any invention is shared between the inventor and the university according to negotiated royalty sharing agreements. Exploiting cross-sectional variation in these agreements across

universities and using pre-sample data on university patenting to proxy for a university's fixed effect, they determine that US universities offering stronger royalty incentives to faculty scientists generate greater licensing income.[13] The incentives include both cash and research lab support, suggesting both monetary and non-monetary research motivations, and their main impact is via an increase in quality rather than quantity of inventions.

2.2 System-level trade-off

One issue with industry-university collaboration for science concerns *who should decide* which discoveries to patent and which to make freely available. Rai and Eisenberg (2003) argue that federal agencies have more appropriate knowledge and incentives to decide what scientific discoveries should be available in the public domain, and thus the Bayh-Dole Act should be reformed so that these agencies have greater discretion to decide when publicly funded research discoveries are patentable or not. Their argument is based, in part, on the key role in patenting and licensing played by university technology transfer professionals who are not academics. They contend that downstream patents built off of publicly available basic research will be more important in incentivizing private firms to develop end products than upstream patents on research discoveries owned by a university. They are particularly concerned by upstream patents on early-stage or basic research discoveries that open up new fields of scientific inquiry, such as the discovery of embryonic stem cells.

However, other studies indicate that federal agencies may not choose optimal research projects. (Moses et al., 2015) find that public funding of medical research is only marginally associated with disease burden in the United States. Private funding of medical research may also be associated with sub-optimal societal outcomes (Krimsky, 2004).

A second issue concerns *which discoveries should be patentable* versus which should be freely available to other researchers. The phrase "tragedy of the commons" describes the overuse of shared resources when people have no incentive to conserve (Hardin, 1968).[14] Heller and Eisenberg (1998) coined a reverse problem as a result of the privatization of biomedical research: the "tragedy of the anticommons."

While in the case of a tragedy of the commons many owners each have a right to use a certain resource and no one can exclude any other individual's use of that resource,[15] a tragedy of the

[13] In order to make more definitive causal conclusions, the authors acknowledge they would need more time series variation in royalty shares or the availability of instruments that influence royalty shares but not licensing income.

[14] British economist William Forster Lloyd first described in the 1830s the typical example of overgrazing of a common pasture, i.e. the commons, that is owned by no one but available to all. Each villager allows her cows to graze on this unregulated commons. By adding an additional cow, a given villager receives all the incremental benefits of the cow, but since the negative overgrazing is shared by all, only a fraction of the consequences. The economically rational villager continues adding cows, as do all other villagers, eventually leading to the complete destruction of the commons (Lloyd, 1980).

[15] For example, Hardin (1968) explained overpopulation, air pollution, and species extinction all as tragedies of

anticommons results when "multiple owners each have the right to exclude others from a scarce resource" (Heller and Eisenberg, 1998, p. 698). In the case of biomedical research, Heller and Eisenberg contend that IPR for key basic scientific discoveries are so fragmented into patents by many different owners that this patent thick may prevent further discoveries down the road. Costs of obtaining necessary licenses from multiple owners may hinder a researcher's ability to advance a scientific line of inquiry, the authors being particularly concerned with the impact on downstream medical innovations.

Murray and Stern (2007) empirically evaluate whether a tragedy of the anticommons exists in biotechnology research; they explore how IPR over a piece of knowledge may impact future scientific research. Given the dual use of knowledge, scientists may have multiple disclosure options for a given discovery, including both academic research publications and patents providing IPR over the underlying knowledge. Using patent-paper pairs in biotechnology and a difference-in-differences empirical strategy, they find a modest anticommons effect to subsequent citations on the order of 10 to 20 percent. However, the authors note that their approach does not quantify the positive impact of IPR on research incentives, e.g. for the scientist making the initial discovery, nor does it identify the mechanism behind the citation reduction. Rather than IPR themselves generating a decrease in follow-on research, the decline may stem from specifics surrounding transacting with intellectual property owners, such as complicated licensing agreements or delays in negotiations for material transfer.

Conclusion

The nature of scientific discovery, particularly in biotechnology, has changed in the last few decades. Foray and Lissoni (2010) write: "[S]cience-driven R&D requires that firms should become participants in science rather than mere users of scientific knowledge" (p. 287). As such, industry-university links have increased with respect to the production of science. In this paper, I outline how IPR between industry and university have evolved over time, in particular to how they relate to biotechnology. I then explore the resulting impacts on scientific knowledge production, focusing on (1) an individual-level trade-off for academic scientists between basic research and commercializing inventions and (2) a system-level trade-off between industry's need for IPR versus the cumulative nature of science built upon freely available basic research.

At the individual level, the extant literature suggests an increase in the rate of university patenting following the implementation of Bayh-Dole, yet this rise may have been the continuation of an earlier trend. At the system level, questions remain regarding what types of discoveries should be made freely available and who should make those decisions.

the commons.

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