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Geistiges Eigentum und Wettbewerbsrecht
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Mohr Siebeck

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Anna Marion Bieri

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The Interdependence between Patent Law, Science, and Research Universities in the United States of America

Mohr Siebeck

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To my parents

Preface

This work was accepted as a doctoral thesis by the University of Bayreuth in the winter semester 2020/2021.

Over several years this project accompanied me on the side of my teaching and research appointment at a research university in the US. Its completion would not have been possible with the support and encouragement of many people.

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Blacksburg, February 2022 Anna Marion Bieri

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Abbreviations

AAU	Association of American Universities
AAUP	Association of American University Professors
AAAS	American Association for the Advancement of Science
AEA	Atomic Energy Act
ArbnErfG	Arbeitnehmererfindergesetz
AUTM	Association of University Technology Managers
BDA	Bayh-Dole Act
BLK	Bund-Länder-Kommission für Bildungsplanung und Forschungsförderung
BMBF	Bundesministerium für Bildung und Forschung
CAFC	Court of Appeals for the Federal Circuit
CFR	Code of Federal Regulations
CPA	Copyright and Patent Agreement
DOD	Department of Defence
EPO	European Patent Office
EPFL	École Polytechnique Fédérale de Lausanne
ETH	Eidgenössische Technische Hochschule
FCST	Federal Council for Science and Technology
FIFG	Bundesgesetz über die Förderung der Forschung und der Innovation
GAO	US General Accounting Office
HERD	Higher Education Research Expenditures
HEW	Department of Health, Education, and Welfare
HFKG	Bundesgesetz über die Förderung der Hochschulen und die Koordination im schweizerischen Hochschulbereich
HHMI	Howard Hughes Medical Institute
HHS	Department of Health and Human Services
IPA	Institutional Patent Agreement
IPI	Swiss Federal Institute of Intellectual Property
NACU	National Association of College and University Attorneys
NAS Act	National Aeronautics and Space Act
NCES	National Center for Education Statistics
NIH	National Institute of Health
NIST	National Institute of Standards and Technology
NLRB	National Labor Relations Board
NRC	National Research Council
NSF	National Science Foundation
NZZ	Neue Zürcher Zeitung
MPEP	Patent Office Manual of Patent Examination Procedure
OECD	Organisation for Economic Co-operation and Development
PAE	Patent Assertion Entity
PatG	Patentgesetz

PCR	Polymerase Chain Reaction
PCT	Patent Cooperation Treaty
PGO	Patent Grant Opposition
PVA	Patentverwertungsagenturen
R&D	research and development
STEM	Science, Technology, Engineering, Math
SWITT	Swiss Technology Transfer Association
TTO	Technology Transfer Office(s)
USC	United States Code
USPTO	United States Patent and Trademark Office
VCA	Visitor Confidentiality Agreement
WARF	Wisconsin Alumni Research Foundation

Introduction

A Research Questions

America's research universities[1] often receive the highest praise in policy discussions: They are considered to be the cornerstone of the 'nation's intellectual infrastructure'[2], the guarantor of 'the high American standard of living'[3], and a 'miracle machine', which has produced 'a torrent of discoveries and trained generations of scientific talent'[4]. While there are numerous accounts of this miracle machine laying the foundation for successful commercial products and business ventures, it also is generally undisputed that one of research universities' key contribution to society remains the search for and dissemination of knowledge – whether commerciable or not.

The transfer of such knowledge from universities to society has historically occurred via traditional transfer channels, such as publications, conferences, by educating and training students, and via consultations, collaborations, and informal exchanges with industry. For a long time, the use of patents (and other intellectual property rights) to transfer knowledge to the outside world has generally not been considered appropriate, mainly because the legal protection and commercialisation of university-developed research results was viewed to be in conflict with the academic mission and its commitment to open science.

The resistance to patents in academia has continuously crumbled over the course of the past century – first very slowly and cautiously but in the past four decades ever more vigorously. In this sense, the 1980 Bayh-Dole Act (BDA)[5] – which allowed universities to retain title to federally funded inventions in order to facilitate their commercialisation – represents the legislative culmination of a gradual process during which the production of scientific knowledge and its

[1] For simplicity, in this work 'research university' refers to institutions in the R1 category of the Carnegie Classification, which stands for doctoral universities with a 'very high research activity', also see infra n. 85.

[2] American Academy of Arts and Sciences, *Public Research Universities* (2017) 5.

[3] NRC, *Research Universities* (2012) ix.

[4] Lander and Schmidt, 'Miracle Machine' (*Washington Post*). It should be noted that in this description the authors include federally funded 'research centers' and point out that federal investment in science and technology is essential as well.

[5] Officially called Universities and Small Business Patent Procedures Act, Public Law 96–517, 94 Stat. 3015 (1980) (codified at 35 United States Code [USC] §§ 200–212).

legal protection have become increasingly intertwined. In doing so, the BDA has ushered in a new era for the strategic importance which patent considerations play in higher education. Influenced by continuous reduction in government spending in higher education, a pro-patent environment, and increasing (global) competition for students and faculty, research universities rely more heavily than ever on patents as a means of protecting and commercialising university research results.

This intertwinement of the institutions of the university and of patents raises two fundamental questions this work attempts to answer: Firstly, who owns federally and non-federally funded university inventions and who benefits from the current ownership regime? Secondly, who should benefit from university inventions and what does this infer for the ownership and the management of university inventions?

The ownership question is of significance in the discussions of the use of patents in academia for two distinct reasons. Firstly, the BDA's key policy assumption is that university ownership (rather than ownership of the government or private contractors) – coupled with patenting – is essential to the successful commercialisation of federally funded inventions. Secondly, in the past decades, universities have extended this logic to *all* university-generated inventions, and today claim ownership of inventions which are derived from federally funded and non-federally funded research.

This implies that the ownership combined with the use of patents is essential to the successful transfer of university inventions, but it also suggests that greatest benefit from university research is derived if such research will be developed into commercially marketable products. The two questions this raises is whether the BDA and universities' technology transfer practices undermine the larger value of university research as a public good to society and whether – in following these ownership- and patent-centred technology transfer practices – universities negate the importance of strategic considerations relating to the dissemination of university research through different transfer channels.

It should be noted that not included in this inquiry will be inventions which result from industry-sponsored research. From universities' earliest involvement with patents, universities have traditionally excluded the application of their policies to industry contracts. This is still common practice today and universities usually negotiate such contracts – including the ownership of related inventions – on a case by case basis.

B Current State of Research

Extensive literature has been published on the topic of the BDA and on universities' patenting and licensing activities. At the most basic level, the literature may be divided in two large pools: on the one hand, there are the legal schol-

ars who have critiqued and analysed the Act's provisions, its implementation, and its impact on and correlation with aspects of US patent law.[6] On the other hand, there are the economists, policy and business scholars who have studied the Act's policy environment, its impact and the impact of universities' patenting and commercialisation activities' on the academic mission and the US economy.[7]

Despite this comprehensive discussion of the legal, economic, and policy aspects of the BDA and universities' patenting activities – and perhaps due to the wide-spread conception that the BDA was the cause of universities' engagement with patents – the large majority of the literature is concerned with universities' patenting activities as they relate to federally funded research only.[8] What is missing is a comprehensive discussion of universities' technology transfer practices (including their patent policies and assignment practices) as they relate to university research in general. Universities receive financial support and tax subsidies from federal and state governments beyond the receipt of federal grants for certain research projects. It thus seems important to assess the effect of university patenting in the context of this broader understanding of 'public funding' and against the background of universities' public role in society.

The focus on the totality of university research is vital as – prompted by the 2011 Supreme Court decision of *Stanford v. Roche*[9] – today universities' technology transfer practices generally do not distinguish between federally funded and non-federally funded inventions. While there has been a considerable amount of coverage of the legal implications of *Stanford*,[10] the history of universities' technology transfer practices against the backdrop of the BDA and *Stanford* and the consequences of the extension of the BDA-regime to all university inventions has not yet been addressed in detail by the literature.

Finally, several notable publications discuss universities' patenting activities and their increasingly business-minded and litigious behaviour and its effect on universities' open science culture and on society.[11] While scholars have proposed changes to the BDA (including enhancing the authority of the feder-

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[6] See e. g. Eisenberg (1996) 82 Va. L. Rev. 1663; Heller and Eisenberg (1998) 280 Science 698; Pulsinelli (2005) 7 Minn. J. L Sci. & Tech. 393; de Larena (2006) 43 Hous. L. Rev. 1373; Locke (2003) 8 Va. J. L. & Tech. 1; Gotkin, *Bayh-Dole Act* (2012).

[7] See e. g. Mowery and others, *Ivory Tower* (2004); Shane (2004) 19 J. Bus. Ventur. 127; Popp Berman (2008) 38 Soc. Stud. Sci. 835; Schacht, *Bayh-Dole Act* (2010); Thursby and Thursby (2003) 301 Science 1052.

[8] Notable exceptions are e. g. Chew (1992) 1 Wis. L. Rev. 259; Smith (1997) 1 Va. J. Law & Tech. 1; Luppino (2009) 78 UMKC L. Rev. 367.

[9] *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems*, 131 S. Ct. 2188, 2192 (S. Ct. 2011).

[10] See e. g. O'Connor (2011) 6 Intell. Prop. J. 29; Takenaka (2011) 44 Tex. Intell. Prop. L. J. 281; Hagelin (2011) 39 AIPLA Q. J. 335.

[11] See e. g. David and Hall, 'Property and the Pursuit of Knowledge: IPR Issues Affecting Scientific Research (2006) 35 Research Policy 767; R. Nelson (2001) 26 J. Tech. Transfer 13;

al government in overseeing universities[12]) and have suggested alternatives to the way universities' technology transfer operations are organised (including changes to the legal ownership of inventions[13]) to mitigate some of the issues that the current ownership regime and universities' patent-centred practices have caused, all proposals suggest a general solution to be applied comprehensively to all institutions.

In contrast, this work develops the perspective that a one-size-fits-all solution will not produce optimal results in terms of the protection of the scientific commons and in terms of the protection of the public interest. Instead, the view is developed that universities ought to approach their involvement with patents and the management of their research on a strategic level.

C Course of the Inquiry

Universities supply the public with the fundamental societal need of knowledge, and in turn have been accorded a special place in society. This special place is rewarded by universities receiving financial support, being exposed to reduced regulatory scrutiny and being exempt from certain taxes. By actively participating in patenting and licensing and other market-oriented activities, however, this special position universities maintain in society may be in peril. To develop an understanding of this seeming disparity between universities' public role and their increasingly business-minded behaviours, *Part I, Chapter 1* reviews the history of the US research university and assesses its regulatory and financial framework.

While research universities initially rejected any engagement with patents, some started to explore the use of patents in the first quarter of the 20th century. To appreciate why universities changed their approach to patents, additionally to the institution of the research university and its role in society, the institution of patents will also have to be examined. *Chapter 2* therefore studies the history of the protection of inventive activity and of US patent law and investigates the theories that underpin US patent law. Particular attention will be paid to the question of why research universities gradually let go of their objections to patents and to the policy arguments for and against university patenting.

Part II places emphasis on the discussion of the legal parameters of the ownership of university inventions. *Chapter 3* defines fundamental concepts, such

Mowery and others (2001) 30 Research Policy 99; Eisenberg and Cook-Deegan (2018) 147 Daedalus 76.

[12] See e. g. Nelson (2004) 33 Research Policy 455; Rai and Eisenberg (2001) Proc. Conf. on Pub. Domain 157; de Larena (2006) 43 Hous. L. Rev. 1373.

[13] Kenney and Patton (2009) 38 Research Policy 1407; Phan and Siegel (2006) 2 Found. Trends Entrep. 77.

as inventorship and ownership, and describes the inventor's central role in US patent law, while also pointing to the actual lack of protection of the inventor by the law. *Chapter 4* then investigates the legal parameters of the ownership of employee inventions under common law and under contract law and develops how these principles apply to university inventors. The discussion highlights universities' current practice of having researchers assign their inventions to the university in pre-invention assignment agreements on the outset of the employment. Finally, *Chapter 5* analyses the history and provisions of the BDA and studies the landmark Supreme Court decision of *Stanford v. Roche*. *Stanford* is of relevance because it emphasised – over 30 years after the passage of the BDA – that universities' interpretation of the Act and their technology transfer practices were not in accordance with the Act.

Part III attempts to analyse the impact the BDA and university patenting had on society and universities and attempts to define an approach to university patenting which is in alignment with research universities' public role. *Chapter 6* thus investigates the BDA's policy goals and its effect on the US economy and the academic research mission. But the analysis goes beyond the Act. Indeed, a distinction this work attempts to draw, is the one between the framework which the BDA attempted to establish, and the way universities interpreted and implemented the Act. This work will thus try to elaborate in what ways universities' patenting practices align or deviate from the Act's intent. In order to so, *Chapter 7* studies universities' past and current intellectual property policies and analyses universities' technology transfer practices. It also investigates the question of how important university ownership is to the successful transfer of university research and compares ownership regimes by examining – amongst other things – Germany's and Switzerland's approach to university patenting.

Finally, *Chapter 7* concludes by proposing a three-pronged solution to the problems the university ownership regime and universities' current technology transfer practices pose, which includes amendments to the BDA, a call for universities to become strategic in regard to how they 'manage' their university inventions and university research in general, and last but not least, a suggestion for state governments to hold universities accountable for how they manage university research.

Part I

University Inventions in History

Chapter 1

The Rise of the Modern Research University

While US research universities today are often associated with the generation of commerciable knowledge, research universities' fundamental role in society goes beyond this. Their important function as the key supplier of scientific knowledge[1] will be examined in detail in this chapter. In order to do so, firstly, the historic origin of the modern research university in Europe – which provided the basis upon which the US research university was built – will be reviewed. Secondly, it will be studied how the US landscape of higher education evolved. Thirdly, the modern US research university including its regulatory and financial framework and its contemporary challenges will be analysed.

A The Research University's Continental European Origin

In Europe, the 19th century was marked by the resurrection of the modern research and teaching university as an institution. In this process, the university transitioned from its role as the steward and disseminator of a predominately stagnant body of knowledge to its new role as the generator of new knowledge through research.[2] The new ideal of a scientific interpenetration of the world and a quickly expanding scientific knowledge base generally presented a fundamental challenge to the often rigidly organised curricula and institutional structure of universities. As a consequence, the scientific revolution frequently took place outside academia and – with a few exceptions – universities continued to teach their existing curricula in the arts, theology, law, and medicine and only gradually caught up with the new knowledge base.[3]

While in many countries the 'old universities' eventually managed to integrate the new material, this happened in different ways and at different speeds

[1] While there is often a distinction made between the production of new *scientific* knowledge (referring to a discovery) versus new *technical* knowledge (referring to an invention), for the purpose of this work this specific distinction will be ignored and scientific research, scientific knowledge, and university research are all understood to refer to scientific and technical knowledge developed at universities.

[2] See e. g. Asche and Gerber, in *Enzyklopädie der Neuzeit Online* (2012) 10; Perkin, in *Higher Education* (2007) 159, 172–173.

[3] Asche and Gerber, in *Enzyklopädie der Neuzeit Online* (2012) 9–10; Perkin, in *Higher Education* (2007) 159, 173–175.

in different countries. In many instances, the initial inability to respond to the changes also led to the founding of technical schools, which would teach relevant applied science and technology.[4] The examples of France and Germany will be discussed in more detail below before the discussion will turn to developments in the US. France's solution focused on the founding of specialised schools, while in Germany a new idea of the university which centred on the unity of the social and natural sciences emerged.

In 1794 in France, universities – which increasingly were perceived as pillars of the old regime – were replaced with a single school: the *École Polytechnique*. The main purpose of the *École Polytechnique* was to educate senior members of the state's technical services. Technical schools which were already in existence (e. g. *École des Mines, École des Ponts et Chaussées, and the École de Génie Maritime*) were eventually linked to the *École Polytechnique* and became the so-called *Écoles d'Application*. These schools provided practical training in individual engineering disciplines and could only be entered into once the general education at the *École Polytechnique* was completed.[5]

In 1929, the French system of higher education was supplemented with the *École Centrale des Arts et Manufactures* in Paris, which was founded on the initiative of a private entrepreneur as a response to demands in industry for trained engineers.[6] During the early 19th century, the French '*Grandes Écoles*' were highly regarded and Paris became the centre of science, attracting scientists from around the world.[7] The French model was not only exported to the French colonies but also inspired *Hautes Écoles* in Belgium and served as a model for other similar institutions, such as the *Technische Hochschulen* in Germany, as will be discussed below.

France also re-introduced universities and yet again, the solution was a nationally unified approach. Accordingly, in 1808 *Napoleon* created the *Université de France* (also called *Université Impériale* or simply *l'Université*): a single, unified organisation with faculties in medicine, law, letters, and science which would serve the whole nation.[8] The landscape of higher education in France continued to be subject to political and intellectual changes throughout the 19th century, which explains its fragmentation and specialisation which remained a characteristic feature until today.[9]

Similarly, in Germany towards the end of 18th century and the beginning of the 19th century, ever more voices also demanded the abolishment of exist-

[4] Perkin, in *Higher Education* (2007) 159, 174–175.

[5] Grelon, in *Industrial Performance* (1993) 42, 42; Weber, *Geschichte der Europäischen Universität* (2002) 154; Charle, in *A History of the University in Europe* (2004) 33, 34.

[6] Grelon, in *Industrial Performance* (1993) 42, 43.

[7] See e. g. Moraw, *Universität Giessen* (1990) 136; one such German scientist was the chemist *Justus Liebig*, see ibid. Also see infra n. 27–31/I and accompanying discussion.

[8] Clark, *Places of Inquiry* (1995) 92.

[9] Charle, in *A History of the University in Europe* (2004) 33, 34.

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