February 26, 2015

Promoting "Academic Entrepreurship" in Europe and the United States: Creating an Intellectual Property Regime to Facilitate the Efficient Transfer of Knowledge from the Lab to the Patient

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Promoting "Academic Entrepreneurship" in Europe and the United States: Creating an Intellectual Property Regime to Facilitate the Efficient Transfer of Knowledge from the Lab to the Patient

by Constance E. Bagley* & Christina D. Tvarnø**

Abstract

In 2014, the European Commission announced the launch of a study of knowledge transfer by public research organizations and other institutes of higher learning "to determine which additional measures might be needed to ensure an optimal flow of knowledge between the public research organisations and business thereby contributing to the development of the knowledge based economy." As the European Commission has recognized, the EU needs to take action to "unlock the potential of IPRs [intellectual property rights] that lie dormant in universities, research institutes and companies." This article builds on our earlier work on structuring efficient pharmaceutical public-private partnerships (PPPPs) but focuses on the regulatory infrastructure necessary to support the efficient commercialization of publicly funded university medical research in both the European Union and the United States. Our comparative analysis of the EU and U.S. approaches to translational medicine shows that there are lessons to be shared. The EU can apply the experiences from the U.S. Bayh-Dole Act and PPPPs in the United States, and the United States can emulate aspects of the open innovation aspects of the European Innovative Medicines Initiative and the tighter patenting standards imposed by the European Patent Office. Thus, a secondary purpose of this article is to suggest amendments to the U.S. laws governing the patenting and licensing of government-funded technology to prevent undue burdens on the sharing of certain upstream medical discoveries and research tools.

Key words: intellectual property, academic entrepreneurship, pharmaceutical public-private partnerships, U.S. Bayh-Dole Act, EU Innovative Medicines Initiative, publicly funded university medical research, technology transfer offices, and game theory.

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"[P]atent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'"[1]

I. Introduction

To improve industry competitiveness[2] as well as to address unmet health needs, government agencies in both the European Union (EU) and the United States are working with public universities and for-profit pharmaceutical firms "to foster translation from the university to the healthcare sector through the generation and support of start-ups, spin-offs, university-industry consortia, and other platforms,"[3] thereby promoting the movement of medical discoveries from the laboratory to the patient, from "bench to bedside."[4] For example, in 2015 President Obama announced the Precision Medicine Initiative, a public-private project that "gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen"[5]; research universities, for-profit pharmaceutical firms, and others will collaborate with the goal of collecting genetic, health, and environmental information from one million Americans in an effort to promote treatments tailored to individual patients.

Notwithstanding multiple initiatives to promote "academic entrepreneurship,"[6] the majority of university technology transfer offices are not profitable; those that are profitable generate an income stream that "is still a relatively small percentage of the total research volume.

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[1] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (emphasis added) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012)).

[2] As EU Internal Market and Services Commissioner Michel Barnier put it: "It is my deeply held conviction there is no sustainable economic growth without innovation. And no innovation without efficient intellectual property protection." Press Release, European Comm'n, European Patents Costs to Be Radically Reduced, ec.europa.eu/unitedkingdom/press/press_releases/.../pr1138_en.htm (last updated Jan. 12, 2012).

[3] Rogerio Gaspar et al., *Towards a European Strategy for Medicines Research (2014-2020): The EUFEPS Position Paper on Horizon 2020*, 47 EUR. J. PHARMA. SCIS. 979, 980 (2012).

[4] *Id.*

[5] White House Press Office, Remarks by the President on Precision Medicine (Jan. 30, 2015), http://www.whitehouse.gov/the-press-office/2015/01/30/remarks-president-precision-medicine (last visited Feb. 25, 2015). *See also* Robert Pear, *U.S. to Collect Genetic Data to Hone Care*, N.Y. TIMES, Jan. 31, 2015, at A12; Meg Tirrell & Cara Caruso, *Obama Seeks $215 Million for Precision Medicine*, CNBC.com (Jan. 30, 2015), www.cnbc.com/id/102382752.

[6] Rosa Grimaldi, Martin Kenney, Donald S. Siegel & Mike Wright, *30 Years after Bayh-Dole: Reassessing Academic Entrepreneurship*, 40 RES. POL'Y 1045, 1045 (2011) (defining "academic entrepreneurship" as the "commercialization of innovations developed by academic scientists" through "patenting, licensing, start-up creation, and university-industry partnerships").

Of the 734 licensing deals entered into by the University of California system between 1981 and 1999, only 188 resulted in positive royalty payments.[7] Only 358 of 2,270 inventions developed at the Max Planck Society, "Germany's largest non-university public research organization . . . dedicated to basic science,"[8] from 1980 through 2004 yielded positive royalty income.[9] In 2007, total licensing income represented just 1% of the Max Planck Society's annual budget.[10] As the European Commission put it: "We need to get more innovation out of our research. Cooperation between the worlds of science and the world of business must be enhanced, obstacles removed and incentives put in place."[11] Yet, as Guido Buenstorf and Matthias Geissler explain:

> Commercializing academic inventions is non-trivial because they are often far from being readily marketable. Prior work suggests that commercialization is complicated by uncertainty stemming from the early-stage character of most university inventions, information asymmetry between inventor and potential licensee, and also the non-codified nature of important elements of the knowledge base underlying the traded technology.[12]

In 2014, the European Commission launched a study of knowledge transfer by public research organizations and other institutes of higher learning[13] "to determine which additional measures might be needed to ensure an optimal flow of knowledge between the public research organisations and business thereby contributing to the development of the knowledge based economy."[14] Regulators in the EU have already identified public-public partnerships as "key elements" of the "Innovation Union" contemplated by Horizon 2020,[15] an EU program for

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[7] Robert A. Lowe & Arvids A. Ziedonis, *Overoptimism and the Performance of Entrepreneurial Firms*, 52 MGMT. SCI. 173 (2006).

[8] Guido Buenstorf & Matthias Geissler, *Not Invented Here: Technology Licensing, Knowledge Transfer and Innovation Based on Public Research*, 22 J. EVOLUTIONARY ECON. 481, 482 (2012).

[9] *Id.* at 496.

[10] *Id.* at 495.

[11] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *Europe 2020 Flagship Initiative, Innovation Union*, at 3, COM (2010) 546 final (Oct. 6, 2010) [hereinafter *EC 6.10.2010 Communication*].

[12] Buenstorf & Geissler, *supra* note 8, at 482.

[13] *European Commission - State of the Innovation Union: Taking Stock 2010 – 2014*, at 57, COM (2014) 339 [hereinafter *EC Taking Stock 2014*].

[14] *Id.*

[15] The European Commission described Horizon 2020 as "the biggest EU research and innovation framework programme ever launched, with over €80 billion dedicated to excellent research, industrial leadership and key societal challenges. It contributes to strengthening the knowledge base in Europe not only by funding research, but also by mainstreaming funding for activities in all stages of the innovation cycle, from frontier research to close-to-

research and innovation approved by the European Parliament and Council in December 2013. The Innovation Union, slated to run from 2014 to 2020, "aims to improve conditions and access to finance for research and innovation, to ensure that innovative ideas can be turned into products and services that create growth and jobs."[16]

Since the successful mapping of the human genome in 2002,[17] researchers at a number of universities in the United States and other parts of the world have worked with for-profit pharmaceutical firms to commercialize their discoveries. Both pharmacogenetics and microbiotics, the study of the microbial cells that outnumber human cells roughly ten to one,[18] require expensive research facilities and additional research before the findings can be converted into treatment regimes. As a result, they are important areas for public-private cooperation.[19]

Pharmacogenetics is the study of genetic traits that "might underlie variation among individuals in drug response, based on individual differences in enzyme structure and function."[20] Its focus is the reaction of genetically diverse patients to a specific, often preexisting, medication — "one drug across many genomes."[21] Pharmacogenomics includes not only pharmacogenetics but also research conducted during the earlier stages in a drug's

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market innovation. It supports and encourages the participation of businesses, including SMEs [small and medium-sized enterprises]. In parallel, billions are being invested in innovation-driven public private partnerships." *Id.* at 12.

[16] *EC 6.10.10 Communication*, *supra* note 11, at 6.

[17] Robert I. Field, *How the Government Created and Sustains the Private Pharmaceutical Industry*, 6 ST. LOUIS U. J. HEALTH L. & POL'Y 11, 28 (2012). The U.S. Government spent $3.8 billion mapping the complete set of human genes. *Id.* at 30. To encourage private scientists to participate in the project, the government put its findings in a public database within twenty-four hours of discovery, with no limitations on their use. *Id.* at 28.

[18] Michael Pollan, *Some of My Best Friends Are Bacteria*, N.Y. TIMES, May 19, 2013, at MM36.

[19] In addition, small biotech firms have entered into agreements with large pharmaceutical firms to develop pharmacogenetic test kits and innovations. Valerie Gutmann Koch, *Incentivizing the Utilization of Pharmacogenomics in Drug Development*, 15 J. HEALTH CARE L. & POL'Y 263, 279 (2012). They include a $200 million agreement between Roche and deCODE Genetics "'to identify disease genes through genetic analysis of the uniquely homogenous Icelandic population.'" *Id.* at 279-80.

[20] *Id.* at 264.

[21] *Id.* at 264. As such, it is at the drug discovery stage where pharmacogenomics "exert[s] its impact" and such impact will be present in products "over the long term." *Id.* Only 1 out of 60,000 compounds created by drug companies are highly successful; roughly 1 out of 6 drugs put into clinical trials are ultimately approved by the U.S. Food and Drug Administration (FDA); and more than 3% of drugs approved by the FDA were subsequently withdrawn between 1971 and 2006 due to negative side effects. *Id.* at 274, 274 n.89, 276.

development to determine "which compounds will be most effective for a particular genome [—] 'many drugs across one genome.'"[22]

Calling precision medicine "one of the greatest opportunities for new medical breakthroughs that we have ever seen," President Obama announced in 2015 the $215 million government-funded Precision Medicine Initiative to collect genetic and other health and environmental information on one million Americans with the goal of developing drugs and treatments that are specific to the needs of each individual patient.[23] Britain had announced a similar initiative in 2013, which was due to launch in April 2015.[24]

Scientists are now applying many of the tools developed for pharmacogenetics to study the human microbiome, the genes of the several hundred microbial species in the human body. [25] A healthy human has more than 100 trillion bacteria, most of which reside in the intestines.[26] More than 99% of a human's genetic information is microbial.[27]

Microbiotics offer possible treatments for certain autoimmune diseases and other ailments. (The term "microbiota" refers to all the microbes in a community and the term "microbiome" refers to their collective genes.[28]) Many scientists believe that this "second genome" can affect one's health more than one's inherited genes, in part because microbiota may be subject to "reshap[ing]" or "cultivat[ion].[29] To this end, the U.S. National Institutes of Health (NIH) created the Common Fund Human Microbiome Project (HMP) in 2007 to conduct research on human microbiota and their role in pregnancy and birth, diabetes, and inflammatory bowel diseases.[30] As the NIH explained:

> Advances in DNA sequencing technologies have created a new field of research, called metagenomics, allowing comprehensive

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[22] *Id.* at 264.

[23] Pear, *supra* note 5.

[24] Nuala Moran, *UK Precision Medicine Initiative Is Poised to Kick Off in April*, BIOWORLD, http://www.bioworld.com/content/uk-precision-medicine-initiative-poised-kick-april-0 (Feb. 11, 2015).

[25] Pollan, *supra* note 18.

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] U.S. Dep't of Health & Human Servs., Nat'l Inst. of Health, *Human Microbiome Project*, http://commonfund.nih.gov/hmp/overview (last updated Sept. 24, 2014).

> examination of microbial communities without the need for cultivation [in a laboratory]. Instead of examining the genomes of individual bacterial strains that have been grown in the laboratory and then trying to reassemble the community of microbes, the metagenomic approach allows analysis of genetic material harvested directly from microbial communities without the need to culture the microbes. In the HMP, this approach is complementing genetic analyses of available reference strains, providing unprecedented information about the complexity of human-associated microbial communities. Other advanced 'omics technologies like transcriptomics, proteomics and metabolomics, which measure the biological properties of whole microbial communities, are being used to provide insights into how the microbiome and human host interact to support health or to trigger disease.[31]

Another endeavor, the American Gut Project, involves researchers at the University of Colorado, Boulder, as well as at other institutions across the globe, and seeks the participation of tens of thousands of "citizen scientists" to provide specimens for study.[32] The project hopes to sequence the microbiome of the participants and to "uncover patterns of correlation between people's lifestyle, diet, health status and the makeup of their microbial community."[33]

Scientist Jeff Gordon predicts that disorders of the microbiome will eventually be treated with "synbiotics" – next-generation probiotic microbes that are given with prebiotic nutrients, as well as with new "therapeutic foods" that will heal various intestinal issues.[34] As such, both Big Pharma and Big Food will most likely have a large stake in "repairing the microbiota of people who can't or don't care to simply change their diets."[35]

Patents and exclusive licenses of patented technology are the primary legal tools used to recoup a firm's investment in the commercialization of a new pharmaceutical compound, biologic, or genetically engineered therapeutic food.[36] Although patents spur investment, they also

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[31] *Id.*

[32] Scientific American, *American Gut*, http://www.scientificamerican.com/citizen-science/american-gut/ (last visited Nov. 18, 2014).

[33] *Id.*

[34] Pollan, *supra* note 18.

[35] *Id.*

[36] *See generally* Bowman v. Monsanto Co., 133 S. Ct. 1761 (2013) (holding that a farmer may not reproduce genetically modified soybean seeds patented by Monsanto by replanting and then harvesting more seeds than he had originally purchased without the permission of the patent holder).

reduce competition, leading to higher prices.[37] They can also impede further innovation. As the U.S. Supreme Court stated in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, "[P]atent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'"[38]

These are not only hotly contested contractual issues[39] but also matters of social and governmental import. Accordingly, "[p]olicy-makers must . . . determine, through the patent system, how to balance the promotion of downstream pharmacogenomic [and other pharmaceutical] research while protecting the rights of innovators."[40]

The purpose of this article is to advance the public policy and academic debate in both the European Union and the United States concerning the intellectual property issues inherent in drug development collaboration among government, academia and private industry, what has been dubbed the "triple helix."[41] We propose solutions that build on aspects of both the European Innovation in Medicines Initiative (IMI) and the Bayh-Dole Act,[42] the U.S. statute governing the patenting and licensing of government-funded university technology. We also extend the game theory analysis of public-private partnerships we presented in an earlier article[43] to include the incentives necessary to persuade academic researchers to share their tacit knowledge with the commercial partner in a PPPP.

In Part II we briefly describe global trends in pharmaceutical research, development and commercialization and outline the role pharmaceutical public-private partnerships can play in this process. In Parts III and IV we discuss the EU Innovative Medicines Initiative and three

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[37] For example, Myriad Genetics was able to charge $3,000 for a test for the two breast cancer genes BRCA1 and BRCA2 because it had patents on those gene sequences while a university lab can sequence 20,000 genes for less than $500. Although the U.S. Supreme Court invalidated Myriad's patent on isolated gene sequences because they are naturally occurring substances, it upheld the patent on cDNA, the synthetic complementary DNA used to develop tests for specific genetic markers. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[38] *Id.* at 2116 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012)).

[39] *See, e.g.*, Suzanne Majewski & Dean V. Williamson, "Incomplete Contracting and the Structure of R&D Joint Venture Contracts," *in* INTELLECTUAL PROPERTY AND ENTREPRENEURSHIP 201 (Gary D. Libecap ed. 2004) (stressing importance of allocating property rights in R&D ventures ex ante by contract).

[40] Koch, *supra* note 19, at 302.

[41] Loet Leydesdorff, *The Triple Helix: An Evolutionary Model of Innovations*, 29 RES. POL'Y 243 (2000) (explaining that universities can play as critical a role as government and industry in knowledge-based societies).

[42] Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-12).

[43] Constance E. Bagley & Christina D. Tvarnø, *Pharmaceutical Public-Private Partnerships: Moving from the Bench to the Bedside*, 4 HARV. BUS. L. REV. 373 (2014).

U.S. National Institutes of Health translational medicine initiatives. In Part V, we discuss technology transfer from academia to industry, including the ownership of inventions, licensing and patent considerations, and the role of university technology transfer offices. In Part VI, we present public policy concerns raised by university licensing. Finally, we conclude in Part VII by proposing an intellectual property regime for the EU designed to promote the commercialization of technology developed in university laboratories with government funds without jeopardizing the historic role of universities in Europe or the goals of the common market reflected in the restrictions on State aid. Our analysis includes the application of game theory to explain how to properly align incentives among academic researchers, universities, and commercial partners.

II. The Global Pharmaceutical Supply Chain

The existing productivity challenge in the pharmaceutical industry is a result of increasing research and development (R&D) costs, decreasing production, and reduced public funding as well as empty or exhausted pipelines. In 2012, the "year of all patent-cliff years," the patents on AstraZeneca's Seroquel IR, Bristol-Myers Squibb's Plavix, and Merck's Singulair all expired.[44] Pfizer's patent on Lipitor expired in late 2011.[45] The combination of patent expiration on existing products, a lack of administrative approval of new products, and increasing development costs has put financial pressure on many pharmaceutical companies around the world,[46] as seen in Table 1.[47]

[44] *Top Pharma Companies by 2012 Revenues*, FIERCEPHARMA (Mar. 26, 2013), http://www.fiercepharma.com/special-reports/top-pharma-companies-2012-revenues.

[45] *Id.*

[46] Tom. R. Denee, Arnold Sneekes, Pieter Stolk, Antoine Juliens, Jan A. M. Raaijmakers, Michel Goldman, Daan J. A. Crommelin & Jorg W. Janssen, *Measuring the Value of Public–Private Partnerships in the Pharmaceutical Sciences,* 11 NATURE REVIEWS DRUG DISCOVERY 419 (2012).

[47] PMLIVE, http://www.pmlive.com/top_pharma_list/global_revenues (last visited Nov. 19, 2014).

Table 1: The Top Fifteen Pharmaceutical Companies by 2013 and 2012 Revenues

Company	Head-quarters	2013 Rank	2013 Revenues (US$b)	2012 Rank	2012 Revenues (US$b)
Pfizer	U.S.	1	47.88	1	51.21
Novartis	EU	2	47.47	2	46.73
Roche	EU	3	39.16	5	38.01
Merck & Co.	U.S.	4	37.44	3	40.60
Sanofi	EU	5	37.12	4	39.51
GlaxoSmithKline	EU	6	33.33	6	33.34
Johnson & Johnson	U.S.	7	28.13	8	25.35
AstraZeneca	U.S.	8	25.71	7	27.93
Lilly	EU	9	20.96	9	20.57
AbbVie	U.S.	10	18.79	11	18.38
Teva	Israel	11	18.31	10	18.54
Amgen	U.S.	12	18.19	14	16.64
Takeda	Japan	13	17.41	13	17.56
Bristol-Myers Squibb	U.S.	14	16.39	12	17.62
Boehringer Ingelheim	U.S.	15	15.79	15	14.66

Source: Data derived from *Top Pharma List*, PMLIVE, http://www.pmlive.com/top_pharma_list/global_revenues (last visited Nov. 19, 2014).

Research published in 2015 in the *Journal of the American Medical Association* found that "[m]edical research in the United States remains the primary source of new discoveries, drugs, devices, and clinical procedures for the world, although the US lead in these categories is declining."[48] Europe was the second largest sponsor in 2011 with a 33% share of total medical research spending (both academic and commercial) compared with the 44% U.S. share.[49] Thirty-

[48] Hamilton Moses III, David H.M. Matheson, Sarah Cairns-Smith, Benjamin P. George, Chase Palisch & E. Ray Dorsey, *The Anatomy of Medical Research: US and International Comparisons*, 313(2) J. AM. MED. ASS'N 174, 181 (2015).

[49] *Id*. at 179.

three percent of biomedical research articles published in 2009 were authored by U.S. scientists, with the number increasing 0.6% per year from 2000 to 2009.[50] In that same period, the number of articles authored by Chinese scientists increased by more than 18% per annum.[51] While the U.S. share of global government and industry funding for medical research has decreased since 2004, spending has markedly increased in Asia, especially in China, India, Japan, Singapore, and South Korea.[52] The U.S share of public funding for medical research dropped from 57% in 2004 to 49% in 2011, while European countries increased their share of public spending by 3.5%.[53] The U.S. share of industry funding dropped from nearly 50% to 41% in the same period.[54] Japan increased its share of industry funding by 3.9% over the same period.[55] A study involving patenting by 492 tenured engineering academics working in the United Kingdom during the period from 1996-2007 showed that "UK researchers receiving funding from industry are more likely to produce patents, controlling for a variety of individual and departmental characteristics."[56]

In 2011, China filed 30% of global life sciences patents, up from just 1% in 1991; the United States increased its share from 11% in 1991 to 24% in 2011.[57] In that same period, the percentage of "highly valuable patents," measured by subsequent citation counts, decreased in both the United States and Europe.[58] Between 2003 and 2013, the European Medicines Agency (EMA) received on average more drug applications (fifty-five per year) and approved more

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[50] *Id*. at 180.

[51] *Id*. at 180.

[52] *Id*. at 178-79.

[53] *Id.* at 179.

[54] *Id*. at 179.

[55] *Id*. at 179.

[56] Cornelia Lawson, *Academic Patenting: The Importance of Industry Support*, 38 J. TECH. TRANSFER 509, 510 (2013). Even small industry grants, "which may support [knowledge] dissemination activities, studentships and consulting," and indicate close links between the industrial sponsor and the academic reseachers, positively affect patenting. *Id*. at 510, 518. Researchers also found a strong positive correlation between industry collaboration and funding and patenting by Norwegian academics, and a positive correlation between industry sponsorship of German science and engineering departments and patent citations. *Id.* at 512 (citing M. Gulbrandsen & J.C. Smeby, *Industry Funding and University Professors' Research Performance*, 34(6) RESEARCH POL'Y 932 (2005), and, H. Hottenrott & S. Thorwarth, *Industry Funding of University Research and Scientific Productivity*, 64(4) KYKLOS 534 (2011)). U.K. academic inventors who had filed a patent application while working in industry, and before becoming an academic, produced patents of higher quality, as measured by the number of forward citations, than patenting academics who had never worked in industry. *Id.* at 517.

[57] Moses et al., *supra* note 48, at 180.

[58] *Id*. at 180.

drugs (forty-two per year) than the U.S. Food and Drug Administration, which averaged twenty-six approvals per year for the same period.[59] In 2013, the EMA received twenty-two more applications and approved sixteen more drugs than the FDA.[60]

Since 2003, private firms have increasingly focused on later-stage clinical trials and product development, reducing their "discovery-level investment" in activities, such as target identification and validity.[61] This shift has widened the "so-called 'valley of death,'" which separates "upstream research on promising genes, proteins, and biological pathways" by academic researchers funded by the government from "downstream drug candidates" [62] that outside firms are willing to fund in hopes of commercializing the academic discoveries.[63] This gap is particularly difficult to bridge given not only the cost of commercializing a compound, biologic or therapeutic food but also the inherent tension between the goals of academia and the commercial sector. Whereas universities (a term we use to include research institutes) often focus on the public dissemination of new knowledge and discoveries, the private sector is often more concerned with capturing the rents available to the firm holding the patent on a given discovery or an exclusive license of such a patent.

As we explain in our article "Pharmaceutical Public-Private Partnerships: Moving from the Bench to the Bedside,"[64] properly structured pharmaceutical public-private partnerships (PPPPs)[65] can help bridge the "valley of death." Used more commonly in the United States than in Europe, a PPPP is an arrangement between a public university or research institute (or a private university or institute doing medical research funded by the government) and one or more private firms in the pharmaceutical industry to develop new medicines that can be sold by the pharmaceutical firm at a profit.[66]

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[59] *Id.* at 181.

[60] *Id*. at 181.

[61] *Id*. at 177.

[62] Arti K. Rai, Jerome H. Reichman, Paul F. Uhlir & Colin Crossman, *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL'Y L. & ETHICS 1, 4 (2008).

[63] *See also EC 6.10.2010 Communication*, *supra* note 11.

[64] Bagley & Tvarnø, *supra* note 43.

[65] Notwithstanding the word "partnership," public-private partnerships "are defined and bound by contracts; they are no more or less than the documents negotiated, approved, and executed." Julia Paschal Davis, *Public Private Partnerships*, 44 PROCUREMENT LAW. 9, 9 (Fall 2008).

[66] As the European Commission stated, "Closing these gaps, and making Europe an attractive place to invest in innovation, requires the intelligent see of public private partnerships as well as changes to the regulatory framework." *EC 6.10.2010 Communication*, *supra* note 11, at 14.

The parties in a PPPP must combine long-form contracting, relational governance, properly aligned incentives, and transparency to move from the Nash prisoners' dilemma equilibrium to the Pareto Optimal Frontier, that is, to create joint utility that gives each party more than it would have been able to generate acting alone.[67] This is depicted in Table 2.

Table 2: An Efficient PPPP[68]

	Accept and Abide by Contract and Abide by Relational Norms	Reject Contract but Abide by Relational Norms	Accept Contract but Deviate from Relational Norms	Reject Contract and Deviate from Relational Norms	Breach Contract
Accept and Abide by Contract and Abide by Relational Norms	5, 5				
Reject Contract but Abide by Relational Norms		2, 2			
Accept Contract but Deviate from Relational Norms			3, 3		
Reject Contract and Deviate from Relational Norms				-2, -2	
Breach Contract	-2, 4				4, -2

As explained in our earlier article:

> If both parties agree to a well-drafted binding contract and abide by relational norms, then they both have a positive utility of 5. These payoffs are arbitrary numbers whose importance is their relative value and sign. If the parties cannot agree on a contract but abide by relational norms then the joint utility (2, 2) would still be positive, that is, greater than it would be if there was no cooperation at all but lower than what would result for a binding contract supplemented by relational governance (5, 5). The same

[67] Bagley & Tvarnø, *supra* note 43, at 386-87.

[68] Excerpted from *id*. at 389.

is true if there is a contract but relational norms are violated (3, 3). Given the critical importance of allocating intellectual property rights by contract, we are assuming that the joint utility is less in this situation, though that may not always be the case. If, however, a party breaches the contract, unless the other party waives its contract rights, this opportunistic behavior results in a loss to the non-breaching party (say, -2), which may be compensable at least in part by damages, and ill-gotten gain by the breaching party (say, 4).[69]

But that is not enough to convert the "dead capital"[70] created in university laboratories by academic researchers into commercially viable products. Success also requires an intellectual property regime that neither unduly stifles new upstream discoveries and the development of tools of broad application by academic researchers nor deprives the pharmaceutical firm funding commercialization of the robust return necessary to justify the expense of developing and testing multiple compounds and biologics, knowing that only about 15% will ever move past clinical trials to governmental approval.[71] It also requires offering university researchers adequate incentives to justify their participation in the commercialization process.

III. The EU Innovative Medicines Initiative and Other EU Programs

As Màire Geoghegan-Quinn, then EU Commissioner of Research, Innovation and Science, explained, the "Innovation Union" requires "(i) excellent science, (ii) industrial leadership and (iii) [the ability to address] societal challenges."[72] The Innovative Medicines Initiative (IMI) is Europe's largest public-private pharmaceutical development partnership. Among other things, it pools 500,000 chemical compounds, of which 300,000 came from AstraZeneca, Bayer Pharma, Merck, Sanoh, and the other member companies with the balance coming from academia and smaller firms.

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[69] *See* Bagley & Tvarnø, *supra* note 43, at 386-89 (discussing further how to avoid the inefficient Nash equilibrium in the Prisoners' Dilemma).

[70] HERNANDO DE SOTO, THE MYSTERY OF CAPITAL: WHY CAPITALISM TRIUMPHS IN THE WEST AND FAILS EVERYWHERE ELSE (2000) (explaining how defined property rights make it possible to convert "dead capital" into an asset that can be sold, shared or hypothecated).

[71] Koch, *supra* note 19, at 274 n.89

[72] *See Farewell Message - Commissioner Màire Geoghegan-Quinn* (Oct. 2014), http://ec.europa.eu/commission_2010-2014/geoghegan-quinn/headlines/news/2014/20140930-farewell_en.htm; *What is Horizon 2020*, EUROPEAN COMM'N, http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020 (last visited Nov. 19, 2014). Carlos Moedas became the EU commissioner for Research, Science and Innovation on November 1, 2014. As such, he is responsible for overseeing the EU research funding programs and Horizon 2020's contribution to the Commission's jobs, growth and investment package through the promotion of the international excellence of the EU's research and science and the strengthening of research capacities and innovation across all Member States.

A. **Goals and Structure of the Innovative Medicines Initiative**

The IMI is designed to provide socio-economic benefits to European citizens by (1) improving drug development and thereby generating faster access to better medicines and (2) enhancing Europe's competitiveness globally by increasing investments in the European pharmaceutical R&D industry, thereby establishing Europe as the most attractive place for pharmaceutical R&D.[73] Research institutions and firms bid for government and industry funds to support research in areas of high medical need.

The public party is the European Union, represented by the European Commission. The private party is the pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and its members. The European Union committed to contribute €1 billion to the first phase of the IMI research program (IMI 1), which is matched by private in-kind contributions of at least €1 billion from the EFPIA member companies and their affiliates.[74] The public funding is directed primarily to academic and non-profit institutions. As of November 2014, forty-seven IMI 1 projects were underway with a budget of €2 billion.[75]

Phase two of the Innovative Medicines Initiative (IMI 2) commenced in 2014 and is slated to run for ten years. Its goal is to build on the successes and lessons learned during IMI 1 and to develop next generation vaccines, medicines and treatments, such as new antibiotics.[76] It has a total budget of €3.276 billion, of which the EU will contribute up to €1.638 billion from the funds authorized for Horizon 2020.[77] EFPIA has committed to provide €1.425 billion through in-kind contributions.[78] Other life science industries may contribute an additional €213 million, either as partners in individual projects or as IMI 2 members.

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[73] *See* Hugh Laverty, *Boosting Drug Development Through Public-Private Partnerships – The IMI Model*, 5 EPMA J. A11 (Feb. 2014), http://www.epmajournal.com/content/pdf/1878-5085-5-S1-A11.pdf.

[74] Section 14 of the IMI Joint Undertaking Model Grant Agreement Annex II– General Conditions defines "in-kind" as "contributions to the project by EFPIA [European Federation of Pharmaceutical Industries and Associations] companies and their affiliated entities, with resources such as personnel, equipment, consumables, declared in accordance with Articles II.4, II.13 and II.14." (On file with the authors.) *See* INNOVATIVE MEDICINES INITIATIVE BROCHURE 3, http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI%20Brochure-Dec2013-Web-Spread.pdf (last updated Dec. 2013).

[75] *See* IMI Ongoing Projects, http://www.imi.europa.eu/content/ongoing-projects (last visited Nov. 26, 2014); Introducing IMI, A Look Back on IMI's First Phase, http://www.imi.europa.eu/content/mission (last visited Dec. 12, 2014).

[76] IMI 2, Goals of IMI 2, http://www.imi.europa.eu/content/imi-2#Budget (last visited Dec. 12, 2014).

[77] IMI 2, Budget, http://www.imi.europa.eu/content/imi-2#Budget (last visited Dec. 12, 2014).

[78] *Id.*

Each IMI call for a project proposal involves open competition for funding and multiple stakeholders, including EFPIA; large, small and medium-sized private pharmaceutical and biotechnology enterprises; universities; hospitals; patient organizations; and public authorities. All IMI contracts are subject to EU regulations, including those pertaining to the ownership of any resulting discoveries and the State aid rules discussed in Part VII.

B. Ownership of IMI-Funded Inventions

Article 41 of Regulation (EU) No. 1290/2013 provides that the results of an IMI-funded research project are owned by the participant that generated them. If, however, the participants in a project jointly generate results and their respective contribution to the joint results cannot be ascertained, then the participants have joint ownership of the results.[79] Similarly, if it is not possible to separate the jointly owned results for the purpose of applying for, obtaining or maintaining the relevant intellectual property rights protection, then the participants own the results jointly. Article 41 requires joint owners to enter into an agreement regarding the allocation of rights and the terms governing the exercise of their joint ownership in accordance with their obligations under the grant agreement. The joint owners may elect not to continue to hold the rights jointly but instead enter into an alternative arrangement, such as transferring their ownership shares to a single owner who agrees to grant access rights to the other participants, once the results are available.

In contrast with the multi-participant IMI framework, the Pfizer Centers for Therapeutic Innovation,[80] and other comparable PPPPs in the United States, involve a single private pharmaceutical firm that solicits proposals from academic scientists for research to be funded by the private firm. The private firm forms an assessment committee that evaluates the proposals to find suitable projects with the goal of developing the firm's business without the involvement or intervention of competitors or pharmaceutical industry trade associations. Often, the pharmaceutical firm becomes the sole owner of the pharmaceutical patent or, if the patent belongs to the researcher or the university, the firm becomes the exclusive licensee of the invention.

C. Action Plan Against the Rising Threats from Antimicrobial Resistance

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[79] *See* Article 41 in Regulation (EU) No. 1290/2013 of the European Parliament and of the Council of 11 December 2013 Laying Down the Rules for Participation and Dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and Repealing Regulation (EC) No. 1906/2006, 2013 O.J. (L 347) 98.

[80] *Centers for Therapeutic Innovation*, PFIZER, http://www.pfizer.com/research/rd_partnering/centers_for_therapeutic_innovation (last visited Nov. 19, 2014).

In 2011, the European Commission launched another type of pharmaceutical development initiative — the Action Plan Against the Rising Threats from Antimicrobial Resistance. In response, AstraZeneca and GlaxoSmithKline announced that they would jointly contribute a total of €224 million to develop new antibiotics.[81] Both firms agreed to share information and to contribute compounds to the venture. Thus, this is a private joint venture involving two direct competitors designed to meet the public demand for new antibiotics. As such, it offers a possible model for the horizontal private-private pooling of resources.[82]

IV. **The U.S. National Center for Advancing Translational Sciences and Other U.S. Programs**

The National Institutes of Health (NIH) in the United States established the National Center for Advancing Translational Sciences (NCATS) in 2011. The President's budget request for NCATS for fiscal year 2015 was $657 million.[83] The NCATS Strategic Alliances Office is designed "to make it easy for industry and academia to interact and partner with NCATS laboratories and scientists" by, among other things, "negotiating standard forms and model agreements between NCATS and outside parties, including universities, pharmaceutical companies and biotechnology companies" in the United States.[84] According to the European Federation for Pharmaceutical Sciences (EUFEPS), which "represent[s] the interests of scientists in industry, academia, government and other institutions engaged in drug research, development, regulation and policymaking through Europe,"[85] Europe will need to pursue similar initiatives to support

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[81] Amy Ritter, *Public-Private Partnerships Step Up*, PHARMTECH TALK (May 30, 2012, 3:37 PM), http://blog.pharmtech.com/2012/05/30/public-private-partnerships-step-up/.

[82] Rai et al., *supra* note 62, at 4. Rai and her coauthors propose a two-step arrangement whereby direct competitors could put their proprietary and secret small molecules into a pool, managed by a trusted intermediary, where they would be tested in secret via high-throughput screening against assays contributed by academic researchers. If the screening revealed a "hit," that is, "molecules that showed significant activity against the target in question [that] could lead to new drug candidates," then "the contributing firm would have an obligation to provide relevant structural information to the academic via the intermediary." *Id.* at 22. Similarly, the academic participant would be required to disclose to the firm that owned the molecule "a general statement of the methodology used to develop its target," again via the intermediary. *Id*. This arrangement has the benefit of making it possible for researchers to run their assays against a wide range of molecules owned by a variety of firms. If there were a match, then the academic would commence second-tier negotiations in hopes of reaching a mutually acceptable agreement for the licensing of the target to the firm owning the relevant molecule. If the parties were unable to reach an agreement, then both the molecule and the target would still be protectable trade secrets by their respective inventors and thus still eligible for a future patent. *Id.* at 25.

[83] *Budget*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIS., http://www.ncats.nih.gov/about/budget/budget.html (last visited Nov. 19, 2014).

[84] *Strategic Alliances for Technology Transfer*, NAT'L CTR. FOR ADVANCING TRANSLATIONAL SCIS., http://www.ncats.nih.gov/research/tech-transfer/alliances.html (last visited Nov. 19, 2014).

[85] *About*, EUROPEAN FED'N FOR PHARM. SCIS., www.eufeps.org/about (last visited Nov. 19, 2014).

the IMI research agenda and to retain Europe's competitive advantage in pharmaceutical innovation.[86]

In 2014, the NIH announced the Accelerating Medicines Partnership between the NIH and ten major pharmaceutical firms that agreed to share tissue and blood samples as well as data in hopes of identifying targets for new drugs to treat Alzheimer's, lupus, rheumatoid arthritis, and type 2 diabetes. The five-year collaboration, which is supported by $230 million in federal funding, is dedicated to decoding the biology behind these diseases. As NIH Director Francis Collins explained, "A drug company really wants to know where it should put its next billion-dollar bet in a new area of therapeutics."[87]

The National Institutes of Health announced in 2015 that the patients and patient advocacy organizations involved in the Precision Medicine Initiative will be invited to work with "academic medical centers, clinicians, scientists from multiple disciplines with creative ideas about how to make this unique opportunity successful, pharmaceutical companies and medical product developers, scientific societies and research coalitions, privacy experts and medical ethicists."[88] Among the larger genome sequencing companies that could benefit from the Precision Medicine Initiative announced in 2015 are Roche Holding AG; Illumina Inc., which has an alliance with defense contractor Lockheed Martin for genomics development; and Thermo Fisher Scientific.[89] Both IBM Corp. and Google Inc. are among large firms expected to help store and interpret genomic and other data as well as electronic health records.[90]

V. University Technology Transfer

Research and development (R&D) by a university supported by governmental funds is frequently the first step in the development of a new drug in both the United States[91] and Europe. Universities in the United States and the EU work with the private sector to commercialize their

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[86] Gaspar et al., *supra* note 3, at 982.

[87] *Drug Companies Join NIH in Study of Alzheimer's, Diabetes, Rheumatoid Arthritis, Lupus*, MEDTECH (Mar. 12, 2014), http://www.medtech.org/news/global.aspx?recId=4452.

[88] Nat'l Inst. of Health, Precision Medicine Initiative, Who Will Participate?, http://www.nih.gov/precisionmedicine/who.htm (last reviewed Feb. 9, 2015).

[89] Sharon Begley & Toni Clarke, *Obama's 'Precision Medicine' Plan to Boost Research, but Faces Hurdles*, REUTERS, Jan. 28, 2015, *available at* http://www.reuters.com/article/2015/01/28/us-health-precisionmedicine-idUSKBN0L10D720150128.

[90] *Id.*

[91] Field, *supra* note 17, at 12.

researchers' discoveries.[92] This is done informally via scientific publications and presentations, through the social networking of scientists and practitioners,[93] and by providing ad-hoc advice and giving academics access to industrial know-how and facilities.[94] Formal mechanisms include research contracts, professorial consulting engagements, licenses, and patent agreements, which are often negotiated by university technology transfer offices (TTOs), also called technology licensing offices. The European Technology Transfer Offices circle (European TTO circle) likened European technology transfer to "an emerging industry: many valuable product ideas; a highly fragmented landscape; a lack of critical mass; wide disparities in terms of performances and developing practices."[95] This lackluster performance is due in part to an academic culture that has not historically valued commercialization[96] and to uncertainty concerning who actually owns intellectual property stemming from government funded research.[97] As the European Commission has recognized, the EU needs to take action to "unlock the potential of IPRs [intellectual property rights] that lie dormant in universities, research institutes and companies."[98]

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[92] *See* Lawson, *supra* note 56, at 509.

[93] *See* Francesco Lissoni, Patrick Llerena & Bulat Sanditov, *Small Worlds in Networks of Inventors and the Role of Academics: An Analysis of France*, 20(3) INDUSTRY & INNOVATION 195, 197, 217 (2013) (finding that the presence of academic inventors and inventors from Centre National de la Recherché Scientifique (CNRS), the preeminent French public research organization, in company technological teams leads to "fast and widespread diffusion of technical and scientific knowledge," especially in the fields of Pharmaceuticals and Biotechnology, and Chemicals and Materials). As Lissoni et al. point out, "Academic and CNRS inventors contribute to inventive activity not only in a direct way (that is, through the patents they produce) but also through their mobility across organizations, which may lead to knowledge diffusion and further inventive activity." *Id*. at 217.

[94] Grimaldi et al, *supra* note 6, at 1046-47.

[95] *European Technology Transfer Offices Circle*, EUROPEAN COMM'N, https://ec.europa.eu/jrc/en/tto-circle (last updated Apr. 30, 2014).

[96] As Michael S. Mireles explained: "[T]he Bayh-Dole Act may not be successful in Europe and Japan--success judged by increased patenting and licensing -- because of the differences in the history, practice, and structure of most European and Japanese university systems compared with the U.S. university system. It may take substantial change in the practice and structure of European and Japanese university systems for legislation similar to the Bayh-Dole Act to be successful." Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States?*, 59 ME. L. Rev. 259, 261 (2007).

[97] *See* Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 119 (2007) ("[W]hat any given country views as 'best practices' in patent law may reflect other practices in other laws – including copyright, trade secret, utility model laws, and, above all, competition laws – that may vary widely from one country to another.").

[98] *EC 6.10.2010 Communication, supra* note 11, at 19.

In the United States, a federal statute, the Bayh-Dole Act,[99] facilitates the transfer of technology from universities to the private sector. Although there are aspects of Bayh-Dole that would give needed structure to the inventions created by public institutions in the EU, we believe that wholesale copying of the Bayh-Dole approach in the EU would be a mistake. Indeed, there are aspects of the EU licensing regime for biotechnology patents that are instructive for U.S. policy makers.

Although much of the empirical work on academic entrepreneurship has focused on patenting activities, it is important to keep in mind both other forms of IP protection, such as copyrights and trade secret protections, and open source initiatives and informal collaboration among academics and industrial researchers,[100] when crafting public policy and university rules.

A. **Comparative Data on Academic Patenting in the United States and Europe**

Francesco Lissoni defines an "academic patent" as "any patent signed by at least one academic scientist, while working at his or her university,"[101] According to the Worldwide Patent Statistical Database maintained by the European Patent Office,[102] academic patenting in Europe is most concentrated in the field of Pharmaceuticals and Biology, which includes cosmetics.[103] This "reflects the important role of public science in scientific disciplines related to these technologies, and the close relationship between scientific discoveries and inventions therein," both in Europe and the United States.[104]

In the United States, universities own 68.7% of academic patents with only 24.2% owned by companies, 5.3% by individual scientists, and 1.7% by the government.[105] In contrast, companies own most academic patents in many parts of Europe: 66.5% in Denmark, 61.4% in France, 72% in

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[99] Thomas J. Siepmann, *The Global Exportation of the US Bayh-Dole Act*, 30 U. DAYTON L. REV. 209 (2004). *See also* EUROPEAN UNION, ECONOMIC POLICY COMMITTEE, WORKING GROUP ON RESEARCH AND DEVELOPMENT, REPORT ON RESEARCH AND DEVELOPMENT, at 34, EPC/ECFIN/01/777-EN Final (Jan. 22, 2002).

[100] *See* Antonio Della Malva, Francesco Lissoni & Patrick Llerena, *Institutional Change and Academic Patenting: French Universities and the Innovation Act of 1999*, 23 J. EVOLUTIONARY ECON. 211, 217-18 (2013).

[101] Francesco Lissoni, *Academic Patenting in Europe: An Overview of Recent Research and New Perspectives*, 34 WORLD PATENT INFO. 197, 198 (2012).

[102] *See* PatStat, http://www.epo.org/searching/subscription/raw/product-14-24.html.

[103] Lissoni, *supra* note 101, at 199.

[104] *Id*.

[105] *Id.* at 201. Data compiled as of 2002.

Italy, 60.5% in the Netherlands, 81.1% in Sweden, and 67.1% in the United Kingdom.[106] As a result, if one counts only patents owned by universities, it would appear that "European academic science does not contribute to technological advancements or, more prosaically, that it does not patent enough."[107] As seen in Table 3,[108] this disparity is reduced or eliminated entirely when one compares not just the number of university-owned patents in the United States with those owned by universities in Europe (which increased from 390 in 1998 to 936 in 2004[109]) but also includes all academic patents, regardless of whether they are owned by universities, individual scientists, or the government.

Table 3

Country	% of Total Domestic Patents Owned by Universities	Academic Patents as a % of Total Domestic Patents
United States	4.0	6.0
France	0.3	3.4
Italy	0.4	4.0
Netherlands	1.0	4.3
Sweden	0.3	6.2

As Lissoni noted in 2012, "Very heated political discussions have taken place over the past few years, about whether technology transfer detracts from basic research."[110] Citing

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[106] *Id*. at 201, Figure 2. As Lissoni explains:

> [T]he type of ownership of academic inventions (which may have a consequence for whether these inventions are eventually marketed), is affected by at least three phenomena: the national IP legislation with respect to academic inventions; the division of labour between public research organizations and the universities in the science system; and the characteristics of universities in terms of autonomy and expertise in self-administration.

Id. at 200.

[107] *Id*. at 197.

[108] Data derived from Lissoni, *supra* note 101, at 201.

[109] Manuel Acosta, Daniel Coronado, M. Dolores León & M. Ángeles Martinez, *The Production of University Technological Knowledge in European Regions: Evidence from Patent Data*, 43(9) REGIONAL STUD. 1167, 1172 (2009). Pharmaceuticals accounted for 39.15% of the 4,580 university-owned European patents granted in the period from 1998 to 2004. The regions with the largest number of pharmaceutical patents were Inner London, U.K. (11.2%), Berkshire, Buckinghamshire and Oxfordshire, U.K. (6.9%), Vlaams Gewest, Belgium (5.1%), Zuid-Holland, the Netherlands (4.6%), and Île de France, France (3.8%). *Id*. at 1173.

[110] Lissoni, *supra* note 101, at 202.

multiple papers, he states: "Overwhelmingly, the evidence suggests that academic inventors are very highly productive scientists: a fixed effect exists, by which highly productive academic scientists are more likely than less productive ones to turn into inventors and, conversely, academic inventors exhibit higher-than-average scientific productivity."[111] Similarly, Rosa Grimaldi et al. report: "Academic research has found little systematic evidence of a destruction of the open culture of science or to support the assertion that universities are performing less basic research."[112] Although "the literature has not yet entirely solved a number of econometric problems of endogeneity," "the published evidence suggests that patenting is followed by an increase in scientific productivity."[113]

Lissoni also cites what he characterizes as the "well-established result, at least for the US, . . . that university-owned academic patents appear to be more general and important than corporate ones, where importance is measured by the number of citations received, and generality by the number of technological classes from which the citations come."[114] The empirical evidence from Europe is more mixed. Based on their analysis of data from the European Patent Office, Emanuele Bacchiocchi and Fabio Montobbio found that patents by European and Japanese academic institutions and public research organizations were not cited more than average.[115] But Dirk Czarnitzki, Katrik Hussinger, and Cedric Schneider found that German academic patents were cited more than the average patent citation rate.[116] Although European academic patents owned by individual inventors are cited less frequently than the average patent, "country specificities emerge, which can be explained by the different legal and institutional environments . . . ."[117] European academic patents, particularly those owned by universities, public research organizations, and governments, are more general than average.[118] In addition, "[i]ndividually owned academic patents appear to be more original than average."[119]

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[111] *Id*. at 202.

[112] Grimaldi et al., *supra* note 6, at 1046 (citations omitted).

[113] Lissoni, *supra* note 101, at 202.

[114] *Id*. at 204 (citations omitted).

[115] *Id.* at 204 (citing E. Bacchiocchi & F. Montobbio, *Knowledge Diffusion from University and Public Research: A Comparison between US, Japan and Europe using Patent Citations*, 34 J. TECH. TRANSFER 169 (2009)).

[116] *Id.* at 204 (citing Dirk Czarnitzki, Katrin Hussinger & Cedric Schneider, *Commercializing Academic Research: The Quality of Faculty Patenting*, 20(5) INDUSTRIAL & CORPORATE CHANGE 1403 (2011)).

[117] Lissoni, *supra* note 101, at 204.

[118] *Id.*

[119] *Id*.

B. Laws Regulating Technology Transfer in the United States

Prior to the enactment of the U.S. Bayh-Dole Act in 1980,[120] neither scientists nor universities in the United States could patent inventions funded with federal government research money.[121] "Under the 'commons' model, the federal government sponsored basic research and encouraged its widespread publication in the public domain without regard for potential commercial applications."[122] As a result, the results of research funded with government grants became part of the public domain or were subject to only nonexclusive licenses.[123]

1. The Bayh-Dole Act

The purpose of the Bayh-Dole Act was to facilitate the commercialization of government-funded research by establishing a uniform set of rules for the ownership of federally funded inventions. The act creates a presumption "that universities own inventions that are developed under their watch."[124] (Similarly, the Stevenson-Wydler Technology Innovation Act[125] gave federal research laboratories the right to transfer technology developed in the government lab to a nongovernment entity, such as a private university or a for-profit firm.[126]) To promote

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[120] Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-12).

[121] David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 997 (2004). *See also* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1663-66 (1996).

[122] Hoffman, *supra* note 121, at 997.

[123] *Id*. at 1004-06. In contrast, "[I]n Canada, since time in memorial [sic], almost since the Flintstones were pushing their stone wheel bicycles around, the universities have had control of the intellectual property. It was up to them to decide or negotiate with their faculty whether it was owned by the inventor or the university." Comments by Thomas Brzustowski, *Proceedings of the Canada-United States Law Institute Conference on Comparative Aspects of Innovation in Canada and the United States—Government Assistance to and Policy toward Innovation*, 32 CAN.-U.S. L. J. 39, 49 (2006). Canada not only gives universities the right to keep the profits generated by the commercialization of government-funded research, it also actively encourages commercialization and provides financial incentives to "'support academic institutions in identifying intellectual property with commercial potential and forging partnerships with the private sector to commercialize research results.'" Jocelyn Downie & Matthew Herder, *Reflections on the Commercialization of Research Conducted in Public Institutions in Canada*, 1 MCGILL HEALTH L. PUBL. 23, 27-28 (2007) (quoting GOV'T OF CANADA, ACHIEVING EXCELLENCE, INVESTING IN PEOPLE, KNOWLEDGE AND OPPORTUNITY 7).

[124] Robert M. Yeh, *The Public Paid for the Invention: Who Owns It?*, 27 BERKELEY TECH. L.J. 453, 453-54 (2012).

[125] Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-22).

[126] The Federal Technology Transfer Act of 1996 amended the Stevenson-Wydler Act and broadened the authority of agencies to enter into a cooperative research and development agreement (CRADA) with non-federal partners. Pub. L. No. 99-502, 100 Stat. 1785 (1996). CRADAs are "partnerships that allow for joint development with a negotiated set of contributions, responsibilities, and remuneration involving each party." Field, *supra* note 17, at 24. Both the government agency and the private partner can contribute services, personnel, and property, but only the private party

commercialization, especially of inventions that require substantial further research and development and testing to get a product to market,[127] Bayh-Dole requires universities (and other nonprofit grantees) to seek to commercialize federally funded research through patents and licensing or to offer to give the exclusive rights to the invention back to the government.[128] "[N]onprofit organizations may retain exclusive title to inventions developed with federal funding, and may freely license such inventions, so long as all resulting profits are used to fund additional scientific research and development."[129] In short, in exchange for patenting government-funded inventions, both public and private universities in the United States can charge and retain licensing fees and royalties.[130] Thus, if a university elects to retain title to a government-funded invention, "the individual inventor (who typically is employed by the institution) has no further rights."[131] As discussed below, the university is, however, required to share royalties with the inventors.[132]

The Act requires all universities that have entered into research funding contracts with a federal agency to "disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters."[133] To meet this requirement, universities generally require all researchers to disclose all inventions to the university's technology transfer office. The institution has two years from the time it discloses the government-funded invention to the federal agency to decide whether the institution wants to retain title to it.[134] If it elects to retain title, the institution must make a

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may contribute money. The government can license the technology to the private firm in exchange for a royalty or waive its ownership rights. *Id.* For example, in 1991 NIH entered into a CRADA with Bristol-Myers Squibb (BMS) for the anti-cancer drug Taxol; under the terms of a 1996 licensing agreement, BMS paid NIH a royalty of 0.5% of BMS's revenues from sales of the drug. *Id.* at 60.

[127] Hoffman, *supra* note 121, at 1007 n.96.

[128] 35 U.S.C. § 202(c)(3). *See also* SEAN O'CONNOR, GREGORY D. GRAFF & DAVID E. WINICKOFF, NAT'L ACAD. OF SCIS., LEGAL CONTEXT OF UNIVERSITY INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER 29 (2010).

[129] Fenn v. Yale Univ., 393 F. Supp. 2d 133, 137 (D. Conn. 2004) (citing 35 U.S.C. § 202(a), and 37 C.F.R. § 401.14(b) ("[t]he Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. § 203")).

[130] DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN N. SAMPAT & ARVIDS A. ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT (2004).

[131] Fenn v. Yale Univ., 393 F. Supp. 2d at 137.

[132] *See* 35 U.S.C. § 202(c)(7)(B).

[133] 35 U.S.C. § 202(c)(1).

[134] 35 U.S.C. § 202(c)(2).

written election to that effect.[135] The Act also states "[t]hat the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times."[136]

Although the government has a "march-in" right to circumvent a patent when a product is "potentially lifesaving," it has rarely, if ever, been used.[137] In addition, federally funded researchers are required to grant the federal government a nonexclusive license to use federally funded inventions.[138] Once the patent expires, the invention becomes part of the public domain.

2. Employers' Rights to Inventions Created by Employees Hired to Invent and Contractual Assignments of Inventions

U.S. patent law's "hired-to-invent" doctrine gives an employer the right to all inventions developed by employees specifically hired to invent. In particular, the hired-to-invent doctrine requires the employee inventor to assign the invention to the employer, even in the absence of a written agreement requiring such an assignment.[139] In the case of inventions by employees not hired to invent, the employer may still obtain the rights to employee inventions as a matter of contract law through an assignment of inventions,[140] which employees are often required to sign before they begin work.

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[135] *Id.*

[136] *Id.*

[137] Field, *supra* note 17, at 24 n.124; Hoffman, *supra* note 121, at 1008 ("In the presumably infrequent cases in which 'a licensee fail[ed] . . . to commercialize [a] technology,' the Act allowed a third party to petition the government for the right to license it for commercial purposes. . . . Unsurprisingly, the federal government has never exercised its 'march-in' rights.").

[138] 35 U.S.C. § 202(c)(4).

[139] Joshua L. Simmons, *Inventions Made for Hire*, 2 N.Y.U. J. INTELL. PROP. & ENT. L. 1, 14-15 (2012). Title does not immediately vest in the employer upon invention. *Id.* at 15. Factors a court will review to determine if an inventor has been hired to invent include, for example: previous assignments of patents by the employee; customary practice in the company; who originally posed the problem solved by the invention; and whether the invention was created during the period of employment. *Id.* at 15 n.55. *See also* William C. Lewis, *Hey! You Stole the Invention I Paid You to Invent!*, NEXSEN PRUET LLC (Oct. 13, 2011), http://www.martindale.com/labor-employment-law/article_Nexsen-Pruet-LLC_1358040.htm ("The 'hired to invent' doctrine is an exception to the rule that an inventor owns all rights to the invention. In general, someone hired to invent something who succeeds in accomplishing the task during the performance of the contract is bound to assign all rights to the invention to the person that hired them.").

[140] Assignment agreements vary in their terms. For example, some include "unconditional general assignment" policies obligating staff to assign all inventions; some agreements assign rights "only for special projects or sponsored research"; and some determine ownership on a case-by-case basis. Sean M. O'Connor, *The Real Issue Behind Stanford v. Roche: Faulty Conceptions of University Assignment Policies Stemming from the 1947 Biddle Report*, 19 MICH. TELECOMM. & TECH. L. REV. 379, 393 (2013).

Many U.S. universities require their researchers to assign their inventions to the university, regardless of the source of funding. For example, the Massachusetts Institute of Technology Guide to the Ownership, Distribution and Commercial Development of MIT Technology provides:

> Patents, copyrights on software, maskworks, and tangible research property and trademarks developed by faculty, students, staff and others, including visitors participating in M.I.T. programs or using M.I.T. funds or facilities, are owned by M.I.T. when either of the following applies:
>
> (1) The intellectual property was developed in the course of or pursuant to a sponsored research agreement with M.I.T.; or
>
> (2) The intellectual property was developed with significant use of funds or facilities administered by M.I.T. . . . [141]

It goes on to provide:

> PATENTS: Research contracts sponsored by the Federal Government are subject to statutes and regulations under which M.I.T. acquires title in inventions conceived or first reduced to practice in the performance of the research. M.I.T.'s ownership is subject to a nonexclusive license to the government and the requirement that M.I.T. retain title and take effective steps to develop the practical applications of the invention by licensing and other means.
>
> Contracts with industrial sponsors provide that M.I.T. retain ownership of patents while the sponsor is granted an option to acquire license rights.[142]

Universities aggressively protect their rights to their employees' inventions. *Fenn v. Yale University*[143] involved Yale University Professor and Nobel laureate in Chemistry John B. Fenn, the inventor of a chemical mass spectometry invention, for which Fenn was issued United States Patent No. 5,130,538 ('538 patent) on July 14, 1992. In 2003, the District Court for the District of Connecticut concluded that Fenn had breached Yale's internal patent policy, under which he was "contractually bound and which gave the university right of first refusal to patent any faculty inventions."[144] The court found that Yale had not exercised its ownership rights in the

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[141] MASS. INST. OF TECH., GUIDE TO THE OWNERSHIP, DISTRIBUTION AND COMMERCIAL DEVELOPMENT OF MIT TECHNOLOGY § 2.1., at 6 (revised June 2010), *available at* http://web.mit.edu/tlo/www/downloads/pdf/guide.pdf [hereinafter M.I.T. GUIDE TO OWNERSHIP].

[142] *Id*. at § 2.1.1., at 6.

[143] 2005 WL 327138 (D. Conn. Feb. 8, 2005).

[144] *Id.* at *1.

patent because of Fenn's failure to be "straightforward" with the university, thereby inducing Yale not to file a patent application and giving Fenn the opportunity to secretly file the application himself. Subsequently, in 2005, the court held that Fenn had committed conversion and statutory theft, entitling Yale to treble damages. In addition, the court ordered Fenn to assign his interests under the '538 patent to Yale, as provided by Yale's 1989 patent policy. The court wrote that Fenn could not profit from his own wrongdoing and that the patent could be reassigned to Yale, its rightful owner. Fenn ultimately was ordered to pay Yale $545,000 in royalties, as well as Yale's legal costs of almost $500,000.[145] For his part, Fenn had testified that he had filed his own patent on May, 19, 1989, "in an attempt to 'show up how [Yale] handled its business, which in my view was incompetent.'"[146] Yale's Office of Collaborative Research had not filed a patent application covering Fenn's invention by May 19, 1989, even though the last day to file for a patent was June 1, 1989.

State labor laws impose some limits on an employer's ability to require employees to assign all inventions. For example, California law provides that an employer may not require an employee to assign an invention that the employee developed entirely on his or her own time without using the employer's equipment, supplies, facilities, or trade secret information except for those inventions that either: (1) relate at the time of conception or reduction to practice of the invention to the employer's business, or actual or demonstrably anticipated research or development of the employer; or (2) result from any work the employee performed for the employer.[147] For most inventions created by university researchers, this limited carve-out will not prevent their employer from claiming all rights to their inventions.

3. Compensation for Inventors

The Bayh-Dole Act includes a provision requiring a nonprofit contractor to share royalties with the inventor.[148] It does not, however, dictate the percentage of royalties that must be paid to the inventor[149] or prescribe a minimum payment.[150] Instead, "[t]he provision that non-profit institutions share royalties was included merely to ensure that inventors were provided with an

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[145] Marius Meland, *Judge Rules for Yale in Patent Dispute with Former Professor*, LAW360 (Feb. 15, 2005), http://www.law360.com/articles/3016/judge-rules-for-yale-in-patent-dispute-with-former-professor.

[146] Fenn v. Yale Univ., 2005 WL 327138, at *4 (D. Conn. Feb. 8, 2005).

[147] CAL. LABOR CODE § 2870(a).

[148] 35 U.S.C. § 202(c)(7)(B).

[149] Alan S. Gutterman, *Bayh-Dole Act—Royalty Sharing Requirements, in* BUSINESS TRANSACTIONS SOLUTIONS § 209:24 (2014).

[150] Platzer v. Sloan-Kettering Inst. for Cancer Res., 787 F. Supp. 360, 368 (S.D.N.Y. 1992) (holding that "Congress' concern was with the reinvesting of funds to further research, not with furthering the private interests of individual inventors.").

adequate incentive to engage in scientific research."[151] Congress intended that "any sharing ratio should be left to the supply and demand of the market . . . ."[152]

It is therefore not surprising that royalty agreements vary by university or research institute. Certain institutions share a fixed percentage of the revenue (after deducting specified costs) generated from licensing the technology, while others implement a sliding scale system whereby the percentage of revenues paid out declines as the amount of revenue increases.[153]

For example, Sloan-Kettering paid its inventor-employees 5% of the royalties it received from their invention pursuant to a sliding scale set forth in the Center's patent policy.[154] The court rejected the inventors' claim for a larger percentage.[155]

> Stanford University's
>
> royalty-sharing policy provides for the distribution of cash net royalties (defined as gross royalties less 15% for OTL's [Office of Technology Licensing] administrative expenses, minus direct expenses) to inventors, their departments, and their schools. In 2012-13, inventors received personal income of $21.7M, departments received $19.4M, and schools received $18.8M. The University assessed an infrastructure charge on the department and school shares of royalty income.[156]

Thus, of the $87 million in gross royalty revenues received by Stanford in 2012-2013, the individual inventors received 25%.[157]

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[151] *Id.*

[152] *Id.*

[153] Gutterman, *supra* note 149.

[154] *Platzer v. Sloan-Kettering Inst.*, 787 F. Supp. at 362.

[155] *Id.* at 368.

[156] STANFORD UNIV. OFFICE OF TECH. LICENSING, ANNUAL REPORT 2013, http://otl.stanford.edu/documents/otlar13.pdf.

[157] *See id.*

M.I.T. distributes one-third of the Adjusted Royalty Income received from licensees to the inventors.[158] "Adjusted Royalty Income is equal to the gross royalty income less (1) a 15% administrative fee and (2) all out-of-pocket costs not reimbursed by the licensees, including all patent filing, prosecution and maintenance fees and certain marketing expenses.[159] If M.I.T. acquires from a company to which intellectual property is transferred "equity in lieu or partial lieu of royalties for intellectual property," any inventor who receives an equity position from that company does not share in MIT's equity. For all other inventors, M.I.T. distributes cash to the inventors upon occurrence of a liquidation event proportionate to what their cash share would have been had no equity been issued to M.I.T.[160]

In 1975, Yale University increased the percentage of net royalties paid to academic inventors from 15% to 50%.[161] It reduced that amount in 1984 to 30% of net royalty income up to $200,000 and 20% of net royalty income in excess of $200,000.[162]

The University of Wisconsin, which operates one of the most successful public university technology transfer operations in the United States, the Wisconsin Alumni Research Foundation (WARF),[163] gives academic inventors 20% of the royalties (before expenses) earned from their discoveries.[164] Although all faculty, staff and students must disclose their discoveries and inventions to WARF,[165] it does not require academic inventors to assign their inventions to the university except where required by funding agreements, such as inventions funded in whole or

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[158] M.I.T. GUIDE TO OWNERSHIP, *supra* note 141, § 4.8(A)., at 16.

[159] *Id.*

[160] *Id.* at § 4.9.2, at 18.

[161] Fenn v. Yale Univ., 283 F. Supp. 2d 615, 622 (D. Conn. 2003).

[162] *Id.* at 623.

[163] Wisconsin Alumni Research Foundation [hereinafter WARF], *For UW Inventors*, http://www.warf.org/for-uw-inventors.cmsx (last visited Jan. 21, 2015) ("Few institutions offer such generous returns, or have been as successful placing technologies and defending intellectual property.").

[164] *Id.*

[165] *Id.*

in part by federal research grants.[166] WARF also returns 15% of royalties to the inventors' departments to fund future research.[167]

4. University Technology Transfer Offices

University technology transfer offices function as the central clearinghouse for university-generated inventions, especially patents.[168] For example, the Technology Licensing Office at the Massachusetts Institute of Technology pursues

> the licensing of technology by researching the market for the technology, identifying third parties to commercialize it, entering into discussions with potential licensees, negotiating appropriate licenses or other agreements, monitoring progress, and distributing royalties to the inventors/authors in accordance with M.I.T. royalty policy. When it is appropriate to do so, M.I.T. may accept an equity position in partial lieu of cash royalties.[169]

Stanford University's Office of Technology Licensing (OTL) spent $9.3 million on patent and other legal expenses in fiscal year 2013, of which $4.0 million was reimbursed by licensees.[170] Excluding patent expenses, its operating budget was $6.6 million.[171] The OTL reported that in the period from 2012 to 2013 Stanford "received $87M in gross royalty revenue from 622 technologies, with royalties ranging from less than $10 to $55M. Forty-two of the 622 inventions generated $100,000 or more in royalties. Six inventions generated $1M or more."[172]

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[166] After disclosing an invention to WARF that was not federally funded (or subject to another funding agreement), the inventor "is free to dispose of the rights to the invention in the manner of his or her choosing." If WARF has expressed an interest in protecting the invention, the inventor may then choose to work with WARF. Univ. of Wisconsin-Madison, *Ownership and Equity Review, Who Has Rights to Inventions*, https://research.wisc.edu/projectagreementsip/intellectualprop/ownership/ (last visited Jan. 21, 2015). "The UW is unique among U.S. universities in that it does not claim ownership rights in the intellectual property generated by its faculty, staff, or students, except when required by funding agreements." Univ. of Wisconsin-Madison, *Intellectual Property*, https://research.wisc.edu/projectagreementsip/intellectualprop/ (last visited Jan. 21, 2015).

[167] WARF, *For UW Inventors*, *supra* note 163.

[168] They play a much less significant role in open source projects and informal collaborations.

[169] M.I.T. GUIDE TO OWNERSHIP, *supra* note 141, § 4.1., at 14.

[170] STANFORD UNIV. OFFICE OF TECH. LICENSING, *supra* note 156.

[171] *Id.*

[172] *Id.*

Stanford held, as of August 31, 2013, equity in 161 companies, issued pursuant to license agreements.[173]

In fiscal year 2013, Stanford's Industrial Contracts Office, a part of OTL, entered into 110 new specialized research agreements with industrial firms that "fund, and sometimes collaborate on, research projects in Stanford laboratories."[174] They included (1) several projects funded by the global chemical company BASF with Stanford investigators in materials science using "plasma-enhanced atomic layer deposition to grow oxide layers with precise thickness control for electronics" and (2) projects funded by The Boeing Company involving researchers in the School of Engineering "studying high-performance and reliable composite adhesive bonding for aerospace systems" and "researching fiber optical sensors and solar energy conversion for aerospace applications."[175]

In the fiscal year ended June 30, 2014, the Wisconsin Alumni Research Foundation earned $43.4 million in royalties and licensing fees and net income of $318.7 from its investment portfolio.[176] WARF paid university inventors $11.5 million, awarded University of Wisconsin at Madison $59.3 million in grants, and provided a $14.3 million grant to the Morgridge Institute for Research, a private, non-profit research center that partners with the University of Wisconsin at Madison "to explore new, uncharted scientific territory."[177] Since its inception in 1925, WARF has provided more than $1 billion in research funds to the university.[178]

C. Laws Regulating Technology Transfer in the European Union

The European Commission stated in 2010 that meeting the goals of the Innovation Union will require (1) giving researchers and innovators the ability "to move easily between public and private institutes," (2) clear rules on the ownership of intellectual property rights, and (3) "sharing and support systems . . . to facilitate knowledge transfer and the creation of university spin-offs and to attract (venture) capital and business angels."[179] The European Technology Transfer Offices circle includes leading European public research organisations that have joined forces "to boost innovation in Europe through a set of initiatives, including: fostering the use of

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[173] *Id.*

[174] *Id.*

[175] *Id.*

[176] WARF, *Financials*, http://www.warf.org/stewardship/financials/financials.cmsx (last visited Jan. 18, 2015).

[177] *Id.;* Morgridge Institute for Research, *About*, *Our Relationship with UW-Madison*, http://morgridge.org/about/our-relationship-with-uw/ (last visited Jan. 21, 2015).

[178] WARF, *For UW Inventors*, *supra* note 163.

[179] *EC 6.10.2010 Communication*, *supra* note 11, at 34.

their knowledge portfolio; sharing best practices, knowledge and expertise; performing joint activities; establishing informal channels of communication with policymakers; organising training programmes; and developing a common approach towards international standards for the professionalisation of Technology Transfer."[180]

1. **Allocation of Ownership Rights Between the University and its Researchers**

The EU Commission has not specified who owns academic inventions funded by the government so the twenty-eight Member States have established their own rules allocating the rights to intellectual property developed in university laboratories.[181] These national rules vary significantly in both form and substance and many have been amended in the last several decades to promote commercialization of university technology, in part to supplement limited government funding for public universities.[182] There is also no standard legislative model in the EU or its Member States for specifying the employer's and the employee's right to inventions or the employee's right to compensation.[183]

Historically, many European countries honored the "professor's privilege," which gave faculty members the right to retain ownership of their inventions even though they were created in the course of their employment.[184] This exempted professors from the usual rules giving employers the right to employee inventions arising out of an employee's assigned duties.[185]

The United Kingdom was the first European country to eliminate the professor's privilege.[186] The United Kingdom Patent Act of 1977[187] provides that academic researchers employed by a university do not own their inventions. In 1985, the U.K. went a step further and gave universities the right to patent their faculty members' inventions and to license them to

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[180] *European Technology Transfer Offices Circle*, EUROPEAN COMM'N, https://ec.europa.eu/jrc/en/tto-circle (last updated Apr. 30, 2014).

[181] *See* Sanna Wolk, *EU Intellectual Property Law and Ownership in Employment Relationships, in* 56 INFORMATION & COMMUNICATION TECHNOLOGY, LEGAL ISSUES, SCANDINAVIAN STUDIES IN LAW 419, 421 (Wahlgren ed., 2010).

[182] Malva et al., *supra* note 100, at 214.

[183] Wolk, *supra* note 181, at 420.

[184] Malva et al., *supra* note 100, at 214.

[185] *Id.* at 214 n.4.

[186] *Id.* at 214.

[187] Sections 39(1), 40(1) & 40(2) of the United Kingdom Patent Act 1977, as amended, www.ipo.gov.uk/patentsact1977.pdf.

third parties.[188] Prior to that time, a public agency – the British Technology Group – was the "nominal" owner[189] of academic discoveries.[190]

In the two-year period from 2000 to 2002, Austria, Denmark, and Germany abolished the privilege.[191] In contrast, Italy introduced it in 2001.[192] Interestingly, all four countries based their new laws on the need to promote commercialization.[193] Sweden continues to honor the privilege so professors in Sweden own the rights to their inventions and have the right to license them to others, including for-profit entities.[194] According to the European Commission, Sweden had "the best performing innovation system in the EU [in 2013], followed by Denmark, Germany and Finland."[195]

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[188] In 1950, Treasury Circular TC 5/50 "granted the 'right of first refusal' of patents created in universities by public funds to the NRDC" [National Research Development Corporation]. NRDC later merged with the National Enterprise Board, creating the British Technology Group. TC 5/50 was rescinded in 1985, effectively allowing universities to "patent and exploit" their intellectual property. *See* Daidree Tofano, Edwin Southern's Microarray: Policy and Intellectual Property Considerations (Apr. 25, 2006), at 15-18 (unpublished senior thesis) (available through Duke University at http://hdl.handle.net/10161/8114). A Treasury circular serves as "guidance to governmental departments" and is not legislation. As such, it may be passed or rescinded without the approval of Parliament and is "subject to change at any time as is seen fit." *Id.* at 15, 17 n.71.

[189] Malva et al., *supra* note 100, at 214.

[190] Maxine Clarke, *British Technology Group – UK Technology Transfer Grows*, 316 NATURE 385 (1985).

[191] Malva et al., *supra* note 100, at 214.

[192] *Id.* at 214. Article 65 of the Italian Industrial Property Code, enforced by Legislative Decree n. 30, enacted on 10.02.2005, provides that a researcher working for a university becomes the owner of all rights related to the patented invention. and each university can determine by itself the maximum amount of royalties that are to be paid to the university by a third party who gets the license to use the invention. *Country Overview, Italia, Who Owns IP in Research and Development*, http://www.biolegis.com/uploads/tx_articles/Who_owns_IP_Natale_Tulli___Associati_2011.pdf (referencing Industrial Property Code (I.P.C.) enforced by the Legislative Decree n. 30 on 10.02.2005, Article 64) (last visited Nov. 24, 2014).

[193] Malva et al., *supra* note 100, at 214.

[194] Ashley J. Stevens & April E. Effort, *Using Academic License Agreements to Promote Global Social Responsibility*, 43 LES NOUVELLES 85, 98 (2008).

[195] EUROPEAN COMM'N, INNOVATION UNION SCOREBOARD 2014, 4, 6 http://ec.europa.eu/enterprise/policies/innovation/files/ius/ius-2014_en.pdf. Switzerland was the European innovation leader, outperforming all of the EU Member States. *Id*.

Certain countries, including Austria,[196] France,[197] Hungary,[198] Italy,[199] the Netherlands,[200] Poland,[201] Portugal,[202] and Spain,[203] include employee inventor compensation provisions in their

[196] Austrian Patent Law entitles an employee to an "adequate, special compensation" for assigning an invention to the employer. If the employment is regulated under civil law, the rights to employee inventions must be transferred to the employer only if the transfer was agreed to in writing. The special compensation is paid in addition to an employee's ordinary salary. The amount is determined on a case by case basis and considers the economic importance of the invention; other exploitations of the invention; and the extent to which the support of the employer's resources contributed to the invention. No additional compensation is paid to employees who are explicitly hired for inventive activities. For employment relationships that are covered by public law ("civil servants, which may also include university employees") the employer has the right to demand the transfer of the rights to the employee's invention even if the transfer was not agreed to in writing. Public employees are also entitled to appropriate compensation for the transfer. *See Compensating Employee Inventors*, TAYLORWESSING (Jan. 2014), http://www.taylorwessing.com/synapse/ti_compensation_employee_inventors.html; *Country Overview: Austria – Who Owns IP in Research & Development*, http://www.biolegis.com/uploads/tx_articles/Who_owns_IP-austria.pdf (last visited Nov. 24, 2014); PATENTGESETZ 1970 [PAT G] [Austrian PATENT LAW] BGBL 1970/250, as amended BGBL I 2013/126.

[197] French Intellectual Property Code (consolidated as of January 1, 2014), section L.611-7. As discussed in Malva et al., *supra* note 100, at 218, the Innovation Act of 1999, Loi no 99-587 du 12 juillet 1999 sur l'innovation et la recherché, http://www.recherche.gouv.fr/technologie/mesur/loi/inovloi.htm, "added explicitly the commercial exploitation of patents and licences to the universities' mission, on the same footing as teaching and research" and made it possible for universities and public research organizations to create technology transfer offices, "to staff them with external personnel, and to run them according to business-like budgetary and accounting rules." The Ministry of Research enacted "guidelines for university-industry cooperation, which included the recommendation to adopt an intellectual property charter (so that, especially in universities, IPR [intellectual property right] matters could be explicitly regulated) as well as negotiation with companies of 'joint ownership agreements' over the results of collaborative R&D." *Id.*

[198] An employee invention is defined as "an invention made by a person who, without being under an obligation by reason of his employment, makes an invention, the exploitation of which falls within the field of business of his employer." "Remuneration for the right to exploit an employee invention shall be paid by the employer," and the remuneration amount for that right "shall be equal to that which would be payable by the employer for a license, on the basis of a patent license agreement," after considering licensing conditions in the field of the invention. Act XXXIII of 1995 on the Protection of Inventions by Patents, Articles 8, 10, 14 (Hungary). "Universities and third parties usually conclude research agreements under the Hungarian Civil Code" where the obligor performs research services and the sponsor pays remuneration; "[i]n practice, the parties agree that the sponsor of the research acquires all IP rights." *Country Overview, Hungary, Who Owns IP in Research & Development*, SZECSKAY, http://www.biolegis.com/uploads/tx_articles/Who_owns_IP_Szecskay_2011.pdf (last visited Nov. 24, 2014).

[199] In Italy, when "inventions [are] produced occasionally by the employee, during his free time, by using his personal technical instruments but exploiting the know how of the employer[,]" the employee owns the rights related to the invention, but the employer has the right to use or buy the patents from the inventor. *Country Overview, Italia*, *supra* note 192. "In any case, the author will be granted not less than 50% of the total amount of the royalties deriving from the license of the invention." *Id.*

[200] In the Netherlands, Article 12 (1) of the Patent Act of 1995 provides that, in a "regular employment relationship," the person who makes the invention may claim the patent. A "more favourable rule is set out in Article 12 (3)" for universities and research institutions – if the invention is made by a university or research institution employee, the employer is entitled to the patent, but the parties may alter this by agreement. Equitable remuneration is generally required for the employee if not provided for in the employment contract. *Country Overview: The Netherlands, Who*

Owns IP in Research and Development, http://www.biolegis.com/uploads/tx_articles/Who_owns_IP-olanda.pd (last visited Nov. 24, 2014).

[201] In Poland, the "default rule" for ownership of industrial property, as stated in Article 11, section 3 of the Industrial Property Law of 2000, as amended, is that the employer owns industrial property created by an employee, unless otherwise agreed. *IP Management, Cooperation Between EU & Strategic Partners, Poland*, HEIP-LINK, http://www.heip-link.net/content/about-heip-link (last visited Nov. 25, 2014). When an invention is made by a creator with the help of an economic entity, the economic entity may enjoy the right to exploit the invention in its own field of development. *Id.* (referencing Article 11, section 5 of Industrial Property Law of 2000).

[202] Industrial property law covers patent innovation in Portugal. If "inventive activity is provided for" in an employment contract, the patent belongs to the company, and the inventor is entitled to remuneration. *Country Overview – Portugal, Who Owns IP in Research & Development* (Oct. 2011), http://www.biolegis.com/uploads/tx_articles/Who_owns_IP__CRA_Law_2011.pdf (referencing Industrial Property Code (CPI), approved by decree-Law 36, 2003 of 5 March, as amended).

[203] Article 17 of the Spanish Patent Act states that if an employee made an invention "related to his professional activity in the company and the knowledge acquired into the company had influenced predominantly his invention or he had utilized company's means to achieve it, the employer would have the right to the invention's ownership or to reserve a right to use the invention for himself," and the worker is entitled to a fair economic compensation. *Country Overview: Spain*, http://www.biolegis.com/uploads/tx_articles/Who_owns_IP_Spain.pdf (last visited Nov. 24, 2014).

national patent legislation. Denmark,[204] Finland,[205] Germany,[206] and Norway[207] have enacted specific employee compensation laws.[208] Other countries apply general principles of labor law. As a result, there is a non-transparent and non-uniform system for determining who owns university inventions created in the EU.

For example, the German Employees' Inventions Act provides that a university can claim exclusive rights to employment inventions created by university researchers and research associates working on its campus using government funding.[209] Section 4 of the Act defines employment inventions "as those, that are made during the duration of the service or employment contract, and that have either developed from such activities of the inventor as were

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[204] Consolidate Act No. 104 of 24 January 2012 on Employees' Inventions, section 5; Consolidation Act No. 210 of 17 March 2009 on Inventions at Public Research Institutions, section 8.

[205] In Finland, the Act on the Right in Employee Inventions provides that an employee shall have the same rights to his or her invention as other inventors, unless otherwise provided by legislation. Generally, an employee owns all rights to an invention created by him or her; a specific procedure and assignment is required to render the invention the property of the employer. The employee is entitled to a "reasonable compensation" if the employer decides to assume the rights to an invention. Linda Berggren, *Finland: Employee Inventions*, BORENIUS LTD. (Feb. 7, 2008), http://www.mondaq.com/x/55254/employee+rights+labour+relations/Employee+Inventions. The law applies to both private and public employment and its provisions are "mainly non-mandatory," meaning it applies only in the absence of a separate contractual arrangement. *Id.* The Employee Invention Act does not apply to university researchers, whose rights are provided by the Act on the Right in Inventions Made at Higher Education Institutions (University Inventions Act). This law "extends the possibility for universities to assume the rights of inventions conceived within the domain of the institution"; prior to the law, the researchers were entitled to retain the rights to their inventions, unless otherwise agreed. If the research involves a party outside the university (collaborative research), the university has the right to acquire the right to the invention. For research not involving outside parties (open research), the inventor may retain the right to the invention. If the university acquired rights to the invention, the researcher is entitled to a "reasonable compensation," the amount of which is determined on a case-by-case basis. *Id.*

[206] German Employees' Inventions Act, section 6.

[207] The Norwegian Employee Invention Act of 17 April 1970, No. 21 provides that when an invention results from a specified task assigned to an employee as part of his or her employment, the employer is "entitled to have all or part of the rights to the invention transferred to it if the exploitation of the invention comes within the sphere of the company's activity." The employee has the right to be compensated for patentable inventions that are transferred. The Employee Invention Act can be modified by contract, but the right to compensation cannot be eliminated. *Employment and Employee Benefits in Norway: Overview*, PRACTICAL L. (Aug. 1, 2012), http://us.practicallaw.com/3-507-2636#a358906 .

[208] *See* Maximilian Haedicke, "Ownership" *in* PATENT LAW: A HANDBOOK ON EUROPEAN AND GERMAN PATENT LAW 242 (Haedicke & Timmann eds., 2013).

[209] German Employees' Inventions Act, *supra* note 206, section Three, § 42.

part of his work, or which are significantly based on experiences or work of the university."[210] Section 5 of the Act requires the employee to notify the employer in writing of service inventions, after which the university "as employer" may claim the right to such inventions.[211] The employer may exercise his rights to make either an unlimited claim or a limited claim to the service invention within four months of notification of the invention; if the employer releases its claim in writing or does not make a claim within four months of notification, the invention becomes a "free invention."[212] Such unclaimed inventions, as well as "all other inventions are free inventions, which are generally at the free disposal" of the employee-inventor, except that Sections 18 and 19 of the German Employees' Inventions Act require the employee to give the university notice of each invention and offer the university a non-exclusive right to make use of the invention before it is otherwise utilized.[213]

Several national patent acts permit universities and their researchers to allocate, by contract, the ownership rights to intellectual property developed in university labs even if the research was government funded. The Danish Act on Inventions at Public Research Institutions applies to inventions that can be patented by the Danish Patent Act. As a general rule, the right to inventions made by a university employee belongs to the employee under Section 7 of the Act on Inventions at Public Research Institutions.[214] The university may, however, pursuant to Section 8(1), claim the rights to the invention if it was made as part of the employee's work for the university.[215] If the research is funded in cooperation with a party not included in this Act, the university may, "on its own and the employee's behalf," in accordance with Section 9, enter into an agreement at the outset waiving the right to the inventions in full or in part resulting from this research.[216] Thus, in certain Member States, the legislative terms are default provisions that may

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[210] *Patents and Licenses, The Legal Protection of Research Achievements*, HUMBOLDT-UNIVERSITÄT ZU BERLIN, https://www.hu-berlin.de/research/transfer/patente_lizenzen/pl_pat_rec_html (last modified July 17, 2013) [hereinafter *Patents and Licenses*].

[211] *Id.* Kay N. Kasper, *Germany: The German Employee's Inventions Act – Beware of Employees' Rights to Inventions*, MAYER BROWN, http://www.mondaq.com/x/26577/Outsourcing/The+German+Employees+Inventions+Act+Beware+of+Employees+Rights+to+Inventions (last updated June 10, 2004).

[212] Kasper, *supra* note 211.

[213] *Patents and Licenses*, *supra* note 210.

[214] Consolidation Act No. 210 of 17 March 2009 on Inventions at Public Research Institutions, § 7.-(1).

[215] *Id.* at § 8.-(1).

[216] *Id.* at § 9.-(1). The Danish Act on Inventions at Public Research Institutions applies to universities governed by the Danish University Act, governmental research institutions, and health research institutions under the Danish regions, among others. *Id.* at § 6.-(1).

be modified by contract, as long as the contract does not conflict with the EU rules on State aid or EU competition law, which are both discussed in Part VII.

2. Compensation for Inventors

In the last several decades there has been heightened interest in the right, if any, researchers in university laboratories in the EU should have to share in the royalties and fees generated by their inventions.[217] The EU Commission has not addressed this issue so, as with the ownership of inventions by university scientists, the twenty-eight Member States have established their own rules concerning the rights, if any, researchers have to share in the fruits of their discoveries.[218] Unfortunately, these national rules vary significantly and can be very difficult for a lay person (or in some cases, even a lawyer) to parse. In addition, they can result in an allocation of IP rights that is not economically efficient given the different utilities universities, private firms and researchers might ascribe to commercialization. Finally, the absence of clear default rules greatly increases transaction costs.

Historically, employee compensation for their inventions was awarded in certain Member States in the EU, such as the United Kingdom, only in "exceptional circumstances."[219] For example, the UK Patents Court awarded two inventors at GE Healthcare Limited total compensation of approximately €1.5 million in *Kelly v. GE Healthcare*[220] but only because the patent was of outstanding benefit to the employer. Experts predict that "compensation in the UK is likely to continue to be an exception rather than the rule, with only claims regarding particularly profitable products having a good chance of success."[221] However, a university can agree by contract to give their researchers a share of royalties and licensing fees. For example, the University of Oxford has "a generous revenue-sharing policy" that "brings significant personal benefits to researchers . . . ."[222] Similarly, Danish patent laws permit the splitting,

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[217] Wolk, *supra* note 181, at 420.

[218] *See id.*

[219] Morag Peberdy & Alain Strowel, *Employee's Rights to Compensation for Inventions - A European Perspective*, *in* LIFE SCIENCES HANDBOOK 63, 63 (2009/10).

[220] Kelly v. GE Healthcare Ltd., [2009] EWHC (Pat) 181.

[221] Peberdy & Strowel, *supra* note 219, at 66.

[222] UNIV. OF OXFORD, RESEARCH POLICIES, http://www.ox.ac.uk/admissions/graduate/applying-to-oxford/university-policies/research-policies (last visited Nov. 26, 2014).

pursuant to contract, of patent licensing revenues between the inventing researchers and their institutions.[223]

In France, for inventions within the scope of employment, an employee-inventor is entitled by statute to remuneration from one to three times the employee's monthly salary, although higher amounts have been awarded.[224] A court of first instance in Paris awarded an employee of French National Railways (SNCF) $750,000.[225] In another French case, the French Supreme Court awarded an employee "additional remuneration" of $830,000 for the transfer of intellectual property rights in a prostate cancer drug to Hoechst Marion Roussel/Raynaud.[226]

In Germany, the compensation for employees in the private sector is between 10% and 20% of the economic value of the invention.[227] Different rules apply to the public sector, however. For example, university inventors receive 30% of the revenues generated from "commercialization" of the invention[228] as do researchers at the Max Planck Society,[229] a public research organization whose scientists were never afforded the "professor's privilege."[230]

3. University Technology Transfer Offices

A number of universities in the EU have established technology transfer offices to work with researchers and for-profit firms to commercialize inventions created in university laboratories. This often includes licensing patents to for-profit firms. An Organisation for Economic Co-operation and Development (OECD) report[231] revealed wide diversity in the structure and organization of technology transfer offices within and across the Member States, however. Variations include on- or off -campus offices, arm's length intermediaries, industry sector-based

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[223] Danish Act on Inventions at Public Research Institutions: Bekendtgørelse af lov om opfindelser ved offentlige forskningsinstitutioner, LBK nr 210 af 17/03/2009, *available at* www.retsinformation.dk/Forms/R0710.aspx?Id=123680. *See also* Siepmann, *supra* note 99, at 224.

[224] Peberdy & Strowel, *supra* note 219, at 65.

[225] *Id.* at 63.

[226] *Id.* at 66.

[227] *Id.* at 65.

[228] *Id.* at 68.

[229] Buenstorf & Geissler, *supra* note 8, at 485.

[230] *Id.* at 482.

[231] OECD, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003).

technology transfer offices, and regional technology transfer offices.[232] The majority appear to be dedicated on-site institutions that are integrated into the university or research institution. For example, Sorbonne University collaborates through strategic alliances with industry, files approximately twenty patents each year, and its intellectual property portfolio, which includes approximately 450 patents and other sources, generates more than one million euros annually in license fees.[233] The Sorbonne

> encourages faculty and students to create spin-off companies and has recently established a complete range of independent structures to facilitate its technology transfer activities. . . . UPMC [Universite Pierre et Marie Curie] also partners with the government ministry, research organizations, private companies, foundations, associations, and laboratories. Research cooperation agreements have been set up with leading industrial groups through the Research and Technology Transfer Department. This department implements the University's science policy, monitors the activities of research and technology transfer, and supports University research organizations."[234]

Humboldt University of Berlin's policy expressly notes the importance of securing patent rights for university inventions:

> Safeguarding the rights to inventions is imperative for effective marketing. HU aims to ensure that university inventions with the potential for wider use are legally protected. Its patent policy places equal importance on the bundling of rights and the equal treatment of all University members. HU supports the academic quality of its research findings by providing optimised patent protection. It also makes the general public aware of the quality of its work by filing its own patent applications.[235]

The Max Planck Society created a separate subsidiary, Max Planck Innovation GmbH, in 1970 to patent inventions, license them to domestic and foreign firms, and provide support for spin-offs.[236] Max Planck Innovation applies for patents "if the invention is patentable and

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[232] *Id.* at 12.

[233] SORBONNE UNIV., CREATING THE FUTURE 14 (2013), www.upmc.fr/modules/.../BrochureUPMC2014lt.pdf.

[234] *Id.*

[235] HUMBOLDT-UNIVERSITÄT, KNOWLEDGE AND TECHNOLOGY TRANSFER, http://www.hu-berlin.de/research/transfer (last modified Nov. 8, 2013).

[236] Buenstorf & Geissler, *supra* note 8, at 485.

considered sufficiently promising, even if no licensee for the technology has been identified yet."[237]

When the University of Copenhagen and certain other universities in Denmark collaborate with industry, they often insist that the university be the legal entity that enters into any agreements with external parties. As a result, external partners may not negotiate directly with individual researchers, faculties, or departments. Instead, all contracts must be negotiated through the University's Tech Transfer Office. In all its agreements, the University of Copenhagen seeks to advance the mission of creating and disseminating knowledge by requiring provisions permitting its researchers to publish their research results and to use them for research purposes. In addition, as discussed further below, the University must observe the EU State aid rules. As a result, favorable, that is, non-market agreements, with specific companies or the use of public funds to further particular private companies is not allowed.[238]

D. Recent Changes to the EU Patent System

The EU has already taken a variety of steps to create a faster and cheaper patenting system. Figures generated as of 2009 showed that it cost a minimum of fifteen times more to patent an invention for all (then) twenty-seven[239] EU Member States than in the United States.[240] The high cost, which the European Commission called "a tax on innovation," is largely attributable to legal and translation fees.[241] All Member States except Italy, Spain, and Croatia have agreed to create unitary patent protection in the EU by adopting two EU Regulations (one to create the Unitary Patent (UP) and a second to establish a translation regime for UPs) as well as an Agreement on a Unified Patent Court (UPC).[242] The UPC will have exclusive and specialized jurisdiction over patent cases to ensure uniform protection. The Regulations entered into force on January 20, 2013, but they will only apply from the date the UPC Agreement takes effect. That will require a minimum of thirteen ratifications, including ratifications by France, Germany, and the U.K.[243] As of January 2015, Austria, Belgium, Denmark, France, Malta and Sweden had

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[237] *Id.*

[238] UNIV. OF COPENHAGEN, COLLABORATING WITH THE UNIVERSITY OF COPENHAGEN, THE UNIVERSITY'S OVERALL PRINCIPLES, A GUIDE FOR OUR COLLABORATION PARTNERS 4 (2012), http://fi.ku.dk/english/box/pixi_eng/KU_s_guide_vedr__samarbejdsaftaler_GB_tileksterntweb.pdf/.

[239] As of December 2014 there were twenty-eight Member States.

[240] *EC 6.10.2010 Communication*, *supra* note 11, at 15.

[241] *Id.*

[242] *EC Taking Stock 2014*, *supra* note 13, at 39.

[243] *Id.*

ratified the agreement.[244] Once the UPC Agreement goes into effect, it will be possible to obtain a European patent based on unitary standards in one step. This is expected to reduce the translation costs of obtaining a patent from approximately €23,000 to €700, saving innovative businesses roughly €250 million.[245] It is anticipated that the first UP providing uniform protection within the territory of the participating twenty-five Member States will be granted in 2015.[246]

The EU is also exploring ways to commercialize unused patented technology by forming a market mechanism for its valuation and transfer.[247] "Technology markets tend to be thin; typically at best a few potential licensees exist for a particular technology, and licensing is based on small-numbers bargaining."[248]

Institutions of higher learning and businesses started forming Knowledge Alliances in 2014.[249] These structured partnerships strive to "design and deliver new curricula and courses, to develop new and innovative ways of teaching and learning, to facilitate the flow of knowledge between higher education and companies, to stimulate interdisciplinary activities/learning and to develop entrepreneurial skills and attitudes."[250] The "ultimate goal" of Knowledge Alliances is to stimulate innovation in and through higher education and make cooperation between higher education and business a "more common feature" of the higher education system in the EU.[251]

What may prove more challenging is providing the strong IP protection necessary to promote commercialization while respecting the EU's longstanding commitment to the public dissemination of publicly funded research.[252] The European Commission asserted in 2014: "The basis for the development of a more efficient knowledge system that protects intellectual property and investments in knowledge while providing the conditions for open collaboration

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[244] *The EU Single Market, Unitary Patent – Ratification Progress*, EUROPEAN COMM'N, http://ec.europa.eu/internal_market/indprop/patent/ratification/index_en.htm (last updated Jan. 29, 2015).

[245] Press Release, European Comm'n, *supra* note 2.

[246] *EC Taking Stock 2014*, *supra* note 13, at 39.

[247] *See Enterprise and Industry*, EUROPEAN COMM'N, http://ec.europa.eu/enterprise/policies/innovation/files/swd-2012-458_en.pdf (last updated Apr. 4, 2014).

[248] Buenstorf & Geissler, *supra* note 8, at 488.

[249] *EC Taking Stock 2014*, *supra* note 13, at 18, 90.

[250] *Id.* at 18.

[251] *Id.* at 18.

[252] *EC 6.10.2010 Communication*, *supra* note 11, at 19 ("The Commission will **promote open access** to the results of publicly funded research.") (emphasis in original).

and knowledge sharing are in place. This concerns in particular the Unitary Patent, the exploration of knowledge markets for patents and licences, and the transition from [ ] the concept of knowledge transfer to a system based on co-creation and open innovation."[253] The Commission noted that while there has been "gradual yet visible progress" by most Member States in "putting strategies in place regarding access and dissemination of scientific information, . . . their approaches vary considerably," with several Member States choosing "soft law rather than hard law when implementing OA [open access]."[254]

Top Institute (TI) Pharma is a self-described "independent research enabler of drug discovery and development" based in the Netherlands.

> [It] sets up and runs multidisciplinary partnerships that advance the development of socially valuable medicines. It links precompetitive, pharmaceutical research and expertise — from science to industry, from the Netherlands and across the globe — in open innovation. TI Pharma provides the third-party governance to build and safeguard the trust necessary in pharmaceutical partnership.[255]

Like the European Commission, TI Pharma asserts that "[o]pen innovation is the way forward — multidisciplinary collaboration between many different stakeholders in pursuit of groundbreaking research. But open innovation needs an independent third party that can bring partners together -- driving R&D towards the medicines we critically need."[256] TI Pharma's partners include small and medium sized enterprises (such as Vertex Pharmaceuticals Inc.), academia and knowledge institutes (such as Erasmus Medical Center Rotterdam and Drugs for Neglected Diseases Initiative (DNDI)), large industry (such as AstraZeneca), and health foundations and patient organizations, as well as regulatory authorities and governments (including the Medicines Evaluation Board and the Netherlands Vaccine Institute).[257]

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[253] *EC Taking Stock 2014*, *supra* note 13, at 34. *See also* EUROPEAN COLLABORATIVE AND OPEN REGIONAL INNOVATION STRATEGIES (EURIS), EMBRACING OPEN INNOVATION IN EUROPE: A BEST PRACTICES GUIDE ON OPEN INNOVATION POLICIES 11 (2012), http://cars.region-stuttgart.de/sixcms/media.php/923/euris_guide.pdf [hereinafter EURIS] (explaining that "Open Innovation is the practice of looking beyond the four walls of your company — towards suppliers, universities, producers of complementary products and services and other firms— to identify and capitalize on new opportunities for innovation.").

[254] EURIS, *supra* note 253, at 55.

[255] *Top Institute Pharma: the Independent Research Enabler*, TI PHARMA, www.tipharma.com/about-our-institute.html (last visited Dec. 1, 2014).

[256] *Vision*, TI PHARMA, http://www.tipharma.com/about-our-institute/vision.html (last visited Dec. 1, 2014).

[257] *Our Pharmaceutical Research Partners*, TI PHARMA, http://www.tipharma.com/partners.html (last visited Dec. 1, 2014).

Open innovation or access is a double-edged sword. On the one hand, it encourages multidisciplinary and multi-party collaboration. On the other, it increases transaction costs and makes coordination far more difficult than a partnership between one pharmaceutical firm and one or several research universities. Intermediaries like TI Pharma can help ameliorate these costs but cannot eliminate them. In addition, at the end of the day, it is critical to be clear who owns the inventions created by such consortia. In the case of drugs for neglected diseases that cannot be sold at a profit, the pharmaceutical companies may be willing to donate their discoveries for the common good. But once a drug has profit potential, the firms that contributed to its development will expect to share in the profits. As the Business for Social Responsibility's Healthcare Working Group (whose founding members include the heads of GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, and Takeda) stated:

> We depend on R&D to promote innovation and we support a variety of approaches such as clear patent policies and, when appropriate, voluntary licensing and collaborative models to increase access to our products. We believe that appropriate intellectual property protection enables innovation and creates the necessary conditions to make our R&D sustainable and enhance innovations over time.[258]

VI. Public Policy Concerns Raised by University Licensing in the United States and the European Union

Public policy questions are raised when a university patents an invention funded by the government and then licenses it to a private entity.[259] Overly broad licenses from academic institutions to private firms can stifle academic discovery and squelch innovation. For example, "reach-back licenses," which give the private firm licensee the right to any follow-on innovations developed by the academic institution, are particularly burdensome. Similarly, if the academic institution has no access to the discoveries the private firm makes when developing and commercializing the technology, this may hamper further work by the academic researchers.

While many universities have dedicated themselves "to the creation and dissemination of knowledge for the public good," [260] the leadership of each university "must decide whether and to what extent to embrace commercially oriented activities" based upon the respective

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[258] BUSINESS FOR SOCIAL RESPONSIBILITY, HEALTHCARE WORKING GROUP, GUIDING PRINCIPLES ON ACCESS TO HEALTHCARE 3, http://www.bsr.org/pdfs/our-work/working-groups/BSR_HCWG_GPAH.pdf (last visited Dec. 1, 2014).

[259] *See generally* Jacob H. Rooksby, *Myriad Choices: University Patents Under the Sun*, 42 J.L. & EDUC. 313 (2013).

[260] Sara E. Crager, Ethan Guillen, & Matt Price, *University Contributions to the HPV Vaccine and Implications for Access to Vaccines in Developing Countries: Addressing Materials and Know-How in University Technology Transfer Policy*, 35 AM. J.L. & MED. 253 (2009).

university's "mission."[261] Certain universities, especially in the United States, "view technology transfer as indelibly linked with their social obligations as universities."[262] Because "[u]niversities . . . are not in the business of developing commercial technologies," some argue that the private sector is better suited to commercializing academic inventions.[263] Technology transfer can be the link between publicly sponsored research and private-sector commercialization.[264] For example, the mission of the Massachusetts Institute of Technology's Technology Licensing Office "is to foster commercial investment in the development of inventions and discoveries flowing from the research at the Massachusetts Institute of Technology and Lincoln Laboratory. We do this through licensing of the intellectual property resulting from our research."[265] M.I.T. asserts, "It is through these investments – and the economic development and new products that follow from them – that university technology provides direct benefits to the public."[266]

Yet, unduly close ties between academic researchers and industry can create conflicts of interest,[267] result in perverse incentives, and force a shift from basic to applied research. In addition to interfering with the creation and transfer of knowledge, licenses to private firms can

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[261] Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CAL. L. REV. 1503, 1566 (2012).

[262] *Id.* at 1566.

[263] *Id.* at 1506.

[264] *Id.*

[265] *MIT Technology Licensing Office*, MIT, http://web.mit.edu/tlo/www/ (last visited Dec. 1, 2014).

[266] MASS. INST. OF TECH., AN INVENTOR'S GUIDE TO TECHNOLOGY TRANSFER AT THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY (2005), http://web.mit.edu/tlo/www/downloads/pdf/inventors_guide.pdf.

[267] *See generally* Bryan A. Liang & Tim Mackey, *Confronting Conflict: Addressing Institutional Conflicts of Interest in Academic Medical Centers*, 36 AM. J.L. & MED. 136 (2010). To help ameliorate the conflicts involved when an inventor will hold equity or options in a closely held company to which a university invention will be licensed, M.I.T. requires prior approval from the Vice President for Research before it will accept equity in lieu of cash royalties. M.I.T. GUIDE TO OWNERSHIP, *supra* note 141, at § 4.10.2., at 19. Similarly, if the inventor will continue as an M.I.T. employee after receiving equity in the licensee, the employee must sign M.I.T.'s Conflict Avoidance Statement. *Id*. Conflicts of interest also arise between industry (i.e., pharmaceutical companies) and doctors when pharmaceutical companies pay doctors for "speaking fees, travel and meals" to promote their products. Katie Thomas, *Drug Company Enlists Doctors Under Scrutiny*, N.Y. TIMES, Nov. 28, 2014, at A1. This can result in a doctor "inappropriately prescribing" a drug company's products, and it has been reported that some drug companies, in their quest to "cultivate relationships" with doctors, seek doctors with "troubled track records to market" their products to other doctors. *Id.* "[D]rug companies have paid billions of dollars" in the past few years to "settle federal charges that they inappropriately marketed their products, sometimes by providing 'speaking fees' in exchange for the doctor's prescribing behavior." Eric C. Campbell, a Harvard Medical School Professor of Medicine who studies these conflicts of interests, said that "This appears to be the business plan. . . . It appears to be, you do whatever you have to do, and you know that eventually you will pay fines, but you will pay the fines and still make a lot more." *Id.*

deprive patients of life-saving therapies. "[S]trong resentment and frustration have emerged as a result of the licensing and patent policies of universities," particularly when universities grant exclusive licenses to firms that "restrict access to essential products in the developing world.*"*[268] Because many licenses give pharmaceutical firms the right to decide where to file patents, the companies *"*generally file strategic patents in many developing countries to minimize the risk of competition from generic drugs.*"*[269]

In response to push-back from a coalition that included the inventor of the HIV drug Zerit®, the former head of the WHO's HIV/AIDS program, and six hundred Yale University professors, researchers and students who signed a petition calling on Yale to "'ease its patent'" on Zerit®, Yale University persuaded its Zerit® exclusive licensee Bristol-Myers Squibb to enter into an "agreement not to sue" with Aspen Pharmacare, the leading generic manufacturer in South Africa. As a result, Aspen was able sell the drug in South Africa at a fraction of the price charged in developed countries.[270]

Notwithstanding their proud history of creating and disseminating knowledge to the public, research universities in the EU and regulators may have to choose between open access and commercialization, at least for certain downstream discoveries. Of course, this is not a binary choice. As we argue later, open access may be suitable for upstream research data and research tools developed in the university laboratory but not for applications of that data or those tools. Indeed, the Union-wide Pilot on Open Research Data in Horizon 2020 recognizes these tradeoffs by giving parties the ability to opt out "under defined circumstances, including conflict with obligation to protect results, with confidentiality obligations, with security obligations or with rules on protection of personal data. They may also opt out if the achievement of the action's main objective would be jeopardised by making specific parts of the research data openly

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[268] Hafiz Aziz ur Rehman, *Equitable Licensing and Publicly Funded Research: A Working Model for India?*, 16 SW. J. INT'L L. 75, 88 (2010).

[269] *Id.*

[270] Stevens & Effort, *supra* note 194, at 87. Universities Allied for Essential Medicines, a student organization that grew out of Amy Kapczynski's work at Yale with Zerit®, "convened" an independent working group that developed the Equitable Access License, which is designed to promote the use of university inventions to promote global health by providing "a mandatory grantback of all improvements made by the primary licensee to the academic institution, which can then license the complete package of intellectual property non-exclusively to third parties who wished to make and sell the products in developing countries." *Id.* at 98. In exchange, the university would charge a 5% royalty on sales in Middle Income Countries and a 2% royalty for sales in Low Income Countries (as defined by the World Bank) and then split the royalties with the primary licensee. *Id.* According to Stevens & Effort, the pharmaceutical firms with which they discussed this matter indicated that they would be unwilling to license academic inventions pursuant to a license that gave the university a grantback of the inventions the private firms generated in the course of developing and commercializing the licensed technology. *Id.* Thus, this approach is unlikely to work for the development of for-profit drugs.

accessible."[271] Thus, if a successful PPPP required keeping research data confidential, that would appear to be permissible.

The public policy issues are particularly acute when a university issues an exclusive license on a foundational technology or research tool funded by the government to a private for-profit pharmaceutical enterprise. For example, Harvard University was criticized after it granted exclusive rights in 1990 to the DuPont Pharmaceutical Company to the "oncomouse," a strain of transgenic mice created with "a proprietary gene-insertion method called Cre-loxP, which enables a researcher to select particular conditions under which expression of a transgene may be induced or repressed."[272] DuPont demanded that scientists (1) stop sharing data generated by research using the mice, (2) submit future scientific journal articles to DuPont for pre-publication review, and (3) give DuPont "'reach-through' rights to downstream inventions arising from the use of transgenic animals created by the Cre-loxP method."[273] The director of the National Institutes of Health (NIH) and others pressured DuPont to relax its restrictions on the use of its transgenic animals and to stop demanding reach-through rights and pre-publication review of research.[274]

Certain universities "have recognized the impact they can have on improving access to medicines that originate on their campuses*"* and view themselves as "ideally suited to address the dire needs of the estimated 10 million people who die each year because they do not have access to existing medicines and vaccines." [275] For this reason, they may be willing to forego some or all license and royalty fee revenue, especially when the invention relates to a disease prevalent in developing countries, such as malaria and tuberculosis. Other universities have sought to maximize the royalty streams available from their research. Particularly at a time when available federal grants from the NIH and other funders have been sharply reduced, royalty income may be seen as necessary to fund further research or other needs, including financial aid for needy students.

To address concerns about access to life-saving drugs, a group of U.S. universities promulgated a statement of "Nine Points to Consider" when patenting or licensing

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[271] *EC Taking Stock 2014*, *supra* note 13, at 55.

[272] Hoffman, *supra* note 121, at 1029. *See also* Edward Lee, *The New Canon: Using or Misusing Foreign Law to Decide Domestic Intellectual Property Claims*, 46 HARV. INT'L L.J. 1, 4-5 (2005) (noting that the Supreme Court of Canada held that the oncomouse was not patentable subject matter because it was a "higher life form," not an article of "manufacture" or "composition of matter" even though the United States, Japan, and the EU had granted Harvard University patents for the transgenic mouse).

[273] Hoffman, *supra* note 121, at 1029.

[274] *Id.* at 1029-30.

[275] Crager et al., *supra* note 260, at 258.

pharmaceutical inventions.[276] That guidance explains that universities should structure licensing agreements in a manner that gives "underprivileged populations," especially in developing countries, no-cost or low-cost access to pharmaceutical innovations.[277] Alternatively, a university may try to license its invention only to a pharmaceutical enterprise with similar humanitarian views, under a concept termed "socially responsible licensing."[278] Or, a university or private firm may seek an NGO (non-governmental organization), such as the Bill and Melinda Gates Foundation,[279] to pay a fair royalty or licensing fee for drugs for patients in developing countries and neglected diseases.

The NIH has adopted protocols offering guidance for when it is appropriate for a research university to patent certain innovations.[280] Although it lacks clear legal authority to do so, the NIH has conditioned grants on an applicant's willingness to forego seeking broad patents on the human genome. As discussed further below, we would encourage Congress to give the NIH express power to do this.

Certain academics argue that exclusive patent licenses are necessary to reduce "the perceived risk of investing in unproven technology to attract private risk capital."[281] But former Harvard University President Derek Bok cautioned: "Zealous campus officials can slow commercial applications and drive up prices of valuable products by granting exclusive patent licenses, where nonexclusive licenses would be feasible, merely to let the university share in any monopoly profits that the exclusive licensee manages to earn."[282] Patent pools, which are discussed in Part VII.B., can help address this issue.

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[276] CAL. INST. OF TECH. ET AL., IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY (White Paper) (2007), *available at* www.otl.stanford.edu/documents/whitepaper-10.pdf.

[277] Crager et al., *supra* note 260, at 259.

[278] Rehman, *supra* note 268, at 88.

[279] *See* Stevens & Effort, *supra* note 194, at 92-93.

[280] Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413 (Apr. 11, 2005); Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090 (Dec. 23, 1999).

[281] Lori Pressman, Richard Burgess, Robert M. Cook-Deegan, Stephen J. McCormack, Io Nami-Wolk, Melissa Soucy, & LeRoy Walters, *The Licensing of DNA Patents by Large US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH. 31, 37 (2006).

[282] DEREK C. BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION 112 (2003). For a discussion of how technology transfer offices are traditionally evaluated and suggestions of new metrics that "could influence the adoption of alternative IP approaches and better evaluate the contribution of genomic research to society," see Rebecca Goulding, Emily Marden & Rachael Manion, *Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research*, 16 B.U. J. SCI. & TECH. L. 194, 195 (2010).

VII. Creating a New Technology Transfer Model for the European Union

Although *The Economist* initially characterized Bayh-Dole as "innovation's golden goose,"[283] it subsequently questioned the influence it had had on university research.[284] There are significant advantages to the U.S. approach to commercializing government-funded inventions, but we submit that the EU should not enact legislation akin to Bayh-Dole without giving universities and public funders more discretion over (1) when technology must be patented to avoid having it revert to the government, (2) who should own the patents, and (3) when exclusive licenses are permissible.

We agree with Liza Vertinsky: "Universities should . . . be viewed not simply as 'engines,' but rather as guardians of their inventions, and the law should be designed to encourage their responsible involvement in shaping the post-discovery future of their wards."[285] This would create a middle ground between the model of open innovation in the IMI and open access in Horizon 2020 on the one hand and the "anticommons" created by the current U.S. system on the other.

The research by Lissoni[286] makes it clear that the research university does not necessarily have to own the IP created by its researchers for commercialization to occur. The EU should, however, act to promote the clear and economically efficient allocation of IP rights to government-funded academic inventions among the governments providing the funding, the private pharmaceutical entities, the public universities, and the academic and industrial researchers engaged in PPPPs and other public-private collaborations. [287] The existing divergent and often opaque national rules in the Member States concerning both the ownership of the IP rights stemming from university research and the rights of the individual researchers to a share of the royalties generated by their discoveries make it harder and more expensive for public and private parties to negotiate and operate efficient PPPPs. The European Commission could enhance transparency, reduce transaction costs, and promote efficiency by promoting at least some harmonization of the Member States' laws regarding the ownership of inventions while permitting the Member States to choose from a menu of options. We also urge the EU to require universities to share at least some part of the royalties and fees they receive as a result of

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[283] *Innovation's Golden Goose*, ECONOMIST, Dec. 12, 2002, http://www.economist.com/node/1456653.

[284] *Bayhing for Blood or Doling Out Cash?*, ECONOMIST, Dec. 20, 2005, http://www.economist.com/node/5327661.

[285] Liza Vertinsky, *Universities as Guardians of their Inventions*, 2012 UTAH L. REV. 1949, 1949 (2012).

[286] Lissoni, *supra* note 101.

[287] *See* Bart Verspagen, *University Research, Intellectual Property Rights and European Innovation Systems*, 20 (4) J. ECON. SURVEYS 607, 618-20 (2006) (explaining that maximizing the likelihood and magnitude of success of a PPPP or other joint research project requires the parties to decide who should own the patents resulting from university research – the government, the university, or the individual researcher).

discoveries funded with public money with the individual researchers or to provide non-financial incentives, such as reduced teaching loads, more graduate students, or better equipped laboratory space. Finally, we applaud recent steps taken to clarify the application of the State aid rules to PPPPs and suggest additional safe harbors.

A. Ensuring a Clear and Efficient Allocation of Intellectual Property Rights

1. Harmonization with Flexibility

The current opaque patchwork system of allocating IP rights to the government or to universities and their researchers impedes efficient technology transfer in the EU. Conversely, clear rules can facilitate the transfer of technology from the university research lab to the marketplace, both by clarifying ownership of inventions and by offering incentives for researchers to collaborate with industry. We assert that the European Commission should, as part of its overall restructuring of patent law in the EU and in furtherance of the Innovation Union, make harmonization a priority.

Even though achieving Union-wide consensus on the ownership of intellectual property will not be easy, we believe that it may not be as difficult as it may at first appear. In practice, by operation of law or pursuant to contract, most of the Member States already give the employer the rights to an invention created by one of its employees if (1) the invention was created in the course of the employee's normal duties and (2) the invention might reasonably have been expected to result from carrying out such duties. The European Commission could clarify ownership rights by establishing a default rule to this effect, which would then apply unless a Member State enacts legislation, taken from a limited menu of options, that clearly articulates who owns the discoveries generated by university researchers utilizing public funds. Thus, Italy and Sweden could elect to keep their current system by giving academic researchers all ownership rights to the inventions while the U.K. and Germany could give those rights to the universities unless the university and its researchers agreed otherwise by contract. Rather than incurring the transaction costs associated with individual assignments of inventions, universities should consider adopting various templates, perhaps through the European Technology Transfer Offices circle. That way, researchers could factor a university's technology transfer rules into account when deciding where to work, thereby enhancing the efficiency of the labor markets in the EU.

Our proposal would permit the Member States to determine, perhaps university by university, the proper balance between a university's role in promoting the free flow of information by treating inventions, especially those funded with government money, as public goods, which should be available to anyone, and its need to raise money to fund future research and to give a private industry partner the financial incentive to commercialize a promising discovery. Compare, for example, the University of Copenhagen technology transfer policy with the policy of the University of Oxford. The University of Copenhagen states that the university "places great importance on its collaborative relations with external partners and we strive to enter collaboration agreements as fast and as smoothly as possible. In this process, the University focuses more on the transfer of knowledge and less on financial return."[288] Other universities

[288] UNIV. OF COPENHAGEN, *supra* note 238, at 3.

focus more on financial return for the university and, in certain institutions, the researchers themselves. For example, the University of Oxford's policy states:

> Oxford's approach to exploitation of IP includes a generous revenue-sharing policy, which brings significant personal benefits to researchers, and a hugely successful and well-resourced technology transfer operation, Isis Innovation. Isis works with University researchers on identifying, protecting and marketing technologies through licensing, spin-out company formation, consulting and material sales.[289]

We would also encourage the EU to adopt a default rule providing that academic researchers and their research units (e.g., their department) are entitled to receive specified percentages of the net revenues received by their university as a result of their inventions. The Member States (or, pursuant to legislation adopted by a Member State, the universities in that State) might be given a range within which they could increase or decrease those default percentages, depending upon their own societal values. At a minimum, each university should be required to specify the share of royalties (or at least the minimum percentage of royalties) payable to the academic inventors for licensed inventions and patents and the equity guaranteed an inventor in the case of a spin-off of university technology.

2. Understanding the Differing Utility Functions of Three Dyads in the EU

Ensuring an efficient allocation of IP rights requires policy makers, universities, and private actors to analyze the varying interests of three dyads involved in the funding and conduct of pharmaceutical research in the EU: (1) the EU and the Member State, (2) the Member State and the university or industrial firm, and (3) the university and its research scientists. The EU funds partnership research among universities and the private pharmaceutical sector through Innovative Medicine Initiative grants. The Member States fund research at the university level, and universities fund research scientists and their departments. Because the players have different utility functions, [290] their disparate and joint interests must be taken into account when allocating IP rights by law or through private contract.

a) The EU and the Member State

The EU's bold plans for an Innovation Union require the development of new healthcare technology and pharmaceutical products that will both make the EU more competitive in the global marketplace and provide better medical outcomes for individuals living in the Member States. The EU Commission has stated that collaboration between public universities and the private pharmaceutical sector is important to the success of the IMI and recommended greater use of PPPPs to achieve this objective.

Aside from wanting to diversify the inputs for innovation and to allocate the rewards in a fair manner to ensure political, social and economic stability, the EU should be agnostic as to

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[289] UNIV. OF OXFORD, *supra* note 222.

[290] *See* Bagley & Tvarnø, *supra* note 43, at 386-90, 396; PRAJIT K. DUTTA, STRATEGIES AND GAMES: THEORY AND PRACTICE 52–53 (1999).

which Member State generates the next blockbuster drug. Rather than picking national champions, the EU should direct human and financial capital to those parties most likely to develop the most significant discoveries at the lowest cost. That is a basic premise of the IMI model of seeking competing bids in response to calls for proposals.

The Member States compete with each other to garner the largest "IMI market share." If a given Member State's universities do not win the competition for limited public and private funding, the Member State will lose valuable opportunities to innovate, provide new jobs, and grow. In this respect, the interests of the EU and the Member States are similar and can be described as a growth agenda to be solved by a properly crafted PPPP contract and the efficient allocation of IP rights. But the individual Member States might be tempted to "put a thumb on the scales" to give their own national firms the right to technology developed by their universities with public funds at lower than EU market rates. As long as the Member States can introduce national legislation that conflicts with the EU objectives, the future of PPPPs in the EU is problematic. This danger can be addressed through both the efficient allocation of intellectual property rights and the proper implementation of the State aid rules.

When crafting the rules allocating IP rights, it is critical for policy makers to keep in mind that the various participants in a PPPP may have different utility functions, which will determine which choices they find rational.[291] If a party's share of the returns from the IP resulting from a PPPP is too low, the counterparty might not collaborate and the contract will fail to meet the parties' objectives.

A French study compared traditional contracting schemes and licensing allocations with the terms of PPPPs[292] based on the European public-private partnership initiative between European Federation of Pharmaceutical Industry and Associations (EFPIA) and the European Commission (DG Research – health priority) that resulted in the Innovative Medicines Initiative. The goal of the study was to establish a model for PPPPs dedicated to creating growth and innovation through an alternative model of collaboration while at the same time ensuring a balance between both academic research and the interests of the industry in discovering and developing innovative drugs for the benefit of all stakeholders, including consumers. [293] The study concluded that the back offices in both the public and the private sector must be educated about the aims and objectives involved in negotiating, signing, executing, operating, and finalizing a PPPP collaboration. In particular, establishing the basis for a common culture on project management and intellectual property, and promoting trans-disciplinary profiles, requires:

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[291] DUTTA, *supra* note 290, at 12.

[292] Jacques Demotes-Mainard, Emmanuel Canet & Lionel Segard, *Public-Private Partnership Models in France and in Europe*, 61THÉRAPIE 325, 326 (2006).

[293] *See* Bagley & Tvarnø, *supra* note 43, at 400-401.

– training personnel (including not just researchers, but also public administrative staff) in project management to ensure fulfillment of contract objectives, adherence to timelines, quality assurance, and the on-time production of all deliverables;

– mobility between the public and the private sector; and

– specialized training in translational medicine or pharmaceutical medicine covering target and drug discovery, preclinical development, clinical trials, and management.[294]

At a minimum, therefore, the European Commission should help ensure that the back offices of both the private and public parties to a PPPP understand the importance of allocating the IP rights efficiently in their IMI or other contracts. Because the allocation will affect the likelihood of success, we further recommend that bidders be required to include their proposed PPPP contract with their bid for IMI funds.

b) The Member State and the University or Industrial Firm

Each Member State should seek to foster collaboration between its academic institutions and industry participants to attract investment without sacrificing the public good created by the academy and its members or violating local cultural norms. Public universities receive grants from the Member State to perform basic scientific research and at the same time can collaborate with industry to generate revenues that can be plowed back into the university to fund further research or meet other funding needs. But universities and pharmaceutical companies have different drivers and underlying motivations. Private pharmaceutical companies are generally driven by a focus on maximizing shareholder wealth (although George W. Merck, the son of the founder of Merck, famously explained that his father's belief was that as long as the firm stayed true to its purpose of remembering that medicine was for the patient, the profits would follow[295]), while universities focus primarily on research and the creation and dissemination of knowledge. Thus, the university must ensure that society can benefit from the publicly funded science through strategic research without unduly restricting use of basic scientific discoveries. At the same time, it must offer sufficient incentives to persuade private firms to commercialize academic discoveries.

The Member States should develop competencies and dynamic capabilities, including national PPPP platforms, to help industry and universities successfully respond to IMI calls.[296]

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[294] Demotes-Mainard, Canet & Segard, *supra* note 292, at 332.

[295] George W. Merck, the son of George Merck, the company's founder, explained his father's vision of the company by stating: "We try to remember that medicine is for the patient. We try to never forget that medicine is for the people. It is not for the profits. The profits will follow and if we have remembered that, they have never failed to appear." SUSAN E. REED, THE DIVERSITY INDEX: THE AMAZING TRUTH ABOUT DIVERSITY IN CORPORATE AMERICA . . . AND WHAT CAN BE DONE ABOUT IT 44 (2011).

[296] *See* Demotes-Mainard, Canet & Segard, *supra* note 292, at 326.

To enhance innovative competencies, both in academia and industry, the Member States must help develop knowledge networks and innovation clusters, of the sort that gave birth to Silicon Valley in the United States. They should facilitate transparency and the sharing of information so transactions are priced properly, build up national infrastructures (by funding basic research, for example, or providing scholarship funds for aspiring scientists), and promote knowledge management and education. Like the European Commission, the Member States should also ensure that national applicants for IMI funds allocate the IP rights in the most efficient way.

c) The University and its Industrial Partners and Academic Researchers

If structured properly, the relationships between a university and its industrial partners can provide unique competitive advantages at both the university and industry level.[297] Game theory can explain the interdependence among the contracting parties to a PPPP,[298] as well as the parties affected by the PPPP, such as individual academic and industry researchers. It also suggests the possible outcomes from various choices and thereby can assist negotiators in better predicting how various contractual provisions are likely to affect the strategy the other party might choose.

The efficient equilibrium for the allocation of IP rights will depend, at least in part, on the ex ante bargaining power of the parties.[299] "R & D expenditures [by a pharmaceutical firm] are strategic and rational if they are chosen to maximize the profit from developing a new drug, giving inferences about the competition's commitment to this line of drug."[300] Ex ante, a university researcher is often unable, due to the lack of capital and know-how, to negotiate effectively with a private company for the transfer of ownership even when such a transfer would create the highest total surplus. [301] Thus, it can be argued that the university researcher should not hold the IP right in the first place; instead, the IP rights would be more efficiently placed at the university level, which holds more capital and has greater bargaining power ex ante. That is the economic foundation of Bayh-Dole.

But the utility attainable from a discovery is not always transferable in ex ante bargaining over IP rights between a university and a private pharmaceutical company. Without the academic's active involvement, most attempts to commercialize are far more likely to fail.[302] In

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[297] *See* Verspagen, *supra* note 287 (discussing the literature on university patenting).

[298] Bagley & Tvarnø, *supra* note 43, at 386-90.

[299] Philippe Aghion & Jean Tirole, *Opening the Black Box of Innovation*, 38 EUR. ECON. REV. 701, 704 (1994).

[300] DUTTA, *supra* note 290, at 5.

[301] Aghion & Tirole, *supra* note 299, at 707-708.

[302] Reddi Kotha, Gerard George & Kannan Srikanth, *Bridging the Mutual Knowledge Gap: Coordination and the Commercialization of University Science*, 56 ACAD. MGMT. J. 498, 503 (2013) (" 'at the time of license, most university inventions are at such an early stage of development that no one knows if they will eventually result in a commercially successful innovation or not. Moreover, they are so embryonic that further development with the

addition, the private ownership of patents by university researchers might in fact lead to a situation in which the individual inventors (if they own the IP rights to their discoveries) can easily transfer them to the private industrial firms that have the capital and other resources to commercialize them. [303] As Lissoni found, this already frequently happens in Europe.[304] "Giving property rights to the research unit is optimal when it is more important to encourage the unit's effort to discover than to boost the customer's financial (and nonfinancial) investment in the research."[305] That reasoning underlies the professor's privilege.

Research by a PPPP is usually conducted by scientists in both the private company and the university. The privately employed researcher is assumed to act as directed by the management of the company and to be appropriately compensated therefor. Absent shirking, the industrial researcher's objectives will be closely aligned with those of its employer. In contrast, the academic researcher, the key player at the university level, may have academic rewards and costs associated with both discovery and commercialization that are different from the employing university. Thus, when deciding how to allocate the financial rewards from inventions by university scientists, it is important for both public policy makers and individual institutions to consider academic researchers' utility function to ensure an appropriate pay-off.

Many academic researchers are driven less by purely monetary rewards, such as shared royalties, than by a desire to create and disseminate knowledge, to improve their own academic research skills, to increase their research capacity, and to ensure their own advancement in the academy.[306] This is often accomplished by being able to hire the best research associates, graduate students, and postdocs; having access to the latest equipment and other laboratory facilities and the most current data and biologic materials, such as cell lines; being the first to publish innovative and impactful research findings; and having the opportunity to interact with and present their findings to leaders in their field. Given that the university owns or at least controls the IP rights to university inventions in most Member States, an academic researcher will be less inclined to collaborate with industry unless there is an incentive (or at least no disincentive) to do so. Because an academic researcher's utility decreases if the cost of participating in a PPPP or other collaborative arrangement is not offset by the benefits, public-private partnerships and other academic-commercial collaborative arrangements require

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active involvement of the inventor is required for any chance of commercialization.'") (internal citation omitted; emphasis in original).

[303] Verspagen, *supra* note 287, at 619.

[304] Lissoni, *supra* note 101.

[305] Philippe Aghion & Jean Tirole, *The Management of Innovation*, 109 QUARTERLY J. ECON. 1185, 1186 (1994). Note that customers are defined as "those parties who directly benefit from the innovation; namely, the manufacturers who commercialize the innovation, the users who will purchase the resulting product, and the suppliers of complementary products . . . ." *Id.*

[306] *See* Buenstorf & Geissler, *supra* note 8, at 487 (noting that "continued involvement in the development of disclosed and licensed inventions comes with opportunity costs for the academic inventor").

"specialised managers in charge of the operational management" as well as administrative procedures that "facilitate contracts" and "optimize intellectual property rights, balancing [not only] industry (patenting) and scientific interest (publishing)"[307] but also, in the case of the EU, the public and economic interests both of the Member State in which the university and its researchers are located and of the European Union as a whole. In addition, university technology transfer offices should be as easy to navigate and user-friendly as possible so the academic researchers do not have to waste valuable research time coming to terms with them.

The game illustrated below, called the "Odd Couple,"[308] shows how two parties with different utility and investment profiles will settle an argument about who should devote more resources to a given task. [309]

	B = 3 hours	**B = 6 hours**
A = 6 hours	-4, -1	4, -1
A = 9 hours	1, 2	1, -1

This text book game involves two individuals living in the same apartment who place different value on having a clean place to live.[310] It assumes that it takes twelve hours to clean the apartment per week and that players have three, six, or nine hours of cleaning as the possible strategies.[311] As seen in the table, if Person A derives the greatest utility from a clean apartment, then (1, 2) is the equilibrium and solution of the game, that is, Person A will spend nine hours

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[307] Demotes-Mainard et al., *supra* note 292, at 329.

[308] DUTTA, *supra* note 290, at 52-53.

[309] *Id*.

[310] *Id*.

[311] *Id*.

cleaning and Person B will spend three hours. Thus the dominant strategy for two players with different utility functions is for the party with the highest utility to invest more, even when a disproportionate share of the benefits accrues to the other party.

In this article, we assume that the pharmaceutical company (or the EU or the Member State) will act similarly to Person A because its pay-off from commercialization is larger than that of the university researcher (Person B). In many of the Member States, the employer owns the invention if it was made in the course of the employee's normal duties, and compensation is only awarded in exceptional circumstances. Yet, the savvy commercial partner realizes that it needs the active involvement of the academic researcher to commercialize most inventions. Similarly, it is important for policy makers at both the Member State and the EU level to appreciate the fact that neither the current applicable law nor the IMI contracting process ensures that academic researchers are adequately compensated either financially or academically or both. As noted earlier, it is optimal to give the IP rights to the academic researcher "when it is more important to encourage the unit's effort to discover than to boost the customer's financial (and nonfinancial) investment in the research."[312]

Thus, the strategy of the University of Copenhagen is problematic if the government of Denmark wants to grow Denmark's translational medicine capabilities because the university "focuses more on the transfer of knowledge and less on financial return."[313] To the extent that its researchers receive neither financial compensation nor non-financial incentives, such as greater prestige, access to better students and the like, they will be less likely to participate in commercialization in an efficient way. If, however, policy makers in Denmark conclude that it is more important for its universities to create common goods in furtherance of open access than to commercialize inventions, then the University of Copenhagen's strategy makes sense.

In contrast with the University of Copenhagen, a number of universities promote commercialization by giving incentives to researchers who develop patentable inventions. For example, Humboldt-University supports the academic quality of its research findings by providing "optimised patent protection" and "equal treatment of all University members."[314] The Sorbonne "encourages faculty and students to create spin-off companies and has recently established a complete range of independent structures to facilitate its technology transfer activities."[315] Oxford University ensures significant personal benefits to researchers by identifying, protecting and marketing technologies through licensing, spin-out company

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[312] Aghion & Tirole, *supra* note 305, at 1186.

[313] UNIV. OF COPENHAGEN, *supra* note 238, at 3.

[314] HUMBOLDT-UNIVERSITAT, *supra* note 235.

[315] SORBONNE UNIV., *supra* note 233.

formation, consulting and material sales, thereby promoting the creation of economically efficient PPPPs.[316]

In addition, certain universities promote closer academic-industrial partnerships and spin-offs by giving tenured professors some period of time, up to two years, during which they can work full-time on a commercialization project without losing the right to return to their tenured academic position. This both enhances the professor's opportunity to share in the financial success of the venture but also reduces his or her opportunity cost if the venture fails.

B. Navigating the "Anticommons"

An "anticommons"[317] exists whenever "property rights cannot be aggregated efficiently to create, for example, effective methods for assembling and screening new molecules or to realize the ambitions of personalized medicine, which would require whole-genome sequencing."[318] This is of particular concern as it affects the public availability of research tools and upstream research related to emerging areas, such as pharmacogenomics[319] and microbiotics. As Heller and Eisenberg explain, "Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of . . . innovation."[320]

Certain empirical studies suggest that patents have not been as much of an impediment to upstream academic research as originally theorized, but that appears due in large part to the fact that "scientists typically ignore patents, and that for the most part, they get away with it."[321] For example, respondents in a study of twenty-five German institutions, including large pharmaceutical firms, small-and-medium sized biotechnology firms, biotechnology research institutions, and clinical institutions associated with universities doing R&D in genetic engineering "indicated that patents on research tools were infringed 'behind locked laboratory doors,' that patentees were generally unaware of such infringements, and that scientists might not be aware of the legal implications of making or using patented research tools."[322] Manufacturers of generic drugs in the United States do not have that option because the Drug

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[316] UNIV. OF OXFORD, *supra* note 222.

[317] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1988).

[318] Reichman & Dreyfuss, *supra* note 97, at 110. For suggested alternatives, see, e.g., Hoffman *supra* note 121, at 999 (recommending the creation of a broad experimental use exemption for patented biotechnology research tools).

[319] Koch, *supra* note 19, at 264.

[320] Heller & Eisenberg, *supra* note 317, at 698-99.

[321] Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1080 (2008).

[322] *Id.* at 1064-65.

Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act)[323] requires them to certify to the Food and Drug Administration that the generic product does not violate any valid patent.[324]

David C. Hoffman articulated a three-prong strategy for dealing with the anticommons created by "patent thickets"[325] and "patent stacking" in the biotechnology space.[326] First, create a broad experimental use exemption for public sector researchers.[327] Second, establish a compulsory licensing regime for certain materials and tools. Third, limit the scope of biotechnological patents by requiring a more complete "enabling description" of the claimed invention. We would encourage regulators in both the EU and the United States to consider these recommendations along with several other variations on the current Bayh-Dole regime.

1. Create a Broad Experimental Use Exemption

The broad experimental use exemption for public sector researchers called for by Hoffman "would cover noncommercial use of any biological material, reagent, or research tool for which an equivalent substitute is not readily available."[328] Such an exemption would legitimize what already happens behind many laboratory doors.

2. Establish a Compulsory Licensing Regime and Provide a Safe Harbor for Patent Pools

We recommend that universities in the EU continue to be precluded from granting exclusive licenses for upstream inventions and research tools funded by the government. This avoids the Harvard oncomouse situation, discussed previously. If a university patents government-funded upstream inventions and research tools, it should be required either to grant nonexclusive

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[323] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C. and 35 U.S.C.).

[324] 21 U.S.C. § 355(b), (c), (j).

[325] A patent thicket has been described as "the overlapping set of patent rights requiring that those seeking to commercialize the technology obtain licenses from multiple patentees." Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1053 n.93 (2005).

[326] Hoffman, *supra* note 121.

[327] *Id*. at 1036-37.

[328] *Id*. at 1036-37. Similarly, Jennifer Vogel proposed a statutory research exemption for non-commercial research utilizing patented genes. Jennifer Vogel, Comment, *Patenting DNA: Balancing the Need to Incentivize Innovation in Biotechnology with the Need to Make High-Quality Genetic Testing Accessible to Patients*, 61 U. KAN. L. REV. 257, 292 (2012).

licenses or to create a collaborative regime, managed by a trusted intermediary, that is open to all at a commercially reasonable rate.

As a possible model for broadly applicable technologies, Hoffman cites the terms under which Stanford University and the University of California licensed the foundational Cohen-Boyer patents on basic recombinant DNA technology, the most lucrative inventions ever created in university laboratories.[329] These universities widely and nonexclusively licensed the technology to public sector researchers, required institutional users to pay "a nominal annual fee for a license covering every researcher at a particular campus or research facility," and then assessed reach-through royalties (which were modest) only for products that came to market.[330]

In addition, as also suggested by Hoffman, the government could create a collective rights organization (CRO) to license "essential reagents and research tools" invented in government or publicly funded university laboratories. Hoffman proposed a U.S. CRO comprising representatives of the NIH, the National Science Foundation, the Biotechnology Industry Organization, and public academic research institutions.[331] Representatives of the analogous organizations in the EU could comprise a comparable CRO in the EU.

Patent pools "allow innovators to share value and cost to encourage free exchange of information and set technology standards" and are often used in the semiconductor, aerospace, and entertainment industries.[332] They can promote the sharing of scientific information and the commercialization of academic discoveries as long as there is proper regard for preserving competition in "innovation markets."[333] As the European Commission noted, "collaborative IPR [intellectual property right] arrangements (cross-licensing, patent pools, etc.) generally have a positive impact, [but] they also need to be examined to ensure they are not used anti-competitively."[334]

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[329] Hoffman, *supra* note 121, at 1040-41.

[330] *Id.* at 1040.

[331] *Id.* at 1039-40.

[332] Moses et al., *supra* note 48, at 187 (citing Josh Lerner & Jean Tirole, *Intellectual Property, A Better Route to Tech Standards*, SCIENCE, Feb. 28, 2014, at 972). "Many [patent] pools simply divide royalties in proportion to the number of patents that each firm has contributed to the pool"; this can result in patents that were "initially different in their importance [being] made equally essential by standardization" thereby "over-reward[ing] minor innovations at the expense of major ones." Lerner & Tirole, at 972. The use of a trusted third-party intermediary to allocate royalties can help avoid such an outcome.

[333] Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for Collaborations Among Competitors (2000), § 3.32(c).

[334] *EC 6.10.2010 Communication*, *supra* note 11, at 19.

These concerns are ameliorated when the pool grants a license to all participants and all comers on a non-discriminatory, nonexclusive basis at a commercially reasonable royalty rate.[335] In contrast, a patent pool limited to particular firms that compete at the same level of distribution would be an unreasonable restraint on trade under U.S. antitrust law[336] and abuse of dominate position under EU competition law.[337] As Arti Rai and her coauthors have noted, "In practice, the overriding focus in most cases is . . . whether the collaboration is likely to accelerate or slow the pace at which R&D efforts are pursued. The agencies specifically recognize that '[t]hrough the combination of complementary assets, technology, or know-how, an R&D collaboration may enable participants more quickly or more efficiently to research and develop new or improved goods . . . .'"[338]

Given the uncertainty under even the more lenient U.S. antitrust standards, we agree with Professor Rai and her colleagues that any horizontal collaboration should be first vetted by the relevant antitrust/competition law authorities. By providing at least some guidance in advance, regulators in both the EU and the United States could reduce transaction costs and thereby facilitate the creation of patent pools that contribute to innovation without unduly hampering competition.

A possible model is the Predictive Safety Testing Consortium (PSTC), managed by Critical Path, a trusted nonprofit intermediary created by the FDA and major pharmaceutical firms. PSTC facilitates multi-firm collaboration on methods to predict and test drug safety.[339] Critical Path "collects membership fees from pharmaceutical firm participants, coordinates the selection of research projects, and (with the assistance of an advisory committee composed of Critical Path and pharmaceutical firm representatives) manages the flow of any confidential information. If the PSTC advisory committee deems it appropriate to seek patents on technology generated by the consortium, Critical Path will own the patent rights."[340] The objective of PSTC

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[335] David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, 3 J. PHIL., SCI. & L. 1 (2003), http://jpsl.org/archives/biotechnology-patent-pool-idea-whose-time-has-come/. As Rai et al. explain, "In recent years, the pooling of patents around information technology standards has become quite common." Rai et al., *supra* note 62, at 26 n.97 (citing Carl Shapiro, *Navigating the Patent Thicket: Cross-Licenses, Patent Pools, and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119 (Jaffe et al. eds., 2001)).

[336] *See, e.g.*, Hartford-Empire Co. v. United States, 323 U.S. 386 (1945).

[337] *See* Commission Guidelines of 14 January 2011 on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Cooperation Agreements, 2011 O.J. (C 11). *See generally* John Temple Lang, *Eight Important Questions on Standards under European Competition Law*, 7 (1) COMPETITION L. INT'L 32 (2011); Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359 (1999).

[338] Rai et al., *supra* note 62, at 35 (citing Dep't of Justice & Fed. Trade Comm'n, *supra* note 333, at § 3.31(a)).

[339] Rai et al., *supra* note 62, at 17.

[340] *Id.* Similarly, the Biomarkers Consortium promotes multi-firm research on biomarkers of drug efficacy and safety. *Id.* at 18.

is "'broad public dissemination of the results of the research and development projects'" undertaken by the Consortium; accordingly, "Critical Path is obligated to license any patents it may own to all comers on commercially reasonable terms."[341]

Another possible model is the Biomarkers Consortium, which promotes multi-firm research on biomarkers of drug efficacy and safety.[342] Unlike Critical Path, the Biomarkers Consortium does not itself retain any intellectual property rights; instead, ownership is defined by the policies followed by the inventor's employer.[343] However, all participants in the Consortium that have an ownership interest in the new data and inventions arising out of a Consortium project must grant a "'non-exclusive, remuneration-free license'" to all of the other participants.[344] Although this model may appeal to for-profit firms, it poses greater competition risks.

3. Require More Complete Enabling Descriptions

The EU already gives less exclusive patent protection for biotechnology inventions than the United States, thereby avoiding some of the anticommons problems inherent in the U.S. regime.[345] For example, the European Directive on Biotechnology,[346] which all of the Member States had implemented by 2006,[347] treats DNA patents "as information products, whose eligibility tests should turn on the quality and industrial applicability of the information revealed."[348] As a result, the European Patent Office requires DNA patent applications to set forth the "industrial applicability of the information revealed."[349] We agree with Hoffman that the United States would be well-served by similar requirements that would limit the scope of

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[341] *Id.*

[342] *Id.*

[343] *Id.*

[344] *Id.* at 18-19.

[345] Hoffman, *supra* note 121, at 1030, 1036.

[346] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13. *See also* Rob J. Aerts, *The Industrial Applicability and Utility Requirements for the Patenting of Genomic Inventions, A Comparison between European and US Law*, 26 EUR. INTELL. PROP. REV. 349 (2004).

[347] *See* State of Play of the Implementation of Directive 98/44/EC, http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf (revised as of Jan. 15, 2007).

[348] Reichman & Dreyfuss, *supra* note 97, at 117. *See also id*. at 94 n.64 (citing the Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 255, arts. 52-53, 57, which requires that an invention have an "industrial application," i.e., the ability to be used in any kind of industry, to be patent eligible).

[349] Reichman & Dreyfuss, *supra* note 97, at 117.

biotechnological patents by requiring the "enabling description" of the claimed invention in the specification to set forth an "'inventive concept or principle whose precise contours are defined by the claims.'"[350]

4. Promote Open Innovation Collaborations

Certain public-private projects, especially those involving the collection of Big Data, are particularly well-suited to open innovation arrangements. For example, the SNP Consortium is a non-profit foundation established by the Wellcome Trust, pharmaceutical and biotechnology firms, and academic research centers with the objective of publishing "'a high-density SNP map of the human genome.'"[351] It has amassed a database of more than 3.1 million SNPs.[352] A SNP, pronounced "snip," is a single nucleotide polymorphism, that is, "a difference in a single DNA building block, called a nucleotide."[353] SNPs "are the most common type of genetic variation among people. . . . For example, a SNP may replace the nucleotide cytosine (C) with the nucleotide thymine (T) in a certain stretch of DNA. . . . [T]here are roughly 10 million SNPs in the human genome."[354] As the NIH explained, "SNPs may help predict an individual's response to certain drugs, susceptibility to environmental factors such as toxins, and risk of developing particular diseases."[355]

Merck & Co. and Washington University created the Merck Gene Index, "a public database of gene sequences corresponding to human genes" designed "to preserve open access to knowledge that could aid in drug discovery."[356] Ironically, had this research been funded with federal money, putting the invention in the public domain, and thereby precluding anyone from patenting it, would not have been an option for Washington University unless it wanted title to the inventions to revert to the U.S. government.

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[350] Hoffman, *supra* note 121, at 1041-42 (quoting Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 846 (1990)).

[351] Koch, *supra* note 19, at 279.

[352] *Id.*

[353] *Genetics Home Reference, What Are Single Nucleotide Polymorphisms (SNPs)?*, NAT'L LIBRARY OF MEDICINE (Dec. 1, 2014), http://ghr.nlm.nih.gov/handbook/genomicresearch/snp.

[354] *Id.*

[355] *Id.*

[356] Vertinsky, *supra* note 285, at 1991. The Merck Gene Index has been described "as an example of efforts to preempt patent rights and protect the public domain for input into drug discovery and development." *Id.* at 1991 n.168 (citing Robert P. Merges, *A New Dynamism in the Public Domain*, 71 U. CHI. L. REV. 183, 188-89 (2004)).

5. Other Recommended Changes to the Bayh-Dole Regime

We submit that the current Bayh-Dole regime, which forces a university to patent an invention or lose its rights, is ill-suited to the development in the EU or the United States of biomedical drugs tailored to individual genomes and other types of translational medicine. At least for upstream inventions and research tools, we argue that universities should have the option of promptly publishing the invention, thereby precluding anyone from obtaining a patent on it.[357] IBM and other software and hardware firms have for a number of years put certain inventions in the public domain in this fashion. In addition, Red Hat and other "open source" software companies[358] have created outlets for publishing prior art, which helps prevent the erroneous patenting of existing technology and the creation of "patent thickets" that unduly inhibit future discoveries.

In addition, we support the European analogue to the recommendation that Congress amend Bayh-Dole to give the NIH, instead of the Commerce Department, the power to dictate, as part of the grant application process itself, the grantee's right to patent the funded work and to exclusively license it.[359] This would not, of course, preclude a private firm from funding a line of research with high economic potential, so there would be a market check on the funding agency's conditions. Thus, to the extent that biotech firms and large pharmaceutical firms develop pharmacogenetic test kits and innovations without using government-funded research, they would be able to patent those inventions without a duty to grant licenses to other private firms.

Given the devastating effect of budget cuts on basic research funding in the United States[360] and the EU, it may be appropriate to give the NIH in the United States, and an

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[357] Vertinsky, *supra* note 285, at 2002 (recommending that "[t]he university's right to elect title should instead be based on a requirement to engage in reasonable efforts to support the public utilization of the invention, with patenting considered as one alternative strategy.").

[358] As Kapczynski and her coauthors noted, "The emergence of free and open source software development has led to increased interest in defining the conditions for sustainable and successful nonproprietary production strategies—for software and more generally for networked information production and some classes of physical resources. These approaches . . . frequently rely upon innovative contractual provisions to create a self-perpetuating commons." Kapczynski et al., *supra* note 325, at 1040. With regard to open source copyright licensing, see generally Robert W. Gomulkiewicz, *Enforcement of Open Source Software Licenses: The MDY Trio's Inconvenient Complications*, 14 YALE J. L. & TECH. 106, 111-16 (2011); Dennis M. Kennedy, *A Primer on Open Source Licensing Legal Issues: Copyright, Copyleft and Copyfuture*, 20 ST. LOUIS U. PUB. L. REV. 345 (2001).

[359] Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 291, 313-14 (2003) (recommending that the NIH and other government agencies be given greater authority to limit the patenting of certain publicly funded research).

[360] "Spending on basic research has fallen" with the director of the NIH, Dr. Francis S. Collins, calling "2013 one of his agency's darkest years" and characterizing the cutbacks as "profoundly discouraging." William J. Broad, *Billionaires with Big ideas are Privatizing American Science*, N.Y. TIMES, Mar. 16, 2014, at A1. One concern with reduced federal funding (and the current trend of increased private funding) is that the "social contract that cultivates science for the common good" is at risk, as the philanthropic funds "tend to enrich elite universities at the expense of poor ones, while undermining political support for federally sponsored research and its efforts to foster a greater diversity of opportunity . . . among the nation's scientific investigators." *Id.* Another concern is that privately funded

analogous institution in the EU, the right to receive a small percentage of the royalties generated by government-funded inventions or, in the EU, government or IMI funded inventions, that are ultimately commercialized. This is tricky, however, because it is important not to distort the grant-approval process to remove funding for the type of research the private markets are most unlikely to fund—basic research. Thus, the government should limit the percentage of publicly funded grants eligible for royalty recovery.

C. Complying with the EU State Aid Restrictions

Another possible impediment to commercializing government-funded inventions in the EU is uncertainty regarding the application to PPPPs of the restriction in Article 107(1) of the Treaty on the Functioning of the European Union (TFEU) on the use of State aid to favor a particular private enterprise. Article 107(1) provides:

> Save as otherwise provided in the Treaties, any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market.[361]

Thus, State aid that distorts or threatens to distort competition is prohibited insofar as it affects trade between Member States.

State aid control is an integral part of EU competition policy and a necessary safeguard to preserve effective competition and free trade in the single market. Absent this control, Member States may use State aid strategically to promote national economic interests without regard for the spill-over effects on other Member States or the adverse effect on the internal market and the common EU interest.[362]

Neither Articles 107 and 108 of TFEU nor EU law in general set forth uniform rules that can be applied to ensure the correct separation of economic and non-economic activities for

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research tends to focus on illnesses that "predominantly afflict white people," thus expanding the unequal gap that exists in disease research along economic and racial lines. *Id.* The effect of private funds on American research has not been quantified, but the National Science Foundation "recently announced plans to begin surveying the philanthropic landscape." *Id.*

[361] Consolidated Version of the Treaty on the Functioning of the European Union art. 107(1), Mar. 30, 2010, 2010 O.J. (C 83) 91.

[362] Directorate for Financial and Enterprise Affairs Competition Committee, Global Forum on Competition, Competition, State Aid and Subsidies, Contribution from the European Union, January 11, 2010 – DAF/COMP/GF/WD (2010)3, at 2.

State aid purposes. Instead, this responsibility rests with the Member States supported by the European Commission.[363]

In principle, all public funding to universities is State aid. As a result, universities in the EU must comply with the State aid rules when they collaborate for economic gain with industry.[364] That is why historically many universities clearly separated their economic and non-economic activities. Fortunately, recent changes in EU policy have made it easier to commercialize government-funded research without violating the State aid restrictions.

State aid that contributes to well-defined objectives of common European interest without unduly distorting competition or affecting trade between Member States may be compatible with the common market under Article 107(3) of TFEU. For example, the EU adopted orphan drug legislation in 2000,[365] which was patterned on the U.S. Orphan Drug Act (ODA) enacted in 1983.[366] In accordance with Article 1, the purpose of the regulation is to lay down an EU procedure for the designation of medicinal products as orphan medicinal products and to increase incentives for the research, development and placing on the market of designated orphan medicinal products.

The ODA provides incentives for private firms to develop (1) drugs for diseases affecting fewer than 200,000 persons in the United States or (2) drugs for diseases affecting a larger population in the United States for which "there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug."[367] The ODA provides a seven-year period of marketing exclusivity for the drug, even if it would not otherwise be eligible for patenting,[368] federal funding through the Food and Drug Administration,[369] and a fifty percent tax credit for qualified expenses for human clinical trials.[370] The EC orphan drug legislation is

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[363] The EU Commission can declare the University's contribution to be compatible with the internal market. In such cases, the agreement must be notified to the Commission prior to commencement.

[364] *See also* Bernhard von Wendland, *State Aid and Public Funding for Universities and Other Research Organisations*, COMPETITION POLICY NEWSLETTER (European Comm'n), (2010-2), at 54-55.

[365] Regulation (EC) 141/2000 of the European Parliament and of the Council of 16 Dec. 1999 on Orphan Medicinal Products, 2000 O.J. (L 18) 1.

[366] Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 15, 21, 26, 35, and 42 U.S.C.). An orphan drug is used to treat a rare disease or condition. 21 U.S.C. § 360aa(a).

[367] 21 U.S.C. § 360bb(a)(2).

[368] 21 U.S.C. § 360cc(a)(2).

[369] 21 U.S.C. § 360ee.

[370] 26 U.S.C. § 45C(a).

similar. In the EU, orphan medicinal products are defined as those intended for the "diagnosis, prevention or treatment of life-threatening or chronically debilitating" conditions that affect no more than 5 in 10,000 people in the European Union.[371] The European Commission has authorized 106 orphan medicines and designated 1,058 products as orphan medical products.[372] The sponsors responsible for these medicines benefit from incentives such as fee waivers for the regulatory procedures or a ten-year market exclusivity.[373] The period of exclusivity "may be curtailed by four years if a product is 'sufficiently profitable.'"[374] In 2003, the British Nuffield Council on Bioethics recommended that regulators "use existing orphan medicine legislation, or any other policy instrument with equivalent effect, to provide incentives for development" of pharmacogenetics products.[375] We agree with this recommendation and, as argued below, consider it consistent with the EU State aid rules.

Article 179(1) of TFEU identifies research and development and innovation (R&D&I) as an important EU objective:

> The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties.[376]

Article 180 provides that the Union shall carry out the following activities, complementing the activities carried out by the Member States: (1) implement research, technological development, and demonstration programmes by promoting cooperation with and between undertakings, research centres and universities; (2) promote cooperation in the field of Union research and technological development with third countries and international organisations; (3) disseminate

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[371] 2014 REPORT ON THE STATE OF THE ART OF RARE DISEASE ACTIVITIES IN EUROPE 9 (C. Rodwell & S. Ayme eds., 2014) [hereinafter RARE DISEASE ACTIVITIES IN EUROPE].

[372] John F. Ryan, *Turning the Challenge of Rare Diseases into an Opportunity for Europe*, THE PARLIAMENT (Nov. 4, 2014), https://www.theparliamentmagazine.eu/articles/opinion/turning-challenge-rare-diseases-opportunity-europe.

[373] RARE DISEASE ACTIVITIES IN EUROPE, *supra* note 371, at 9.

[374] Dan Phair, *Orphan Drug Programs, Public-Private Partnerships and Current Efforts to Develop Treatments for Diseases of Poverty*, 4 J. HEALTH & BIOMEDICAL L. 193, 207 (2008).

[375] NUFFIELD COUNCIL ON BIOETHICS, PHARMACOGENETICS: ETHICAL ISSUES, SUMMARY AND RECOMMENDATIONS xix (2003) http://nuffieldbioethics.org/wp-content/uploads/2014/07/Pharmacogenetics-Summary-and-recommendations.pdf.

[376] Consolidated Version of the Treaty on the Functioning of the European Union art. 179(1), Mar. 30, 2010, 2010 O.J. (C 83) 128 [hereinafter Treaty on the Functioning of the EU].

and optimise the results of Union research and technological development; and (4) stimulate the training and mobility of researchers in the Union.[377]

Both the Europe 2020 strategy[378] and the "Innovation Union" flagship initiative acknowledge that State aid can "actively and positively contribute . . . by prompting and supporting initiatives for more innovative, efficient and greener technologies, while facilitating access to public support for investment, risk capital and funding for research and development."[379] Collaboration between universities and the pharmaceutical industry through PPPPs can stimulate innovation, spur growth, and enhance value by decreasing the general innovation gap in the pharmaceutical industry and increasing the competitiveness of EU commercial firms. But the contract must pass muster under the State aid balancing test, pursuant to which "the Commission balances the negative effects on trade and competition in the common market with its positive effects in terms of contributing to the achievement of well-defined objectives of common interest."[380] The balancing test examines the following elements:

(1) Is the aid measure aimed at a well-defined objective of common interest (eg growth, employment, cohesion, environment)?

(2) Is the aid well designed to deliver the objective of common interest i.e. does the proposed aid address the market failure or other objective?

(i) Is State aid an appropriate policy instrument?

(ii) Is there an incentive effect, i.e. does the aid change the behaviour of firms?

(iii) Is the aid measure proportional, i.e. could the same change in behaviour be obtained with less aid?

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[377] Treaty on the Functioning of the EU art. 180, Mar. 30, 2010, 2010 O.J. (C 83) 129.

[378] *Communication from the Commission of 3 March 2010 - Europe 2020, A Strategy for Smart, Sustainable and Inclusive Growth*, COM (2010) 2020 final.

[379] *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU State Aid Modernisation (SAM)*, at ¶ 10, COM (2012) 209 final (citing COM (2010) 2020 final, *supra* note 378, at 20). Before granting State aid, Member States must either (1) obtain the authorisation from the Commission (notification) or (2) ensure that the State aid is exempted by a general Commission Block Exemption Regulation, which considers the most obvious market failures and allows Member States to take State aid measures that could lead to limited market distortions. Hence, the Commission can focus on large State aid cases with high risk of competition and trade distortions. *See generally State Aid in General*, http://ec.europa.eu/agriculture/stateaid/gl-chapters-1-and-2_en.pdf (last visited Dec. 5, 2014).

[380] *See* Bente Tranholm-Schwarz, Peter Ohrlander, Bruno Zanettin, Mercedes Campo & Georges Siotis, *The Real Economy—Challenges for Competition Policy in Periods of Retrenchment*, COMPETITION POLICY NEWSLETTER 3-4 (2009-1), http://ec.europa.eu/competition/publications/cpn/2009_1_2.pdf.

(3) Are the distortions of competition and effect on trade limited, so that the overall balance is positive?[381]

In 2012, the European Commission launched "State Aid Modernisation (SAM), an ambitious reform package of State Aid policy with three key objectives: to foster growth in a strengthened, dynamic and competitive internal market, in line with the objectives of the Europe 2020 growth strategy; to focus enforcement on cases with the biggest impact on internal market; [and] to streamline rules and ensure faster decisions."[382] The revised Enabling regulation, adopted by the Council in 2013, introduced new categories of aid that the Commission may decide to exempt from the obligation of prior notification, including innovation aid. The European Commission has identified the following R&D&I measures for which State aid may, under specific conditions, be compatible with the internal market:

(a) aid for R&D projects where the aided part of the research project falls within the categories of fundamental research and applied research, of which the latter can be divided into industrial research and experimental development. . . .;[383]

(b) aid for feasibility studies related to R&D projects, which aims at overcoming a market failure primarily related to imperfect and asymmetric information;[384]

(c) aid for the construction and upgrade of research infrastructures, which mainly addresses the market failure stemming from coordination difficulties. . . .;[385]

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[381] Notice from the European Union of Dec. 30, 2006 Community Framework for State Aid for Research and Development and Innovation, at § 1.3.1., 2006 O. J. (C 323).

[382] *EC Taking Stock 2014*, *supra* note 13, at 38.

[383] Communication from the Commission – Framework for State Aid for Research and Development and Innovation, at ¶ 12 (a), 2014 O.J. (C 198) [hereinafter Commission Framework for State Aid]. "Such aid is mainly targeted at the market failure related to positive externalities (such as knowledge spill-overs), but may also address a market failure caused by imperfect and asymmetric information or (mainly in collaboration projects) a coordination failure." *Id.*

[384] *Id.* at ¶ 12 (b).

[385] *Id.* at ¶ 12 (c). "High-quality research infrastructures are increasingly necessary for ground-breaking research, as they attract global talent and are essential for example for information and communication technologies and key enabling technologies." *Id.* Key enabling technologies are defined and identified in the *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A European Strategy for Key Enabling Technologies – A Bridge to Growth and Jobs*, COM(2012) 341 final (June 26, 2012).

(d) aid for innovation activities, which is mainly targeted at market failures related to positive externalities (knowledge spill-overs), coordination difficulties and, to a lesser extent, asymmetric information. . . .;[386]

(e) aid for innovation clusters . . . .[387]

If, however, a PPPP agreement is not on market terms — for example if the university does not demand the market price for its share of intellectual property rights transferred to the for-profit firm as a result of the collaboration — then the university's entire contribution to the project might be considered as State aid.[388]

Thus, an exemption to the State aid restrictions is available, pursuant to Article 107(3)(b) and 107(3)(c) of TFEU,[389] for pharmaceutical R&D performed by a partnership between a university and a private enterprise as long as the arrangement, including the royalties and licensing fees payable, is on market terms. Hence, both to reduce transaction costs[390] and to provide more certainty with respect to the EU competition laws and the State Aid Regulation, we propose that regulators in the EU create a safe-harbor for PPPPs using pre-approved standardized licensing contracts, such as the Uniform Biological Materials Transfer Agreement.[391] Universities are

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[386] Commission Framework for State Aid, *supra* note 383, at ¶ 12 (d).

[387] *Id.* at ¶ 12 (e). Coordination problems can hamper the development of clusters, or limit the interactions and knowledge flows within and between clusters. State aid could help address this market failure, first by supporting the investment in open and shared infrastructures for innovation clusters and, second, by supporting, for no longer than ten years, the operation of clusters for the enhancement of collaboration, networking, and learning. *Id.*

[388] *Id.* at ¶ 28 (d) (stating that the Commission considers that "no indirect State aid is awarded to the participating undertakings" if "the research organisations [defined to include universities] . . . receive compensation equivalent to the market price for the [intellectual property rights] which result from their activities and are assigned to the participating undertakings").

[389] *See also Communication from the Commission - Investing in Research: An Action Plan for Europe*, COM (2003) 226 final/2 (June 4, 2003); *Communication from the Commission of 3 March 2010 - Europe 2020 – A Strategy for European Union Growth*, COM (2010) 2020 final; Case 173/73 Italy v. Comm'n E.C.R. 709 (1974); Case C-487/06 P British Aggregates Ass'n v. Comm'n, E.C.R. I-10515 (2008).

[390] Joshua Fairfield, *The Cost of Consent: Optimal Standardization in the Law of Contract*, 58 Emory L.J. 1401, 1409 (2009) ("The economic analysis of boilerplate discusses the benefits of contract standardization for contract drafters. It argues quite effectively that network effects cause contract drafters to reuse contract language (in the form of boilerplate) to save themselves drafting costs, economize on learning costs, reuse 'safe' language that has been vetted by courts, and signal to prospective counterparties that the contract drafter does not seek an unfair advantage through the drafting process."). *See also* Marcel Kahan & Michael Klausner, *Standardization and Innovation in Corporate Contracting (or the "Economics of Boilerplate")*, 83 VA. L. REV. 713, 719-20 (1997) (defining "learning benefits" as "(a) drafting efficiency; (b) reduced uncertainty over the meaning and validity of a term due to prior judicial rulings; and (c) familiarity of a term among lawyers, other professionals, and the investment community.").

[391] Further information about this agreement can be accessed at: *Uniform Biological Materials Transfer Agreement (UBMTA)*, ASS'N OF UNIV. TECH. MANAGERS,

often willing to acquire materials in accordance with such agreements but demand more favorable terms when asked to transfer their own materials, creating a collective action problem.[392] By offering a safe harbor for parties willing to accept such an agreement, regulators in the EU could help facilitate the transfer of materials as well as technologies. As a logical first step, we would recommend that the European Commission add a State aid safe harbor to the European IMI regime, provide guidance on the contractual provisions that would come within it, and require bidders for IMI funds to include their proposed contract with their bid.

Because one-size rarely fits all,[393] the standardized contracts "blessed" by the EU regulators could provide alternative licensing terms from which the parties to a PPPP could select. Like Beirne Roose-Snyder and Megan Doyle, who proposed "a comprehensive approach to humanitarian licensing for universities—a Global Health Licensing Program," which includes "a toolbox of access licensing options for technology transfer offices to use during licensing negotiations,"[394] we would encourage the European Commission to offer various alternative arrangements. One might be a nonexclusive license of the sort offered by Stanford University and the University of California when it licensed the Cohen-Boyer recombinant DNA patents.[395] Another would be patent pools open to all that allow non-participants to obtain non-exclusive licenses at a commercially reasonable rate, perhaps as determined by a trusted intermediary. At the same time, certain practices, such as mandatory reach-back licenses and prohibitions on the publication of adverse test results by academics receiving private funding,[396] should be prohibited. Universities and private firms would still be permitted to negotiate customized contracts that do not violate these prohibitions but they would not have the benefit of ex ante governmental approval.

VIII. Conclusion

PPPPs and other forms of public-private technology transfer represent powerful tools for bringing life-saving therapies to patients. While not yet widely employed in the European pharmaceutical industry, they can both enhance competitiveness and improve societal and individual patient welfare. As a result, we argue that policymakers in the EU should encourage

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http://www.autm.net/AM/Template.cfm?Section=Technology_Transfer_Resources&Template=/CM/ContentDisplay.cfm&ContentID=2810 (last visited Dec. 5, 2014).

[392] Rai & Eisenberg, *supra* note 359, at 305-06.

[393] Beirne Roose-Snyder & Megan K. Doyle, *The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level*, 35 AM. J. L. & MED. 281, 284 (2009) ("No single approach will meet the needs of every negotiating partner or every type of licensed intellectual property, and there is no silver bullet to bridge the access gap.").

[394] *Id.* at 284.

[395] Rai & Eisenberg, *supra* note 359, at 300.

[396] Downie & Herder, *supra* note 123, at 24 (offering examples of instances when private firms threatened legal action if an academic published negative results or commentary).

utilization of such arrangements and facilitate their formation and operation by clarifying the applicability of the State aid limitations.

A comparative analysis of the EU and U.S. approaches to translational medicine shows that there are lessons to be shared. PPPPs and other forms of collaborative research and university technology licensing can significantly enhance research, development, and commercialization in the pharmaceutical sector and other similar industries. The EU can apply the experiences from Bayh-Dole and technology transfer in the United States, and the United States can emulate the open innovation aspects of the European IMI concept, the open access objectives embodied in Horizon 2020, and the tighter patenting standards imposed by the European Patent Office. In particular, the EU could encourage the Member States to permit universities to obtain patents on government-funded inventions, perhaps with a royalty-sharing arrangement akin to what Denmark has enacted. At the same time, the U.S. Congress should consider amending the Bayh-Dole Act to promote more open innovation for certain upstream research and research tools to remove obstacles to cooperative research and commercialization.

There is another option available to lawmakers in both the EU and the United States, in addition to "concrete legislation." Because the PPPP contract is the law of the parties, regulators could promote more efficient allocations of intellectual property rights by developing model contracts for the allocation of IP rights generated by publicly sponsored research. For example, Congress could require the inclusion of a specific clause in a PPPP contract relating to research funded by the National Institutes of Health in the United States. Similarly, the European Commission could, as a start, require a specific clause in an IMI contract then later offer standard contract terms for other types of PPPPs and also outline a safe harbor procedure for ensuring that university inventions are licensed on market terms. Both the United States and the EU could at least offer templates from which grant applicants could choose. Then a funding agency could take those contractual terms into account when reviewing grant applications. For basic research that depends primarily on university scientists for success, the preferred allocation might be to the scientists. For more applied research, it might be best to rely on university technology transfer offices to negotiate directly with the industry partner.