

## **Pharmaceutical Public-Private Partnerships in the United States and Europe: Moving from the Bench to the Bedside**

By

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### **Abstract:**

Both to address unmet medical needs and to improve industry competitiveness, regulators in both the United States and the European Union have taken bold steps to translate academic research from the university lab to the patient. A pharmaceutical public-private partnership (PPPP), which is a legally binding contract between a private pharmaceutical enterprise and a public research university (or a private university doing research funded with public funds), can be a significant tool to ensure a more efficient payoff in the highly regulated world of pharmaceuticals. In particular, a properly framed binding contract, coupled with respect for positive social norms, can move the parties away from an inefficient prisoners' dilemma Nash Equilibrium to the Pareto Optimal Frontier. When coupled with appropriate attention to the difficult task of coordinating the actions of interdependent actors, a PPPP arrangement can enhance the likelihood of successful commercialization by flipping the parties' incentives as compared with more traditional contracts. Because PPPPs are less common in Europe than in the United States, a key purpose of this article is to provide an annotated roadmap that universities, private firms, and EU policy makers can use to create efficient PPPPs to enhance for-profit innovation in the pharmaceutical industry in Europe. A secondary purpose is to suggest amendments to the U.S. laws governing the patenting of government-funded technology to prevent undue burdens on the sharing of certain upstream medical discoveries and research tools. Our analysis is not only comparative; it also combines, we believe for the first time, a game theory and law and management approach to for-profit PPPPs.

**Key words:** Public-Private Partnership, Pharmaceutical Industry, Intellectual Property, Game Theory, Contract Law, Relational Norms, and Law and Management.

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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.’”<sup>1</sup>

## Introduction

Both to address unmet medical needs and to improve industry competitiveness, regulators in both the European Union (“EU”) and the United States have taken bold steps “to foster translation from the university laboratory to the healthcare sector through the generation and support of start-ups, spin-offs, university-industry consortia, and other platforms,”<sup>2</sup> that is, to promote the movement of discoveries from “bench to bedside.”<sup>3</sup> For example, the EU Innovative Medicines Initiative (IMI), discussed in Part V below, is a public-private partnership initiative that invites competitors to bid for government funds. The IMI is an open innovation program designed to improve the drug development process with a €2 billion budget provided by participating governments and industry participants.

In the United States, the National Institutes of Health (“NIH”) established the National Center for Advanced Translational Sciences (NCATS) in 2011, with a fiscal year 2012 budget of US \$575 million.<sup>4</sup> Its Strategic Alliances Office “aims 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.”<sup>5</sup> According to the European Federation for Pharmaceutical Sciences (EUFEPS), “the only pan-European body to represent the interests of scientists in industry, academia, government and other institutions engaged in drug research, development, regulation and policymaking through Europe,”<sup>6</sup> Europe will need to pursue similar initiatives to retain a competitive advantage in pharmaceutical innovation and “to support the progress of the present implementation of the IMI research agenda.”<sup>7</sup>

Experts predict that NCATS could help address the “valley of death” – “the large research and funding gap that sets federally funded basic researchers (those . . . in nonprofit research institutions, academia, hospitals, and federal laboratories) on one side and the pharmaceutical industry on the other.”<sup>8</sup> As John C. Reed, professor and Donald Bren chief executive chair at the Sanford-Burnham Medical Research Institute in La Jolla, California, explained:

[P]rivate companies and venture capitalists are increasingly reluctant to fund

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<sup>1</sup> Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013), quoting Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1305 (2012).

<sup>2</sup> Rogerio Gaspar et al., *Toward a European Strategy for Medicines Research (2014-2020): The EUFEPS Position Paper on Horizon 2010*, 47 EUR. J. PHARMACEUTICAL SCIENCES 979, 980 (2012).

<sup>3</sup> *Id.*

<sup>4</sup> National Center for Advancing Translational Sciences, <http://www.ncats.nih.gov/research/cts/cts.html>.

<sup>5</sup> *Id.*

<sup>6</sup> European Federation for Pharmaceutical Sciences, <http://www.eufeps.org/>.

<sup>7</sup> Gaspar et al., *supra* note 2, at 982.

<sup>8</sup> John C. Reed, *NCATS Could Mitigate Pharma Valley of Death*, GENETIC ENG'G & BIOTECH. NEWS (May 15, 2011), <http://www.genengnews.com/gen-articles/ncats-could-mitigate-pharma-valley-of-death/3662/>. See also Arti K. Rai, Jerome H. Reichman, Paul F. Uhlir & Colin Crossman, *Pathways across the Valley of Death: Novel Intellectual Property Strategies for Accelerating Drug Discovery*, 8 YALE J. HEALTH POL'Y, L. & ETHICS 1, 4 (2008) (proposing a two-tier regime for promoting “intensive, large-scale collaboration between academics, who possess unique skills in designing assays that can identify promising targets, and pharmaceutical firms that hold libraries of potentially useful small molecules as trade secrets, making them largely off limits to these same academic scientists.”)

the crucial early stages of preclinical development—the research necessary to “translate” promising discoveries made in laboratories into optimized candidate therapeutics ready for testing in clinical trials.

This gap includes many steps in the drug discovery and development process, including assay development, high-throughput screening, medicinal chemistry, exploratory pharmacology, and rigorous preclinical testing of drug efficacy and safety in animal models of disease.<sup>9</sup>

This article focuses on pharmaceutical public-private partnerships (PPPPs)<sup>10</sup> involving a public university or research institute (or a private university or institute doing medical research funded by the government) and a private firm in the pharmaceutical industry to develop new drugs that can be sold by the pharmaceutical firm at a profit.<sup>11</sup> For example, Bristol-Myers Squibb formed a public-private partnership with ten cancer research institutes – the International Immuno-Oncology Network – to “facilitate the translation of scientific research findings into clinical trials and, eventually, clinical practice, as well as advance innovation in drug discovery and development.”<sup>12</sup> Such arrangements are common in the United States but have not yet taken hold in the EU.

In contrast to the PPPPs discussed in this article, there are a variety of international public-private partnerships involving the World Health Organization, including Global Alliance for Vaccines and Immunizations, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Stop TB Partnership and the Roll Back Malaria Partnership, that are designed to provide affordable medicines for so-called “diseases of poverty” in developing countries.<sup>13</sup> For example, Pfizer, Merck Serona, and Chemtura have joined the World Health Organization’s Tropical Disease Network and allow its TD Compound Evaluation Network “to submit targets for in-house screening against a subset of the firms’ respective chemical libraries.”<sup>14</sup> Partnerships of this sort, which are “highly integrated relationships among states, international organizations, companies, NGOs, research institutes, and/or philanthropic

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<sup>9</sup> Reed, *supra* note 8. One of the NIH programs transferred to NCATS is the Molecular Libraries Probe Production Centers Network (MLPCN), “the first federally funded network to facilitate drug discovery by producing early-stage small molecule leads.” *Id.* As Dr. Reed explained: “These centers, most of which reside in universities and nonprofit research institutes across the U.S., provide federally funded researchers and even small biotechnology companies with access to drug discovery capabilities previously found only within large pharmaceutical companies. Those capabilities include large chemical libraries, assay development, ultra high-throughput robotic screening, cheminformatics, medicinal chemistry, project management, and several other drug discovery-related services that typically don’t exist in academic labs and departments.” *Id.* The NIH’s Molecular Libraries Small Molecule Repository contains more than 100,000 small molecules generated by the academic researchers. Molecular Libraries Initiative, General Information, <http://mli.nih.gov/mlsmr/general-information>. These molecules are put into the public domain so are available for researchers doing “high-throughput screening (HTS) of small molecule libraries against assays containing target proteins to identify promising compounds that may lead to patentable drugs.” Rai et al., *supra* note 8, at 7. Unlike biologics, comprising macromolecules expensive to produce, small molecule drugs can be mass produced at a low cost. *Id.* at 3.

<sup>10</sup> As Julia Paschal Davis notes, 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.” 44 PROCUREMENT LAW 9, 9 (Fall 2008).

<sup>11</sup> Unlike Gian Luca Burci, who defines a pharmaceutical public-private partnerships as a “long-term collaborative arrangement among a group of diverse stakeholders, some of which of a public nature (e.g. government agencies and intergovernmental organizations) and others of a private nature (e.g. non-governmental organizations, private commercial companies, research institutes, professional associations etc.) to jointly pursue a discreet public health goal,” Gian Luca Burci, *Public/Private Partnerships in the Public Health Sector*, 6 INT’L ORG’S L. REV. 359, 361 (2009), we include in the public side public universities and research institutes and private universities and research institutes that receive government funding for medical research.

<sup>12</sup> *Public-Private Partnerships Step Up*, APPLIED CLINICAL SCIENCES ONLINE (June 4, 2012).

<sup>13</sup> Dan Phair, *Orphan Drug Programs, Public-Private Partnerships and Current Efforts to Develop Treatments for Diseases of Poverty*, 4 J. HEALTH & BIOMEDICAL L. 193, 193 (2008).

<sup>14</sup> Rai et al., *supra* note 8, at 30.

foundations,”<sup>15</sup> are designed to address the market’s failure incentivize private firms to develop and market drugs that are not profitable absent government or NGO funding.<sup>16</sup> Although certain aspects of our analysis are applicable to such arrangements, there are significant differences so, except as otherwise noted, we use the term “pharmaceutical public-private partnerships (PPPPs)” to refer to for-profit arrangements.

We believe that properly structured PPPPs, coupled with an appropriate intellectual property regime, can be effective tools for meeting the objectives articulated by Maire Geoghegan-Quinn, EU Commissioner of Research, Innovation and Science, in “Horizon 2020—the Framework Programme for Research and Innovation,”<sup>17</sup> namely, “(i) excellent science, (ii) industrial leadership and (iii) societal challenges.”<sup>18</sup> The primary purpose of this article is to promote their broader use in the EU by providing an annotated roadmap for universities, private pharmaceutical firms, and policymakers in the EU. A secondary purpose is to suggest amendments to the U.S. laws governing the patenting of government-funded technology to prevent undue burdens on the sharing of certain upstream medical discoveries and research tools. Our analysis is not only comparative; it also combines, we believe for the first time, a game theory and law and management<sup>19</sup> approach to for-profit PPPPs.

In Part I, we describe the pharmaceutical market then, in Part II, we explain how a partnership arrangement between a public university<sup>20</sup> and a private firm can promote drug innovation and discuss key aspects of such an arrangement. In Part III, we use game theory to explain why efficient PPPPs need to be supported by a binding contract, the free exchange of information, and positive aligned incentives. Part IV provides lessons from public-private partnerships in the construction industry and applies them to pharmaceutical public-private partnerships. We discuss the European Innovation in Medicines Initiative and other European developments in Part V. In Part VI, we address the intellectual property issues inherent in drug development collaboration between academia and private industry and propose modifications to the Bayh-Dole Act,<sup>21</sup> which is the U.S. statute governing the patenting and licensing of university technology funded by the federal government. We also discuss the challenge of harmonizing the rules on technology transfer in the EU and suggest solutions. We conclude in Part VII by summarizing our roadmap for PPPPs in the EU, which could also be adopted in whole or in part in the United States.

## I. The Pharmaceutical Market

In 2011, worldwide expenditures on pharmaceuticals approached \$1 trillion.<sup>22</sup> That year,

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<sup>15</sup> Lisa Clarke, *Responsibility of International Organizations under International Law for the Acts of Global Health Public-Private Partnerships*, 12 *CHI. J. INT’L L.* 55, 59 (2011).

<sup>16</sup> Nathaniel Lipkus, *How to Understand Product Development: Public-Private Partnerships as Vehicles for Innovation in Combating Neglected Disease*, 10 *MICH. ST. U. J. MED. & L.* 385, 390-96 (2006).

<sup>17</sup> <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/435>. Horizon 2020, which runs from 2014-2020, is the financial instrument for implementing the “Innovation Union.” Funded with a budget of €80 billion, it is designed to secure the EU’s global competitiveness by consolidating all research and innovation funding currently provided through the Framework Programmes for Research and Technical Development, the innovation-related activities of the Competitiveness and Innovation Framework Programme, and the European Institute of Innovation and Technology.

<sup>18</sup> Gaspar et al., *supra* note 2, at 980.

<sup>19</sup> Constance E. Bagley, “Forward” in *LEGAL STRATEGIES: HOW CORPORATIONS USE LAW TO IMPROVE PERFORMANCE* v (Antoine Masson & Mary J. Shariff eds., 2010) (describing emerging field of law and management, which includes the ability of firms to use law for competitive advantage).

<sup>20</sup> We use “public university” to include private universities, research institutes, and similar academic institutions conducting medical research funded, at least in part, by the government.

<sup>21</sup> Bayh-Dole Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-212).

<sup>22</sup> IMS Institute for Informatics, *The Global Use of Medicines: Outlook Through 2016* (July 2012), at 5, *available at* [http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines\\_Outlook\\_Through\\_2016\\_Report.pdf](http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines_Outlook_Through_2016_Report.pdf).

France, Germany, Italy, Spain, and the United Kingdom alone spent \$159 billion on medicines.<sup>23</sup> The United States spent \$325 million.<sup>24</sup> The pharmaceutical industry is one of the largest single industries in the both the EU and the United States,<sup>25</sup> and it is highly concentrated.<sup>26</sup> As seen in Table 1,<sup>27</sup> the ten largest firms earned roughly \$467 billion in 2012.

Table 1 Top Ten Pharmaceutical Firms in 2012

	<b>Name</b>	<b>Headquarters</b>	<b>2012 Revenues (US \$ billions)</b>
1.	Johnson & Johnson	U.S.	\$67.20
2.	Pfizer	U.S.	\$58.99
3.	Novartis	EU	\$56.67
4.	Roche	EU	\$47.80
5.	Merck	U.S.	\$47.27
6.	Sanofi	EU	\$46.41
7.	GlaxoSmithKline	EU	\$39.93
8.	Abbott Laboratories/AbbVie	U.S.	\$39.87
9.	AstraZeneca	EU	\$27.97
10.	Bayer HealthCare	EU	\$24.30

The health care sector accounted for approximately 9 percent of EU GDP in 2010<sup>28</sup> and nearly double that in the United States.<sup>29</sup> Because the total expenditure on health care is rising faster than economic growth in both the EU and the U.S., the ratio of health care spending to GDP is increasing. A substantial portion of the growth in health care expenses is attributable to pharmaceuticals.

The development of new pharmaceuticals is both high risk<sup>30</sup> and high cost, with new drugs costing a billion dollars or more to bring to market.<sup>31</sup> Innovation losses in the pharmaceutical industry's development of new drugs are increasing.<sup>32</sup> Although the number of approved new molecular entities has remained steady in the past ten years, the cost side has increased significantly in both the United States and the EU.<sup>33</sup> Members of the

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> Gaspar et al., *supra* note 2.

<sup>26</sup> In the period from 2003 to 2007, roughly 80 percent of all pharmaceutical patents granted pursuant to the Patent Cooperation Treaty were issued to firms domiciled in just thirteen developed countries. Anand Grover, Brian Citro, Mihir Mankad & Fiona Lander, *Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability under the Right to Health*, 40 J.L., MED. & ETHICS 234, 238 (2012).

<sup>27</sup> Sales data from FiercePharma, Top Pharma Companies by 2012 Revenues, <http://www.fiercepharma.com/special-reports/top-pharma-companies-2012-revenues#ixzz2ZAg0zpeW>.

<sup>28</sup> For data see [http://ec.europa.eu/competition/sectors/pharmaceuticals/overview\\_en.html](http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html). According to the European Commission the 9 percent covers the pharmaceutical sector (prescription and non-prescription medicines), medical devices, and health services.

<sup>29</sup> Natalie Jones, *Health Care in America: Follow the Money*, NPR (Mar. 19, 2012), <http://www.npr.org/blogs/health/2012/03/19/148932689/health-care-in-america-follow-the-money>.

<sup>30</sup> Valerie Gutmann Koch, *Incentivizing the Utilization of Pharmacogenetics in Drug Development*, HEALTH CARE L. & POL'Y 263, 274, 274 n. 89, 275 (2012) (citing data showing that 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 Food and Drug Administration ("FDA"), and more than 3 percent of drugs approved by the FDA are subsequently withdrawn due to negative side effects).

<sup>31</sup> Pharm. Research & Mfrs. of Am., 2011 Profile 10 (2011). As Valerie Koch notes, others dispute this calculation. Koch, *supra* note 30, at 274 n. 87, citing Donald W. Light & Rebecca Warburton, *Demystologizing the High Cost of Pharmaceutical Research*, 6 BIOSCIENCES 34, 36, 38-39 (2011).

<sup>32</sup> ALFONSO GAMBARDELLA, LUIGI ORSENIGO & FABIO PAMMOLLI, GLOBAL COMPETITIVENESS IN PHARMACEUTICALS: A EUROPEAN PERSPECTIVE 2-3 (2000).

<sup>33</sup> Edward F.X. Hughes, Michael Hu, Karl Schultz, Jack Sheu & Daniel Tschopp, *The Innovation Gap in Pharmaceutical*

pharmaceutical industry in both the U.S. and the EU are looking for new ways to institutionalize and sustain pharmaceutical innovation and to sell new products.<sup>34</sup> This productivity challenge can be explained in part by an increase in research and development (R&D) costs,<sup>35</sup> reduced output, and depleted pipelines.<sup>36</sup> At the same time, pharmaceutical enterprises suffer from inefficient internal processes to perform basic science and to assess the value of “proof of concept” inventions, especially when they involve distant knowledge domains.<sup>37</sup> In addition, the shareholders of the major pharmaceutical firms have grown accustomed to dramatic returns from “blockbusters,”<sup>38</sup> which are costly to develop. “Even as it might fight it, industry is anticipating change, admitting that ‘[t]he era of the blockbuster is ending.’”<sup>39</sup>

The national market for medicines is highly regulated with competition and corporate behavior being shaped by national health systems, national regulatory requirements for price and product information, legal rules governing human trials and authorization procedures, and rules governing property rights.<sup>40</sup> In the EU, the European Medicines Agency coordinates regulatory oversight of the pharmaceutical industry in the Member States.<sup>41</sup> It also acts as a liaison between the EU, the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (“ICH”), and the World Health Organization (“WHO”).<sup>42</sup> In the United States, the Food and Drug Administration (“FDA”) regulates the testing, approval, and marketing of pharmaceuticals as well as medical devices. Other developed countries have similar regulators.<sup>43</sup> Thus, competitiveness in the pharmaceutical industry is negatively affected by market fragmentation and different research systems.

Patents make it possible for the pharmaceutical industry to extract rents by preventing the production and sale of cheap generics.<sup>44</sup> The Agreement on Trade-Related Aspects of Intellectual Property Rights (the “TRIPS Agreement”)<sup>45</sup> requires World Trade Organization members to grant and honor patents on pharmaceuticals. Although the Doha Agreement<sup>46</sup>

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Drug Discovery & New Models For R&D Success, Kellogg School of Management (Mar. 12, 2007), *available at* <http://www.kellogg.northwestern.edu/biotech/faculty/articles/NewRDMModel.pdf> (last visited Aug. 3, 2013).

<sup>34</sup> GAMBARDILLA, ORSENIGO & PAMMOLLI, *supra* note 32, at 7 (2000).

<sup>35</sup> U.S. Government Accountability Office, *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts 1* (2006), *available at* <http://www.gao.gov/new.items/d0749.pdf> (noting that industry R&D costs increased 147 percent between 1993 and 2004 but that FDA submissions for new chemical molecules have generally decreased since 1995).

<sup>36</sup> Robert F. Service, *Surviving the Blockbuster Syndrome*, 203 SCI. 1796 (2004).

<sup>37</sup> Reddi Kotha, Gerard George & Kannan Srikanth, *Bridging the Mutual Knowledge Gap: Coordination and the Commercialization of University Science*, 56 ACAD. MGMT. J. 498 (2013).

<sup>38</sup> C.J. Tralau-Stewart, C.A. Wyatt, D.E. Kleyn & A. Ayad, *Drug Discovery: New Models for Industry–Academic Partnerships*, 14(1-2) DRUG DISCOVERY TODAY 95 (2009). A drug is considered a blockbuster if it has annual global sales of more than \$1 billion. Koch, *supra* note 30, at 274.

<sup>39</sup> Koch, *supra* note 30, at 273.

<sup>40</sup> There has been limited harmonization since 1990 involving the United States, the EU, and Japan pursuant to the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use. ICH Global Cooperation Group, ICH Information Brochure (May 2001), *available at* <http://www.ich.org/LOB/media/MEDIA410.pdf>.

<sup>41</sup> Council Regulation 2309/93, 1993 O.J. EEC (L214).

<sup>42</sup> Overview of European Medicines Agency, at <http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm> (last visited July 8, 2013).

<sup>43</sup> Katherine A. Davis, Comment, *An International Drug Administration: Curing Uncertainty in International Pharmaceutical Liability*, 18 NW. J. INT’L L. & BUS. 685, 718 (1998).

<sup>44</sup> Jerome H. Reichman & Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85, 95 (2007).

<sup>45</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. (1994).

<sup>46</sup> World Trade Organization, Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC2 (Nov. 14, 2001). All countries, other than the Least-Developed Countries (“LDCs”) were required to stop reverse-engineering patented drugs to produce cheap generics by 2005. This restriction applies to even LDCs as of 2013. Decision of the Council for TRIPS of 29 November 2005, Extension of the Transition Period under Article 66.1 for Least-Developed Country Members, WT/IP/C/40 (Nov. 30, 2005). As Aaron Fellmeth points out, the adequate supply and

permits countries “to issue compulsory licenses to meet the health needs of nations unable to produce locally needed medicines,”<sup>47</sup> developing countries continue to have difficulties obtaining essential medicines at affordable prices.<sup>48</sup>

Pharmaceutical patents spur investment, but they also reduce competition, leading to higher prices.<sup>49</sup> 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.’”<sup>50</sup>

Since the successful mapping of the human genome in 2002,<sup>51</sup> there has been increased focus on both tailoring existing drugs to targeted populations (“‘many drugs across one genome’”) and on developing new drugs tailored to particular genomes to improve efficacy and reduce side effects (“‘many drugs across one genome’”).<sup>52</sup> Company scientists at GlaxoSmithKline have published a number of scientific papers in top medical journals promoting pharmacogenetics,<sup>53</sup> and a number of small biotech firms have entered into agreements with large pharmaceutical firms to develop pharmacogenetic test kits and innovations.<sup>54</sup> They include a \$25 million deal between GlaxoSmithKline and Incyte Genomics to create diaDEXUS and a \$42.5 million agreement between Abbott Laboratories and Genset to develop tests for gauging drug response (both entered into in 1997) and a \$200 million agreement between Roche and deCODE “‘to identify disease genes through genetic analysis of the uniquely homogenous Icelandic population.’”<sup>55</sup>

As a result of this competitive and regulatory environment, the pharmaceutical industry has tried multiple strategies to increase new product development and the return on investment. Examples include increasing R&D efforts, horizontal consolidation, biotech in-licensing and acquisitions,<sup>56</sup> and outsourcing to “drug discovery” firms.<sup>57</sup> In this article, we focus on for-profit PPPP arrangements between government-funded academic institutions and private pharmaceutical firms designed to spur pharmacogenomics and other drug innovations.

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distribution of drugs for the developing countries is also impeded by contracts that guarantee the developed country’s pharmaceutical firm exclusive rights to the clinical test data necessary to secure marketing approval of new drugs. Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement*, 45 HARV. INT’L L.J. 443, 445 (2004). Although important, this topic is beyond the scope of this article.

<sup>47</sup> Reichman & Cooper Dreyfuss, *supra* note 44, at 97.

<sup>48</sup> Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317 (2005).

<sup>49</sup> For example, Myriad Genetics was able to charge \$3,000 for a test for the two breast cancer genes BRCA-1 and BRCA-2 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. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>50</sup> *Id.* at 2116, quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1305 (2012).

<sup>51</sup> Robert I. Field, *How the Government Created and Sustains the Private Pharmaceutical Industry*, 6 ST. LOUIS J. HEALTH L. & POL’Y 29 (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, the government put its findings in a public database within twenty-four hours of discovery, with no limitations on their use. *Id.* at 29.

<sup>52</sup> Koch, *supra* note 30, at 265-68.

<sup>53</sup> *Id.* at 273-74.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* at 279-80.

<sup>56</sup> Arlene Weintraub, *Potential for Deals Drives a Big Surge in the Biotech Sector*, N.Y. TIMES (July 11, 2013) (for example, in June 2013, Johnson & Johnson bought Aragon Pharmaceuticals, a biotech firm with a prostate cancer treatment in midstage human trials, for \$650 million cash plus the potential for an additional \$350 million if certain research milestones are met).

<sup>57</sup> Hughes et al., *supra* note 33.

## II. Key Aspects of the PPPP Arrangement

### A. The Need for Collaboration

The pharmaceutical industry is a science industry for which innovation is the fundamental source of competitiveness.<sup>58</sup> If pharmaceutical enterprises try to operate all aspects of their businesses in-house, demands on investment and the corresponding risk increase. If, instead, pharmaceutical enterprises cooperate and partner with external inventors and funding sources (including the government), the risk and need for investment decreases and the cost can be shared with the partner.<sup>59</sup> When members of the pharmaceutical industry are looking for new ways to institutionalize and sustain pharmaceutical innovation and to sell new products, they now often look for university partners.<sup>60</sup>

For example, Pfizer Inc. has created multiple Centers for Therapeutic Innovation (CTI) in the United States. As of April 2013, Pfizer had partnered with twenty-one academic medical research centers in the United States<sup>61</sup> after receiving more than 300 applications from researchers.<sup>62</sup> The objective of this initiative is to conduct joint research aimed at finding new “biotherapeutic modalities” “across all therapeutic areas” to “transform research and development through a focus on translational medicine.”<sup>63</sup> The Centers for Therapeutic Innovation manage the PPPPs on a project-by-project basis. The incentives, operating models and goals for both the academic and Pfizer researchers are designed to achieve a positive Proof-of-Mechanism study in humans.<sup>64</sup>

Although several studies have shown that public sector research can and already does play an important role in the discovery of new drugs, the interaction and collaboration between the public and private sectors is both limited and complex.<sup>65</sup> In particular, public sector universities have often not been credited as a significant partner. Traditionally, the pharmaceutical entities have co-financed research projects by academic researchers and, in the end, taken ownership of all the resulting intellectual property. In some cases, the private firms have paid royalties to the academic institutions or individual researchers on successful products.

Forming partnerships of any sort increases coordination costs, however, including transaction costs.<sup>66</sup> A study of sixty-two American universities concluded that most

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<sup>58</sup> Giulio Bottazzi, Giovanni Dosi, Marco Lippi, Fabio Pammolli, & Massimo Riccaboni, *Innovation Aids Corporate Growth in the Evolution of The Drug Industry*, 19 INT’L J. INDUSTRIAL ORG. 1161 (2001).

<sup>59</sup> YVES L. DOZ & GARY HAMEL, *ALLIANCE ADVANTAGE: THE ART OF CREATING VALUE THROUGH PARTNERING* (1998).

<sup>60</sup> GAMBARDELLA, ORSENIGO & PAMMOLLI, *supra* note 32, at 7. See also Walter W. Powell, Kenneth W. Koput & Laurel Smith-Doerr, *Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology*, 41 ADMIN. SCI. Q. 116, 118 (1996) (“In addition to research universities and both start-up and established firms, government agencies, nonprofit research institutes, and leading hospitals have played key roles in conducting and funding [biotechnology] research, while venture capitalists and law firms have played essential parts as talent scouts, advisors, consultants, and financiers.”). In biotechnology and other fields “where knowledge is advancing rapidly and the sources of knowledge are widely dispersed, organizations enter into an array of alliances to gain access to different competencies and knowledge.” *Id.*

<sup>61</sup> Pfizer, Press Release, CHOP Collaborates with Pfizer’s Centers for Therapeutic Innovation to Speed Pediatric Research & Development, Apr. 3, 2013, *available at* [www.press.pfizer.com/press-release/chop-collaborates-pfizers-centers-therapeutic-innovation-speed-pediatric-research-deve](http://www.press.pfizer.com/press-release/chop-collaborates-pfizers-centers-therapeutic-innovation-speed-pediatric-research-deve).

<sup>62</sup> Pfizer, Centers for Therapeutic Innovation, [www.pfizer.com/research/rd\\_works/centers\\_for\\_therapeutic\\_innovation.jsp](http://www.pfizer.com/research/rd_works/centers_for_therapeutic_innovation.jsp).

<sup>63</sup> Pfizer, *supra* note 61.

<sup>64</sup> Pfizer, Centers for Therapeutic Innovation, Translating Leading Science into the Clinic, *available at* [www.pfizer.com/files/research/partnering/](http://www.pfizer.com/files/research/partnering/).

<sup>65</sup> Ian Cockburn & Rebecca Henderson, *Public-Private Interaction in Pharmaceutical Research*, 93 PROCEEDINGS NAT’L ACAD. SCIENCES (USA), 12725–12730 (Nov. 1996). See also Michael D. Rawlins, *Cutting the Cost of Drug Development?*, 3 NATURE REVIEWS DRUG DISCOVERY 360 (2004); Thomas P. Stossel, *Regulating Academic-Industrial Research Relationships—Solving Problems or Stifling Progress?*, 353(10) NEW ENG. J. MED. 1060 (2005).

<sup>66</sup> For a further discussion of coordination costs, ex ante and ex post, see Kendall W. Artz & Thomas H. Brush, *Asset Specificity, Uncertainty and Relational Norms: An Examination of Coordination Costs in Collaborative Strategic Alliances*, 41 J. ECON. BEHAV. ORG. 337 (2000). See also Robert C. Ellickson, *Of Coase and Cattle: Dispute Resolution Among*

university inventions “are so embryonic that further development with the active involvement by the inventor is required for any chance of commercialization.”<sup>67</sup> As a result, “In the pharmaceutical industry, firm connectedness to the academic community, such as through collaboration and coauthoring scientific articles, is a key determinant of successful drug discovery.”<sup>68</sup> If the coordination challenges can be properly managed, strategic alliances can improve the competitive advantage of pharmaceutical enterprises in the market and enhance public welfare by yielding new drugs.

## B. Objectives of the PPPP Relationship

The objectives of the PPPP arrangement are to complete some or all of the steps from basic science to drug commercialization optimally for all parties (from a game theory perspective, to create joint utility) by creating a fully collaborative team with a high level of cooperation, trust, information sharing,<sup>69</sup> including open access to the books and records for all participants, and positive joint incentives.<sup>70</sup> The PPPP contract should incorporate all of these attributes regardless of whether the cooperation deals with the identification and validation of new targets, access to new technologies, pharmacogenomics, pre-clinical pharmacology, structural analysis of biomolecules, diagnostic tools and microarray development, bioinformatics, or identification and validation of biomarkers.

To deliver an efficient framework for collaboration, the PPPP contract must include mechanisms for encouraging cooperative behavior, leading to a win-win approach rather than a traditional competitive perspective.<sup>71</sup> Thus, the PPPP contract should encourage the parties to collaborate with a strong focus on attaining common goals, by sharing gains or losses and information, and by instituting risk and reward systems to build and share innovation. It should also promote continuous long-term improvement. Therefore, we argue, a PPPP agreement should both be reduced to writing and be coupled with respect for relational norms, thereby ensuring the most efficient transaction. If the PPPP contract and the relational forms of governance address the key factors optimally, they can change the payoffs in the game and thereby enhance the joint values. In particular, as discussed in Part III, the PPPP arrangement will move the parties away from an inefficient prisoners’ dilemma Nash equilibrium to a Pareto Optimal Frontier. This is in contrast to a traditional arm’s length contract, which often consists of each party self-optimizing rewards and minimizing its own risks while allocating the cost of future breaches.

If the contract objectives are joint utility, efficiency, and innovation and commercialization optimization, the fulfillment obligations must balance and meet the needs

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*Neighbors in Shasta County*, 38 STAN. L. REV. 623, 686 (1986) (“[L]aw and economics scholars need to pay more heed to how transaction costs influence the resolution of disputes. Because it is costly to carry out legal research and to engage in legal proceedings, a rational actor often has good reason to apply informal norms, not law, to evaluate the propriety of human behavior.”).

<sup>67</sup> Richard Jensen & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 AM. ECON. REV. 240 (2001).

<sup>68</sup> Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CAL. L. REV. 1503, 1534 (2012).

<sup>69</sup> See Oliver Hart, *Incomplete Contracts and Public Ownership: Remarks, and an Application to Public-Private Partnerships*, 113 ECON. J., Conference Papers C69-C76 (Mar. 2003).

<sup>70</sup> Henrik Andersen, Fuguo Cao, Christina D. Tvarno & Ping Wang, *PPP - An International Analysis from a Legal and Economic Perspective* (pdf), available at [www.cbs.dk](http://www.cbs.dk); Matton Van den Berg & Peter Kamminga, *Optimising Contracting for Alliances in Infrastructure Projects*, 23(1) INT’L CONSTRUCTION L. REV. 59, 59 (2006).

<sup>71</sup> Scott E. Masten, *Transaction Costs, Mistakes, and Performance: Assessing the Importance of Governance*, 14 MANAGERIAL & DEC. ECON. 119-129 (1993); IAN R. MACNEIL, *THE NEW SOCIAL CONTRACT: AN INQUIRY INTO MODERN CONTRACTUAL RELATIONS* (1980); Kendall W. Artz & Thomas H. Brush, *Asset Specificity, Uncertainty and Relational Norms: An Examination of Coordination Costs in Collaborative Strategic Alliances*, 41 J. ECON. BEH. & ORG. 337 (2000); Paul A. Rubin & Joseph R. Carter, *Joint Optimality in Buyer-Supplier Negotiations*, 3 J. PURCHASING & MATERIALS MGMT. 20 (1990).

and interests of the academic researchers, the research universities, industry, and the government or other public provider of research funding. The academics must fulfill their own and their university's desire to create and disseminate knowledge, which requires optimization of publishing data and results in international journals. Such publications both disseminate knowledge and enhance the career opportunities for the researchers. Although some academic researchers may be willing to defer publication until a patent application is filed, significant publication delays are problematic.<sup>72</sup> The industry players need the resources in the public sector to fill the innovation gap and change the model of drug development so they can develop and commercialize innovative drugs and earn an attractive return on investment in R&D for their shareholders.<sup>73</sup> From a societal perspective, joint utility is achieved when consumers gain access to a new drug more rapidly and cheaply than would be the case if there were no public-private collaboration.

Contract negotiation, collaboration management, funding, timelines, the production of deliverables, confidentiality, the sharing of intellectual property, and understanding the differences among the parties are all crucial contractual elements that must be considered to make the PPPP work effectively. Behind the PPPP arrangement, there will usually be an industry-specific, agreed-upon document. A committee-type collaborative body, which includes representatives from all of the parties, is usually necessary to establish the terms of the contract. If there is a cooperative body involved, it is crucial that the parties hand over the contract negotiation to the cooperative body and that such body follows the PPPP framework contract during the contract period.<sup>74</sup>

Even when there is no cooperative body, it is important for all the negotiators to keep in mind the importance of ensuring the free flow of information and the alignment of incentives. Drafters and negotiators should focus especially on common goals and joint utility, rather than on traditional views of control and claims of exclusive property rights.

It is critical to conduct specialized training for both the researchers and the administrative and managerial staff, which may include training in translational or pharmaceutical medicine covering target and drug discovery, preclinical development, clinical trials, and management.<sup>75</sup> This helps ensure the proper functioning of an alternative project organization with a project-oriented collaborative culture that enables physical mobility among the academic and industry staff and researchers.<sup>76</sup>

The parties should thus consider appointing a joint project manager group, comprising representatives from all of the PPPP's institutions, with weekly meetings and a strong back line to the analytical staff.<sup>77</sup> They might also form a project committee, a committee of coordinators, or an alliance committee with representation from all parties, then give that body the responsibility for managing the project. For example, such a committee should

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<sup>72</sup> Rai et al, *supra* note 8, at 25.

<sup>73</sup> See also J. Demotes-Mainard, E. Canet & L. Segard, *Public-Private Partnership Models in France and in Europe*, 61(4) THÉRAPIE, 325 (June-August 2006); Ismail Kola & John Landis, *Can the Pharmaceutical Industry Reduce Attrition Rates?*, 3 NATURE REV. DRUG DISCOVERY 711-715 (2004); A. Nissim, Y. Gofur, S. Vesselier, G. Adams & Y. Chernajovsky, *Methods for Targeting Biologicals to Specific Disease Sites*, 10 TRENDS MOLECULAR MED. 269 (2004); Mark Fishman & Jeffery Porter, *A New Grammar for Drug Discovery*, 437 NATURE, 491-493 (2005).

<sup>74</sup> Berg & Kamminga, *supra* note 70, at 63; R. BADEN HELLARD, *PROJECT PARTNERING: PRINCIPLE AND PRACTICE* (1995); JOHN BENNETT & SARAH JAYES, *TRUSTING THE TEAM: THE BEST PRACTICE GUIDE TO PARTNERING IN CONSTRUCTION* (1995); J.J. Myers, *Alliance Contracting: A Potpourri of Proven Techniques for Successful Contracting*, 18 ICLR 56, 58 (2001).

<sup>75</sup> Demotes-Mainard, Canet & Segard, *supra* note 73. Demotes-Mainard, Canet & Segard describe two PPP models: the simultaneous PPP and the sequential PPP and several other PPP situations, in which the partnership consists of services or expertise and in which the public sector acts as an infrastructure providing equipment, competences or research material for the industry as well as situations in which a small or medium enterprise (SME) may act as a subcontractor for an academic laboratory.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

discuss and decide the substantive criteria for common goals, incentives, and responsibilities.<sup>78</sup>

### C. The Critical Importance of an Appropriate Intellectual Property Regime

The sharing of intellectual property is a crucial contractual element in a PPPP.<sup>79</sup> 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 that can hamper further work by the academic researchers. These are not only hotly contested contractual issues but also matters of social and governmental import. Accordingly, “Policy-makers must . . . determine, through the patent system, how to balance the promotion of downstream pharmacogenomics [and other pharmaceutical] research while protecting the rights of innovators.”<sup>80</sup> We return to this topic in Part VI.

### III. Shifting the Parties Away from an Inefficient Prisoners’ Dilemma Nash Equilibrium to the Pareto Optimal Frontier

Game theory, which “demonstrate[s] how strategic interactions can lead to inefficient results,”<sup>81</sup> explains why the parties to a PPPP cannot maximize joint positive utility unless they both (1) enter into a legally binding contract that explicitly supports the alliance elements instead of just a gentleman’s agreement and (2) respect relational norms. To be effective, the PPPP must ensure that the parties act as agreed and have access to symmetrical information, that is, that they both cooperate and coordinate their actions.<sup>82</sup> In short, the goal is to ensure that the parties do not return to their former traditional ways of doing business.<sup>83</sup> A properly framed binding contract, coupled with respect for positive social norms, can move the parties away from an inefficient prisoners’ dilemma Nash equilibrium<sup>84</sup> to the Pareto

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<sup>78</sup> Van den Berg & Kamminga, *supra* note 70; R. SCOTT, *PARTNERING IN EUROPE: INCENTIVE-BASED ALLIANCING FOR PROJECTS* (2001); B. Colledge, *Obligation of Good Faith in Partnering of UK Construction Contracts*, 17 ICLR 175 (2000); D. Jones, *Project Alliances*, 18 ICLR 411 (2001); Alan Crane & Richard Saxon, *The Future*, in *PARTNERING AND COLLABORATIVE WORKING* 55-56 (D. Jones, D. Savage & R. Westgate eds., 2003).

<sup>79</sup> 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).

<sup>80</sup> ERIC RASMUSEN, *GAMES AND INFORMATION: AN INTRODUCTION TO GAME THEORY* 302 (1989).

<sup>81</sup> Ian Ayers, *Playing Games with the Law*, 42 STAN. L. REV. 1291, 1315 (1990). As Thomas Shelling explained, “There are non-zero-sum games that permeate the economy that have settled into, or have been forced into, inefficient equilibria.” THOMAS S. SHELLING, *STRATEGIES OF COMMITMENT AND OTHER ESSAYS* 151 (2006).

<sup>82</sup> Richard H. McAdams, *Beyond the Prisoners’ Dilemma: Coordination, Game Theory, and Law*, 82 S. CAL. L. REV. 209, 218 (2009) (“[C]ooperation failures are not the only obstacles individuals face in achieving their ends. Game theory identifies another pervasive problem: the need to coordinate.”). Because the participants’ goal is to coordinate their behavior, “Each player’s choice of strategy thus depends on the choice made by her counterparts.” Robert Ahdieh, *Beyond Individualism in Law and Economics*, 91 B.U. L. REV. 43, 63 (2011). Ahdieh further explains: “Because of this interdependence, there are ‘multiple equilibria’ in coordination games: more than one set of choices from which neither party will deviate, absent a change in strategy by their counterpart as well. As a result, the solution to coordination games—and hence the determination and prediction of relevant social outcomes—does not lie in any single individual alone.” *Id.* Instead, the players’ “strategies are interdependent, such that each one’s choice depends on the other’s.” *Id.* at 64.

<sup>83</sup> As Berg and Kamminga stated in regard to contracting a strategic alliance, the contract “effectively supports the alliance form and prevents parties from reverting to their former uncooperative and adverse behavior when conflicts arise.” Berg & Kamminga, *supra* note 70, at 59.

<sup>84</sup> As Ayers explains, “A set of strategies is a Nash equilibrium if no player has an incentive to deviate from her strategy given that the other players do not deviate.” Ayers, *supra* note 81, at 1297. Although all dominate strategy equilibria are also Nash equilibria, the converse is not true. *Id.* at 1297 n. 36.

Optimal Frontier, “the locus of achievable joint evaluations from which no joint gains are possible.”<sup>85</sup>

As Ian Ayers noted, “While the defining aspect of cooperative games is the ability to make binding commitments, the leading game-theoretic models of bargaining and contracting are non-cooperative. In these models, the binding, externally-enforced nature of contracts are ‘black boxed’ as binding payoffs for struck bargains.”<sup>86</sup> In this Part and in Part VI we look inside that “black box” in the context of PPPPs.

#### A. Avoiding the Prisoners’ Dilemma

The prisoners’ dilemma game,<sup>87</sup> which involves two people who have been arrested while in possession of stolen goods, demonstrates why two individuals will choose not to cooperate to their mutual advantage when they cannot ensure that the other party will not seek a better deal by defecting. The game assumes that a prosecutor has only enough evidence to convict the prisoners for possession of stolen goods unless one or both of them confess to burglary. The penalty for possession of stolen goods is substantially less than the sentence for burglary. The two prisoners are placed in isolation and therefore cannot talk to each other. The prosecutor visits each prisoner and offers each the same deal. If a prisoner confesses and testifies against the other prisoner, he will go free, while the other will receive the maximum sentence of four years. If both prisoners confess, they will each get two years in prison for burglary. If neither confesses, each prisoner will get half a year in prison for possession of stolen goods. As seen in Table 2, “confession” is the dominant strategy<sup>88</sup> because it is the optimal choice for each player regardless of what the other player does. Thus, the game ends with both players spending two years in prison instead of only half a year, demonstrating that decisions that are rational from an individual’s view are not rational when compared with the results attainable if both parties can communicate with each other and reach a binding agreement.

Table 2: The Prisoners’ Dilemma

	Keep quiet	Confess
Keep quiet	- 1/2, - 1/2	-4, 0
Confess	0, - 4	- 2, - 2

<sup>85</sup> HOWARD RAIFFA, THE ART AND SCIENCE OF NEGOTIATION 139 (1982). An outcome is deemed Pareto optimal if it is impossible to make any party better off without making at least one other party worse off. *Id.*

<sup>86</sup> Ian Ayers, *Symposium – Just Winners and Losers: The Application of Game Theory to Corporate Law and Practice: Three Approaches to Modeling Corporate Games: Some Observations*, 60 U. CIN. L. REV. 419, 422 (1991). Ayers quotes Eric Rasmusen for the proposition that “[c]ooperative game theory may be useful for ethical decisions, but its attractive features are inappropriate for most economic situations, and the spirit of the axiomatic approach is very different from the utility maximization of current economic theory.” *Id.* at 423. But Ayers goes on to acknowledge, “As an empirical matter, it is possible that the equity axioms of the cooperative solution concepts correspond more directly to reality.” *Id.* This prediction is borne out by research by behavioral economists who combine economics with psychology to test how test subjects actually respond to various scenarios. *See, e.g.*, GEORGE A. AKERLOF & ROBERT J. SHILLER, ANIMAL SPIRITS: HOW HUMAN PSYCHOLOGY DRIVES THE ECONOMY, AND WHY IT MATTERS FOR GLOBAL CAPITALISM 1 (2009) (“To understand how economics work and how we can manage them and prosper, we must pay attention to the thought patterns that animate people’s ideas and feelings, their *animal spirits*.”); Ahdieh, *supra* note 82, at 44 (“Experimental studies by both economists and psychologists have revealed systematic deviations from rationality across a wide array of settings.”).

<sup>87</sup> See ANATOL RAPPAPORT & ALBERT M. CHAMMAH, PRISONERS’ DILEMMA (1965); David M. Kreps, Paul Milgrom, John Roberts, & Robert Wilson, *Rational Cooperation in the Finitely Repeated Prisoners’ Dilemma*, 27 J. ECON. THEORY 245 (1982). Game theory also shows that “many markets are inefficient because of strategic behavior or information asymmetry.” RASMUSEN, *supra* note 80, at 196 (1989).

<sup>88</sup> “[A] set of strategies constitutes a dominant strategy equilibrium if each player’s strategy is a best response to any strategies of other players.” Ayers, *supra* note 81, at 1297 n.36.

The aim of the PPPP contract is to move the parties from the negative payoffs of (-2, -2) and to avoid the dangerous (0, -4) and (-4, 0) situation by making it possible for both partners to achieve positive utility. This requires both cooperation and coordination. Changing the payoffs and making the incentives to cooperate more valuable while also making deviations from cooperation more expensive will promote cooperation.<sup>89</sup> Parties can increase the levels of both cooperation and coordination by looking at the future and envisioning repeat games. Repeat games facilitate knowledge transfer between the inventor team and the licensee, thereby reducing coordination costs,<sup>90</sup> which can result not just from misaligned incentives<sup>91</sup> but also from the inability “to synchronize joint efforts, either because of inadequate mutual knowledge or difficulty in creating such knowledge.”<sup>92</sup>

In a pure-coordination game, the players’ interests are convergent; in contrast, in a pure-conflict game, the interests are divergent.<sup>93</sup> Both are games of strategy because “each player’s best choice of action depends on the action he expects the other to take, which he knows, depends, in turn, on the other’s expectations of his own.”<sup>94</sup>

PPPPs are what Thomas Shelling calls mixed-motive or bargaining games because they involve both mutual dependence and conflict.<sup>95</sup> For example, the academic researchers and private firms need each other to take an invention from the bench to the bedside, but the private firm may prefer to be the exclusive owner of all the intellectual property while the academics may prefer to put at least some of it in the public domain.

As discussed further in Part III(B), coordination requires trust, cooperation, and negotiation of an appropriate binding agreement with a focus on the agreed-upon common goals as well as on the efficient sharing of monitoring, control and property rights, coupled with positive incentive mechanisms. By creating a game changing legally binding contract and respecting relational norms, the parties can solve the inefficiency in the game and generate joint positive payoffs of the sort depicted in Table 3.

Table 3: The Efficient PPPP

	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 Contact and Deviate from Relational Norms	Breach Contract
Accept and Abide by Contract and Abide by	5, 5				

<sup>89</sup> Ongoing relationships such as joint ventures and long term PPPs can be seen as a precursor to more intimate cooperation compared with short and finite activities. Long-term relationships can by themselves overcome the dilemma and achieve the optimum outcomes. See Ronald W. McQuaid, *The Theory of Partnership*, in PUBLIC-PRIVATE PARTNERSHIPS: THEORY AND PRACTICE IN INTERNATIONAL PERSPECTIVE 28–29 (Stephen Osborne ed., 2007).

<sup>90</sup> Kotha, George, & Srikanth, *supra* note 37.

<sup>91</sup> Bengt Holmstrom & Paul Milgrom, *The Firm as an Incentive System*, 84 AM. ECON. REV. 972 (1994).

<sup>92</sup> Kotha, George & Srikanth, *supra* note 37, at 498, citing scholars from the knowledge-based view of the firm, including Robert M. Grant, *Toward a Knowledge-based Theory of the Firm*, 17 STRAT. MGMT. J. 109 (1996); Steven Postrel, *Multitasking Teams with Variable Complementarity: Challenges for Capability Management*, 34 ACAD. MGMT. REV. 273 (2009).

<sup>93</sup> THOMAS C. SHELLING, *THE STRATEGY OF CONFLICT* 86 (2006).

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 87.

Relational Norms					
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

If both parties agree to a well-drafted binding contract and abide by relational norms, then they both have a positive utility of say 5. (These payoffs are arbitrary numbers whose importance is their relative value and sign.) If they 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 from a binding contract supplemented by relational governance (5,5). The same 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 then, unless the other party waives its contract rights, this opportunistic behavior results in a loss to the nonbreaching party (say, -2), which may be compensable at least in part by damages, and ill-gotten gain by the breaching party (say, 4).

As discussed in Part VI(C), a trusted intermediary can ensure that neither party seeks to gain advantage at the expense of the other. In this way, it is like a defense attorney hired by two prisoners who is bound in advance to pass along only plea bargains offered by the prosecutor that treat both prisoners the same.<sup>96</sup>

#### B. Relational Governance as a Complement to not Substitute for a Binding Contract

As explained in the literature on incomplete contracting,<sup>97</sup> it is impossible, without incurring virtually unlimited transaction and monitoring costs, to devise a long-form contract that covers every contingency. However, contrary to the assertion that an enforceable long-term contract is inherently antithetical to trust building and other relational norms and instead encourages opportunistic behavior,<sup>98</sup> a study of outsourcing arrangements between U.S. and Indian firms found that “clearly articulated contractual terms, remedies and processes of dispute resolution” can complement trust-building behavior, such as bilateralism, flexibility,

<sup>96</sup>Ayers, *supra* note 85, at 423-24 (“By pre-committing through joint counsel to ignorance, the prisoners can thus mitigate their incentives to fink on each other.”).

<sup>97</sup> See, e.g., Hart, *supra* note 69; Liza Vertinsky, *Universities as Guardians of their Inventions*, 2012 UTAH L. REV. 1949, 1979 (2012) (“Contracts governing investment of effort and transfer of tacit knowledge will inevitably be incomplete and difficult to enforce as a result of asymmetric information and hidden effort levels.”).

<sup>98</sup> See, e.g., Charles W. L. Hill, *Cooperation, Opportunism, and the Invisible Hand: Implications for Transaction Cost Theory*, 15 ACAD. MGMT. REV. 500 (1990).

and repeated exchanges.<sup>99</sup>

Similarly, a study of German contracts for the purchase of software in Asia and Eastern Europe found that German companies use formal contracts “as a communication document,” which is especially important when there are “no common sociocultural norms that could implicitly govern the exchange beyond the contract itself.”<sup>100</sup> As one German expert put it, “[O]ne still needs a contract as the basis of cooperation so that everyone knows what one talks about and what is expected.”<sup>101</sup> Even if a German company elects not to sue for breach of contract because the verdict could not be enforced in court, German companies use private enforcement mechanisms to ensure contractual performance, including (1) checking the reliability of potential business partners, (2) dividing transactions into milestone phases with an option to abandon if a milestone is not met, (3) monitoring and controlling the actions of their foreign contracting party by, for example, securing the right to access directly that party’s internal project management systems, and (4) relying on “overarching reputational networks, which consist of companies, foreign trade chambers, and trade associations.”<sup>102</sup> These techniques are also available to the participants in a PPP. As Thomas Dietz explained, by performing real-time monitoring and employing milestones, which are both forms of relational contracting, “the involved actors turn the transaction from a simple prisoner’s dilemma into a repeated game . . . .”<sup>103</sup>

Legally astute managers work with counsel as partners to create shared value by remaining actively involved in the negotiation process and using it as a way to get to know the counterparties better, to clarify expectations and objectives, and thereby strengthen relationships.<sup>104</sup> As Steve Huhm, the vice president of strategic outsourcing for HP Services, remarked: “Negotiating these kinds of deals requires being honest, open, and credible. Integrity is critical to our credibility.”<sup>105</sup> In short, “[T]he goal is to create value by crafting a workable deal, not to position the company for a lawsuit.”<sup>106</sup>

Asymmetric information can lead to inefficient contracting even in the absence of transaction costs.<sup>107</sup> Open books and sharing of all transaction-relevant information pursuant to binding agreements reduce “moral hazard” and “adverse selection” and, from that, reduce the risk of “hold-up” and “defection.” Thus, symmetric information is a requirement for aligning incentives and obtaining joint optimization.<sup>108</sup> The greater the volume of information exchanged, the larger the possibility of optimizing the joint utility.

For example, the in-house staff at Pfizer works side-by-side with leading academics in basic and translational science in Pfizer’s Centers for Therapeutic Innovation.<sup>109</sup> The researchers have access to Pfizer “compound libraries, proprietary screening methods, and

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<sup>99</sup> Laura Poppo & Todd Zenger, *Do Formal Contracts and Relational Governance Function as Substitutes or Complements?*, 23 STRAT. MGMT. J. 707 (2002).

<sup>100</sup> Thomas Dietz, *Contract Law, Relational Contracts, and Reputational Networks in International Trade: An Empirical Investigation into Cross-Border Contracts in the Software Industry*, 37 L. & SOC. INQUIRY 25, 39 (2012).

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* at 54.

<sup>103</sup> *Id.*

<sup>104</sup> Constance E. Bagley, *Winning Legally: The Value of Legal Astuteness*, 33 ACAD. MGMT. REV. 378 (2008).

<sup>105</sup> Quoted in HARVARD BUSINESS REVIEW, HARVARD BUSINESS REVIEW ON WINNING NEGOTIATIONS 108 (2011). See also Darin Bifani, *Win the Battle or Build a Relationship: How Japanese Style Could Help American Negotiators*, 12 BUS. L. TODAY 25, 28 (2003).

<sup>106</sup> CONSTANCE E. BAGLEY, WINNING LEGALLY: HOW TO USE THE LAW TO CREATE VALUE, MARSHAL RESOURCES, AND MANAGE RISK 93 (2005).

<sup>107</sup> Ian Ayers, *The Possibility of Inefficient Corporate Contracts*, 60 U. CIN. L. REV. 387 (1991).

<sup>108</sup> See also Steven Shavell, *Contracts*, in THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 433 (1998).

<sup>109</sup> See Pfizer, *supra* note 61.

antibody development technologies that are directly relevant to the investigators' work."<sup>110</sup> Academic principal investigators (PIs), postdocs, and Pfizer scientists work jointly on research projects within the Centers for Therapeutic Innovation laboratory and also in the academic laboratories. This facilitates the transfer of tacit knowledge and enables the inventor team and the licensee to better synchronize their commercialization efforts. Furthermore, by establishing a compensation mechanism that rewards cooperation and joint optimization, a well-drafted PPPP contract creates the opportunity for changing the parties' behavior in various scenarios.

This approach is consistent with the "proactive law movement," which began in Scandinavia and then was officially embraced by the European Economic and Social Committee in 2009.<sup>111</sup> In the case of contracts:

A proactive contract is crafted for the parties, especially for the people in charge of its implementation in the field, not for a judge who is supposed to decide about the parties' failures. Instead of providing the most advantageous solution for one of the parties, in case of the failure of the other party to comply with its contractual obligations, the proactive contracting process and documents seek to align and express the interests of both sides of the contract in order to create value for both.<sup>112</sup>

Studies point to the win-win aspect of pharmaceutical public-private partnerships to develop low-cost drugs for developing countries, which often result from the public sector's need for medicine with the potential for only a small or even negative return on investment for the pharmaceutical company. For example, Nwaka analysed the development of malaria drugs in developing countries pursuant to Medicines for Malaria Venture's partnerships.<sup>113</sup> In the Medicines for Malaria Venture Win-Win Proposition-partnerships, the parties must commit to a long-term relationship and share the risks and rights under a common understanding with joint goals. Nwaka found a positive correlation between the distribution of intellectual property rights and the degree of targets achieved. Because the Malaria Venture partnerships involve the public's demand for expensive medicine—not private industry's demand for marketable drugs—Nwaka's results cannot be attributed directly to the types of PPPPs analyzed in this article. Nonetheless, they illustrate existing alternative contractual models within the pharmaceutical industry based on the idea of cooperation and accordingly offer insights for other types of PPPPs.<sup>114</sup> Additional insights can be gleaned from the experience in the United States and the EU with public-private partnerships in the infrastructure space.

#### **IV. Lessons from Public-Private Partnerships in the Construction Industry**

The construction industry has used long-term partnering contracts as a strategic tool to maximize the utilization of public and private core competencies and other resources and to diversify risk.<sup>115</sup> A traditional arm's-length contract in the construction industry would be

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<sup>110</sup> *Id.*

<sup>111</sup> Opinion of the European Economic and Social Committee, "The Proactive Law Approach: A Further Step toward Better Regulation at European Union Level," O.J. C175, vol. 52, July 28, 2009 (EU). See also GEORGE SIEDEL & HELENA HAPIO, PROACTIVE LAW FOR MANAGERS: A HIDDEN SOURCE OF COMPETITIVE ADVANTAGE 11-12 (2011).

<sup>112</sup> Gerlinde Berger-Walliser, Robert C. Bird & Helena Haapio, *Promoting Business Success through Contract Visualization*, 17 J.L. BUS. & ETHICS 55, 61 (2011).

<sup>113</sup> Solomon Nwaka, *Drug Discovery and Beyond: The Role of Public-Private Partnerships in Improving Access to New Malaria Medicines*, 99 TRANSACTIONS OF THE ROYAL SOCIETY OF TROPICAL MEDICINE AND HYGIENE 20, 25 (2005).

<sup>114</sup> See also B. Stirmer, *Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases*, 15 EUR. J. HEALTH L. 391 (2008).

<sup>115</sup> Christina D. Tvarnø, *Law and Regulatory Aspects of Public-Private Partnerships: Contracts Law and Public Procurement Law*, in INTERNATIONAL HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS 216 (Graeme A. Hodge, Carsten Greve & Anthony E. Boardman eds., 2010).

based on optimising each party's own utility by defining the performance expectations in terms of quality and quantity, breach, warranties, liability and dispute solutions. In contrast, partnering contract paradigms in the construction industry include clauses incorporating trust, cooperation, symmetrical information, positive incentives, and successive negotiation.<sup>116</sup> As a result, construction public-private partnerships are in many respects analogous to PPPs.

In the United States, the concept of infrastructure partnering dates back to the 1960s when the U.S. government developed a method of stimulating private investments in infrastructures.<sup>117</sup> The goal was to protect the public interest while at the same time bringing investment potential and added value from the private sector.<sup>118</sup> The economic recessions in the 1970s led other governments to seek more efficient ways to provide services and infrastructure by "contracting out." Great Britain and the United States were particularly strong proponents of privatization in the 1980s.<sup>119</sup> The use of public asset sales, outsourcing, and divestitures of state-owned enterprises became a vehicle for improved public service in a free market economy.<sup>120</sup>

In Great Britain, some of the first attempts to establish a new type of contract stemmed from problems related to poor quality construction, high costs, and the lack of competition. In 1998, Sir John Egan presented the report, *Rethinking Construction*,<sup>121</sup> which focused particularly on "lean" production and cooperation, and resulted in the development of the partnering concept.<sup>122</sup> Based on the results of the Egan report, the construction industry adopted a new contract model using collaboration, negotiation and common utility – "the partnering contract." *Rethinking Construction* asserted that "[e]ffective partnering does not rest on contracts. Contractors can add significantly to the cost of a project and often add no value for the client. If the relationship between a constructor and an employer is soundly based and the parties recognize their mutual interdependence, then formal contract documents should gradually become obsolete."<sup>123</sup> For the reasons provided in Part III(A) we respectfully disagree and view formal contracts and trust-building as complements not substitutes.

The first model partnering contract was created in 2000.<sup>124</sup> It included clauses incorporating trust, cooperation, information, positive incentives, and successive negotiation.<sup>125</sup> The objective of a partnering contract is to reduce cost and price; to increase quality; to reduce risk and failure; to improve coordination; and to share responsibility and capacity. By using a well-crafted partnering contract, the parties can achieve additional value compared with other approaches, as long as there is an effective implementation structure and the objectives of all parties can be met within the strategic alliance.

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<sup>116</sup> *Id.* See also Neil Alderman & Chris Ivory, *Partnering in Major Contracts: Paradox and Metaphor*, 25(4) INT'L J. PROJ. MGMT. 386 (2007); Christina D. Tvarnø, *Why the EU Public Procurement Law Should Contain Rules that Allow Negotiation for Public Private Partnerships: Innovation Calls for Negotiating Opportunities*, in EU PUBLIC PROCUREMENT, MODERNISATION, GROWTH AND INNOVATION: DISCUSSIONS ON THE 2011 PROPOSALS FOR PROCUREMENT DIRECTIVES, JURIST-OG ØKONOMFORBUNDET 201-219 (Grith Skovgaard Ølykke, Carina Risvig Hansen & Christina D. Tvarnø eds., 2012).

<sup>117</sup> See also R. Scott Fosler, *Book Reviews*, in *Public-Private Partnership: New Opportunities for Meeting Social Needs*, 46(4) PUB. ADMIN. REV. 364 (Brooks et al. eds., 1986); Nutavoot Pongsiri, *Regulation and Public Private Partnerships*, 15(6) INT'L J. PUB. SECTOR MGMT. 487 (2002).

<sup>118</sup> Andersen, Cao, Tvarnø & Wang, *supra* note 70, at 25 n. 30.

<sup>119</sup> Pongsiri, *supra* note 117.

<sup>120</sup> DONALD F. KETTL, *SHARING POWER, PUBLIC GOVERNANCE AND PRIVATE MARKETS* (1993).

<sup>121</sup> SIR JOHN EGAN, *RETHINKING CONSTRUCTION* (1998).

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> PCC 2000, *ACA Standard Form of Contract for Project Partnering* (2008).

<sup>125</sup> *Id.* See also Neil Alderman & Chris Ivory, *Partnering in Major Contracts: Paradox and Metaphor*, 25(4) INT'L J. PROJ. MGMT. 386 (2007); Christina D. Tvarnø, *Why the EU Public Procurement Law Should Contain Rules that Allow Negotiation for Public Private Partnerships: Innovation Calls for Negotiating Opportunities*, in EU PUBLIC PROCUREMENT, MODERNISATION, GROWTH AND INNOVATION: DISCUSSIONS ON THE 2011 PROPOSALS FOR PROCUREMENT DIRECTIVES, JURIST-OG ØKONOMFORBUNDET 201-219 (Grith Skovgaard Ølykke, Carina Risvig Hansen & Christina D. Tvarnø eds., 2012).

The utilization of the partnering contract concept led to the creation of public-private partnerships (PPPs) for the construction of public buildings and infrastructure.<sup>126</sup> The governmental attention to the efficiency of market mechanisms and the success of privatization efforts in several countries led to increased governmental interest in PPPs.<sup>127</sup> Over time, governments found a way to better serve their citizens by tapping the private finance markets to fund higher quality construction while reducing taxes.<sup>128</sup> At the same time, private companies discovered new markets and developed new ways to compete and meet consumer demand.

In a traditional PPP infrastructure project, the legal relationship has a relatively long duration because the financing partner focuses on regaining the private investment. Often, it is the public sector's need for financing that drives the decision to pursue a PPP. But as an added benefit, the private sector's key competencies (e.g., designing, managing, and building the project) are usually more efficient than the public sector's.<sup>129</sup> Further, this type of arrangement incorporates an alternative model of risk sharing whereby risks that would otherwise be borne solely by the public sector can be transferred to the private party, to the extent that this is efficient with regard to the specific project.<sup>130</sup> Research on infrastructure PPPs has emphasized both that (1) the public party must give up some degree of control and accept that the private party must be able to realize an attractive yield on its investment and (2) the private party must possess sufficient expertise to reduce the total cost over time.

In the case of pharmaceutical public-private partnerships, the pharmaceutical enterprise needs the public-funded research and the skills of the academic scientists, due to its own lack of path-breaking in-house innovation and investment in basic science, especially across disciplines. Private firms also need the intellectual property regime and contract enforcement mechanisms provided by government. In turn, the pharmaceutical firm bears the significant legal and financial risks associated with developing, approving, and marketing new products.

From a societal perspective, it makes sense to share resources efficiently between both the resource holder and the resource demander, but the private pharmaceutical enterprise must cede some control to the public party and accept that the public party stands in a superior negotiating position because the public party has resources (funding, research, and the ability to confer legal rights) the private party needs. Thus, the private pharmaceutical enterprise must identify the positive gains with respect to both the private and the public agenda and accept a contract favorable to the public party to obtain joint positive utility. In the next Part, we discuss the steps the EU has taken to develop a form of for-profit PPPP based on open innovation.

## **V. The EU Innovative Medicines Initiative and other Policy Developments**

### **A. Innovative Medicines Initiative**

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<sup>126</sup> In the late 1990s, national governments could no longer regard themselves as having a purely domestic role in an increasingly internationalized world. Instead, they were forced to act more like market players. Richard Common, *The East Asia Region: Do Public-Private Partnerships Make Sense?*, in PUBLIC-PRIVATE PARTNERSHIPS, *supra* note 100, at 135.

<sup>127</sup> Pongsiri, *supra* note 117.

<sup>128</sup> INTERNATIONAL HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS (Graeme A. Hodge, Carsten Greve & Anthony E. Boardman eds., 2010).

<sup>129</sup> The economic (private) operator plays an important role, participating in all the different stages of the project (design, completion, implementation, funding). The public partner concentrates primarily on defining the objectives to be attained in terms of public interest, quality of services provided, and pricing policy. It also takes responsibility for monitoring compliance with these objectives.

<sup>130</sup> The European Commission notes that a PPP does not necessarily require the private partner to assume all the risks, or even the major share of the risks, linked to the project. The precise distribution of risk is determined case by case, according to the respective abilities of the parties concerned to assess, control and bear this risk.

In the EU, the Innovative Medicines Initiative (IMI) is a pharmaceutical public-private partnership initiative that differs in substantial respects from the PPPPs that are the focus of this article. 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 and thereby establishing Europe as the most attractive place for pharmaceutical R&D.<sup>131</sup> The IMI research projects are focused on non-competitive research in areas of high medical need -- based on the principle of open innovation.

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 IMI research programme, which is matched by private in-kind contributions.<sup>132</sup> The public funding is directed primarily to academic and non-profit institutions. As of May 2013, forty projects were in operation with a budget of € 1.2 billion.<sup>133</sup>

Each IMI call for a project proposal involves multiple stakeholders, including the pharmaceutical industrial trade association; large, small and medium-sized private pharmaceutical and biotechnology enterprises; universities; hospitals; patient organisations; and public authorities. In particular, IMI contracts involve public funding in response to IMI calls for proposals in open competition that is subject to EU regulation.

In contrast, the Pfizer Centers for Therapeutic Innovation, and other comparable PPPPs in the United States, involve a single private pharmaceutical firm that solicits proposals from academic researchers 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 the pharmaceutical industry in general. Thus, IMI contracts are different from the PPPPs that are the focus of this article.

Nonetheless, the tools explained in this article, including using legal clauses and relational governance techniques to promote joint utility, could also be relevant in IMI calls. Such clauses could be added to the existing IMI Grant Agreement,<sup>134</sup> or parties might add language to the project agreement to the effect that "the internal organisation of the consortium" shall be in accordance with the IMI Grant Agreement.

## B. Action Plan Against the Rising Threats from Antimicrobial Resistance

In response to the European Commission's Action Plan Against the Rising Threats from Antimicrobial Resistance, which was launched in November 2011, AstraZeneca and GlaxoSmithKline announced that they would jointly contribute a total of €224 million to

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<sup>131</sup> IMI regulation (EU) No. 1024/2012 entered into force on 4 December 2012. The IMI Model Framework Service Contract (Framework Contract Number IMI.2013.FWC.029) contains no corresponding provisions on joint optimization between the parties as discussed in this article. Available at: [http://www.imi.europa.eu/sites/default/files/uploads/documents/Procurement/IMI.2013.FWC\\_029\\_EventOrganisation\\_Model-Framework-Service-Contract\\_2013-04-16.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/Procurement/IMI.2013.FWC_029_EventOrganisation_Model-Framework-Service-Contract_2013-04-16.pdf).

<sup>132</sup> 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.) The private in-kind contribution is worth at least another €1 billion and comes from the member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA). See the IMI Highlights, May 2013, at [http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI\\_Highlights\\_May2013\\_final.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI_Highlights_May2013_final.pdf).

<sup>133</sup> IMI Highlights, May 2013, available at [http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI\\_Highlights\\_May2013\\_final.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI_Highlights_May2013_final.pdf).

<sup>134</sup> IMI Joint Undertaking Model, Grant Agreement, "Core," article 1, subsection 4. (On file with the authors.)

develop new antibiotics.<sup>135</sup> 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 pooling of private resources.<sup>136</sup>

### C. Patent Package and Inventions Contrary to “Ordre Public” or Morality

The EU Member States and the European Parliament agreed in 2012 on a patent package comprising two Regulations and an international Agreement, laying the groundwork for unitary patent protection in the EU.<sup>137</sup> The patent package implements enhanced cooperation among the Member States. All Member States except Italy and Spain have agreed to create legislative-based unitary patent protection in the EU by adopting two EU Regulations and an Agreement on a Unified Patent Court, which will have exclusive and specialized jurisdiction over patent cases to ensure uniform protection.<sup>138</sup> Once these Member States ratify the Agreement on a Unified Patent Court, it will be possible to obtain a European patent based on unitary standards in one step. This is expected to reduce the costs of obtaining a patent from approximately €23,000 to €700.

Article 53(a) of the European Patent Convention provides that patents shall not be granted for “inventions the commercial exploitation of which would be contrary to ‘ordre public’ or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States . . . .” The *Directive on the Legal Protection of Biotechnological Inventions* precludes patents on processes for cloning human beings, using human embryos for commercial or industrial purposes, “processes for modifying the germ line genetic identity of human beings,” and “processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”<sup>139</sup> Depending on how these provisions are interpreted, they could affect the ability of pharmaceutical firms in the EU to patent certain genetic inventions

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<sup>135</sup> *Public-Private Partnerships Step Up*, APPLIED CLINICAL TRIALS ONLINE (June 4, 2012).

<sup>136</sup> Arti K. 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.” Rai et al., *supra* note 8, 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.

<sup>137</sup> Regulation No. 1257/2012 of the European Parliament and of the Council, Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection, O.J. EU (L361/1) (Dec. 17, 2012); Council Regulation (EU) No. 1260/2012, Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection with Regard to the Applicable Translation Arrangements, O.J. EU (L3361/89) (Dec. 17, 2012). The draft agreement on the Unified Patent Court can be found at <http://register.consilium.europa.eu/pdf/en/12/st16/st16351-co03.en12.pdf>.

<sup>138</sup> *Id.* The U.S. Congress enacted similar legislation in 1982 when it granted exclusive jurisdiction over patent cases to the United States Court of Appeals for the Federal Circuit. Appeals from that court go directly to the United States Supreme Court. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended at 28 U.S.C. §§ 41-49).

<sup>139</sup> Directive 98/44/EC of the European Parliament and of the Council 1998 on the Legal Protection of Biotechnological Inventions of July 6, 1998, O.J. EC (L 213/13). For a discussion of the impact of this Directive on stem cell research, see Clara Sattler de Sousa e Brito, Case Note, *Biopatenting: “Angst” v. European Harmonization - The ECJ Decision on Stem Cell Patents*, 3 EUR. J. RISK REG. 130 (2012).

#### D. Other Initiatives

Other recent legislative-based initiatives have led to improved marketing authorization procedures, the harmonization of data protection in the EU, better access to medicines for children, and a new regulatory framework for advanced therapies.<sup>140</sup> Thus, the focus at the law and policy level is generally on competition, legislation and public funding, but not on the important tool of using game theory to optimize collaboration through contracts and relational governance. As argued above, a PPPP is a form of strategic alliance that can flip the incentives and ensure joint utility and the optimal transaction by improving the gains from the partnership and ensuring greater economic efficiency. In the next Part, we explain the intellectual property infrastructure necessary to convert the “dead capital”<sup>141</sup> created by the universities into commercially viable products.

### VI. Intellectual Property Issues Inherent in Academic-Industry Collaborations

As noted earlier, the sharing of intellectual property is a crucial contractual element in a PPPP.<sup>142</sup> Although this article does not purport to enumerate all of the intellectual property issues present in a PPPP, certain issues warrant discussion, including ownership of inventions, licensing and patent considerations, the role of university technology transfer offices, public policy concerns raised by university licensing, and technology transfer in the EU.

#### A. The Bayh-Dole Act

In the United States, R&D by a university is frequently the first step in the development of a new drug. The federal government funds the bulk of academic research in the United States,<sup>143</sup> thereby raising questions as to who actually owns the invention – the government, the contractor-university, the inventor, or the private entity that “commercializes” the invention.<sup>144</sup>

Prior to the enactment in 1980 of the Bayh-Dole Act,<sup>145</sup> neither scientists nor universities could patent inventions funded with federal government research money.<sup>146</sup> “Under the ‘commons’ model, the federal government sponsored basic research and encourage its widespread publication in the public domain without regard for potential commercial applications.”<sup>147</sup> As a result, the results of research funded with government grants became part of the public domain or were subject to only nonexclusive licenses.<sup>148</sup>

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<sup>140</sup> Maria Dolores Cabezas, *Current Trend in Pharmaceutical Law in EU*, 14 PHARMACEUTICALS POL’Y & L. 195 (2012).

<sup>141</sup> HERNANDO DESOTO, *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 or hypothecated).

<sup>142</sup> 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 joint ventures by contract ex ante).

<sup>143</sup> Field, *supra* note 53, at 12.

<sup>144</sup> Robert M. Yeh, *The Public Paid for the Invention: Who Owns It?*, 27 BERKELEY TECH. L. J. 453 (2012). See also Thomas P. Stossel, *Regulating Academic-Industrial Research Relationships —Solving Problems or Stifling Progress?*, 353(10) NEW ENG. J. MED. 1060-65 (2005).

<sup>145</sup> Pub. L. No. 96-517, 94 Stat. 3015 (codified as amended at 35 U.S.C. § 200-12).

<sup>146</sup> 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 (1996).

<sup>147</sup> Hoffman, *supra* note 146, at 997.

<sup>148</sup> *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 then up to them to decide or negotiate with their faculty whether it was owned by the inventor or the university.” Comments by Thomas Brzustowski,

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 with a presumption “that universities own inventions that are developed under their watch.”<sup>149</sup> (Similarly, the Stevenson-Wydler Technology Innovation Act<sup>150</sup> 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.<sup>151</sup>) To promote commercialization, especially of inventions that require substantial further research and development and testing to get a product to market,<sup>152</sup> Bayh-Dole requires universities to seek to commercialize federally funded research through patents and licensing or to give the exclusive rights to the invention back to the government.<sup>153</sup> 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.<sup>154</sup> In addition, federally funded researchers are required to grant the federal government a nonexclusive license to use federally funded inventions.<sup>155</sup> In exchange for patenting government-funded inventions, both public and private universities in the United States can charge licensing fees and royalties.<sup>156</sup> Once the patent expires, the invention becomes part of the public domain.

## B. University Technology Transfer Offices

Because “only about 50 percent of all patented inventions (including those arising from university research) ultimately achieve commercialization,”<sup>157</sup> the process by which a university transfers discoveries to the private sector for commercialization (“university technology transfers”) is a priority for academics, industry, and governments. Research laboratories can transfer academic discoveries and inventions to the private sector for commercialization both informally through scientific publications and presentations and formally through research contracts, consulting engagements, licenses, and patent agreements.<sup>158</sup>

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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, 50 (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. PUBLICATION 23, 27-28 (2007), quoting Government of Canada, “Executive Summary: Achieving Excellence,” available at <http://www.innovation.gc.ca/gol/innovation/site.nsf/en/in02425.html>.

<sup>149</sup> Yeh, *supra* note 144, at 453-54.

<sup>150</sup> Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 35 U.S.C. § 3701-15 (2013)).

<sup>151</sup> For example, the NIH can enter into a Cooperative Research and Development Agreement (“CRADA”) with a private firm to commercialize promising technology. CRADAs are “partnerships that allow for joint development with a negotiated set of contributions, responsibilities, and remuneration involving each party.” Field, *supra* note 53, at 24. Both the government agency and the private partner can contribute services, personnel, and property, but only the private party 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 1996 NIH entered into a CRADA with Bristol-Myers Squibb (“BMS”) for the anti-cancer drug Taxol, which paid NIH a royalty of 0.5% of BMS’s revenues from sales of the drug. *Id.* at 60.

<sup>152</sup> Hoffman, *supra* note 146, at 1007 n. 96.

<sup>153</sup> 35 U.S.C. § 202(c)(3). See also Sean O’Connor, Gregory D. Graft & David E. Winickoff, *Legal Context of University Intellectual Property and Technology Transfer*, NAT’L ACAD. SCIENCES REPORT 29 (2010).

<sup>154</sup> Field, *supra* note 53, at 24 n.124; Hoffman, *supra* note 146, 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.”).

<sup>155</sup> 35 U.S.C. § 202(c)(4).

<sup>156</sup> DAVID MOWERY, RICHARD NELSON, BHAVEN SAMPAT & ARVIDS ZIEDONIS, *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT* (2004).

<sup>157</sup> Hoffman, *supra* note 146, at 1507.

<sup>158</sup> *Id.* at 1507-08.

Universities typically license their discoveries to private firms for commercialization.<sup>159</sup> As one scholar explained:

Once universities secure legal ownership rights to inventions, including those that are federally funded, entities ranging from startups to mature companies license those inventions. Subsequently, the companies may provide additional funding for collaborative research where IP rights are allocated between the universities and private collaborators according to contractual agreements. The terms of in-and out-licensing agreements are governed by private contracts and invariably contain complex arrangements.<sup>160</sup>

To deal with the complex issues involved in patenting and licensing inventions, many research universities in the United States have established technology transfer offices (“TTOs”) or technology licensing offices (“TLOs”) that function as “central clearinghouses for university generated inventions.”<sup>161</sup> These offices, which tend to deal with the more “formal” transfer of technology, ensure compliance with Bayh-Dole “by collecting invention disclosures, coordinating patent prosecution, and negotiating licenses with firms.”<sup>162</sup> The parties to a PPPP should take into consideration the role and function of the university’s TTO when drafting the PPPP agreement to avoid the inefficiency of a traditional licensing game.

As an example, the Pfizer’s Centers for Therapeutic Innovation PPPPs are governed by an agreement that provides that all joint inventions will be jointly owned, with Pfizer holding an exclusive option to license a drug after proof of mechanism. In the event Pfizer exercises its option, any jointly developed enabling intellectual property (IP) will be licensed from the institution. If Pfizer declines, the IP and other joint assets revert to the academic institution.<sup>163</sup>

### C. Public Policy Concerns Raised by University Licensing

Public policy questions are raised when a university patents an invention then licenses it to a private entity.<sup>164</sup> Although most universities have dedicated themselves “to the creation and dissemination of knowledge for the public good,”<sup>165</sup> the leadership of each university must “decide whether and to what extent to embrace commercially oriented activities” based upon the respective university’s “mission.”<sup>166</sup>

Certain universities “view technology transfer as indelibly linked with their social obligations as universities.”<sup>167</sup> 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.<sup>168</sup> Thus, “the link that connects publicly sponsored research and private-sector commercialization is technology transfer.”<sup>169</sup>

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<sup>159</sup> Hafiz Aziz ur Rehman, *Equitable Licensing and Publicly Funded Research: A Working Model for India?*, 16 SW. J. INT’L L. 75-78 (2010).

<sup>160</sup> Yeh, *supra* note 144, at 470.

<sup>161</sup> *Id.* at 473.

<sup>162</sup> Lee, *supra* note 68, at 1514.

<sup>163</sup> See Pfizer, *supra* note 61.

<sup>164</sup> Jacob H. Rooksby, *Myriad Choices: University Patents under the Sun*, 42 J. L. & EDUC. 313 (2013).

<sup>165</sup> 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).

<sup>166</sup> Lee, *supra* note 68.

<sup>167</sup> *Id.* at 1566.

<sup>168</sup> *Id.* at 1506.

<sup>169</sup> *Id.*

Yet, unduly close ties between academic researchers and industry can create conflicts of interest<sup>170</sup> 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 deprive patients of life-saving drugs. As a result, “strong 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.<sup>171</sup> Specifically, many licenses entitle the pharmaceutical enterprises to “determine the countries where they intend to file subsequent patents”; for-profit companies “generally file strategic patents in many developing countries to minimize the risk of competition from generic drugs.”<sup>172</sup>

In response to pressure from a coalition built by Yale Law School student Amy Kapczynski in 2000 and 2001, which included the inventor of the HIV drug Zerit®, the Dean of Yale’s School of Public Health, the former head of the WHO’s HIV/AIDS program, and 600 Yale professors, researchers and students who signed a petition calling on Yale to “‘ease its patent’” on Zerit®, Yale University persuaded its exclusive licensee Bristol-Myers Squibb to enter into an “agreement not to sue” with Aspen Pharmaceutical, the leading generic manufacturer in South Africa; as a result, Aspen was able to sell the drug in South Africa at a fraction of the price charged in developed countries.<sup>173</sup>

Thus, 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.”<sup>174</sup> 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.

To address concerns about access to life-saving drugs, a group of universities promulgated a statement of “Nine Points to Consider” when patenting or licensing pharmaceutical inventions.<sup>175</sup> 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.<sup>176</sup> 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.”<sup>177</sup> Or, a university or private firm may seek an NGO, such as the Bill and Melinda Gates Foundation,<sup>178</sup> to pay a fair royalty or licensing fee for drugs for patients in developing countries and neglected diseases.

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<sup>170</sup> Bryan A. Liang & Tim Mackey, *Confronting Conflict: Addressing Institutional Conflicts of Interest in Academic Medical Centers*, 36 AM. J. L. & MED. 136 (2010).

<sup>171</sup> Rehman, *supra* note 159, at 88.

<sup>172</sup> *Id.*

<sup>173</sup> Ashley J. Stevens & April E. Effort, *Using Academic License Agreements to Promote Global Social Responsibility*, 43 LES NOUVELLES 85, 87 (2008). Universities Allied for Essential Medicines, a student organization that grew out of Kapczynski’s work at Yale, developed the Equitable Access License, which is designed to promote the use of university inventions to promote global health by giving universities “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 want to make and sell the products in developing countries. *Id.* at 98. In exchange, the university would charge a 5 percent royalty on sales in Middle Income Countries and 2 percent for sales in Low Income Countries then split the royalties with the primary licensee. *Id.* According to Ashley J. Stevens and April E. Effort, the pharmaceutical firms with which they discussed the matter, indicated that they would be unwilling to license academic inventions pursuant to a license that gave the university a grant-back 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.

<sup>174</sup> Crager et al., *supra* note 165, at 258.

<sup>175</sup> Cal. Inst. of Tech. et al., *In the public Interest: Nine Points to Consider in Licensing University Technology* (2007), available at <http://otl.stanford.edu/industry/resources/whitepaper-10.pdf>.

<sup>176</sup> Crager et al., *supra* note 165, at 259.

<sup>177</sup> Rehman, *supra* note 159, at 88.

<sup>178</sup> Stevens & Effort, *supra* note 173, at 85.

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 continue to fund further research or other needs, including financial aid for needy students.

Further policy issues arise when a university issues an exclusive license on a foundational technology or research tool to a private for-profit pharmaceutical enterprise. For example, Harvard University came under criticism after it granted in 1990 exclusive rights 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.”<sup>179</sup> 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.”<sup>180</sup> 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.<sup>181</sup>

The NIH subsequently adopted protocols offering guidance for when it is appropriate for a research university to patent certain innovations.<sup>182</sup> 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.

Certain academics counter that exclusive patent licenses reduce “the perceived risk of investing in unproven technology to attract private risk capital.”<sup>183</sup> But former Harvard President Derek Bok states, “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.”<sup>184</sup>

One solution is to instead create patent pools, which grant a license to all participants and all comers on a non-discriminatory, nonexclusive basis at a commercially reasonable royalty rate.<sup>185</sup> Such an arrangement can also help mitigate competition law concerns as long as it is open to all public institutions and private firms.<sup>186</sup>

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<sup>179</sup> Hoffman, *supra* note 146, 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).

<sup>180</sup> Hoffman, *supra* note 146.

<sup>181</sup> *Id.* at 1029-30.

<sup>182</sup> 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).

<sup>183</sup> 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 U.S. Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH. 31 (2006).

<sup>184</sup> 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).

<sup>185</sup> David B. Resnik, *A Biotechnology Patent Pool: An Idea Whose Time Has Come?*, 3 J. PHIL., SCI. & L. 1 (2003). As Rai and her coauthors explain, “In recent years, the pooling of patents around information technology standards has become quite common.” Rai et al., *supra* note 8, 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 (Adam Jaffe et al. eds., 2001).

<sup>186</sup> In contrast, a patent pool limited to particular firms would be an unreasonable restraint on trade under U.S. law (*see, e.g., Hartford-Empire Co. v. United States*, 323 U.S. 386 (1945)) and abuse of dominate position under EU competition law (*see* Commission Guidelines of 14 January 2011 on the Applicability of Article 101 of the Treaty on the Functioning of the

For example, the Innovative Medicines Initiative, Europe's largest public-private pharmaceutical development partnership, pools 500,000 chemical compounds, of which 300,000 came from Astra Zeneca, Bayer Pharma, Merck, Sanoh, and the other member companies with the balance coming from academia and smaller firms. Similarly, the Predictive Safety Testing Consortium (PSTC), managed by Critical Path, a trusted nonprofit intermediary created by the FDA and the major pharmaceutical firms, facilitates multi-firm collaboration on methods to predict and test drug safety.<sup>187</sup> 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."<sup>188</sup> The objective of PSTC is "broad public dissemination 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."<sup>189</sup>

Patent pools can be problematic on antitrust grounds to the extent that they unduly restrict "innovation markets."<sup>190</sup> 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, and R&D collaboration may enable participants more quickly or more efficiently to research and develop new or improved goods . . . .'"<sup>191</sup> Given the uncertainty even under the more lenient U.S. law, we agree with Professor Rai and her colleagues that any horizontal collaboration should be first vetted by the relevant antitrust/competition law authorities.

#### D. Proposed Amendments to Bayh-Dole

Scholars in the United States have encouraged Congress to amend Bayh-Dole to address concerns that it has stunted innovation by creating an "anticommons,"<sup>192</sup> which occurs when "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."<sup>193</sup> This is of particular concern as it affects the public availability of research tools and upstream research related to emerging areas, such as pharmacogenomics, the study of genetic traits that "might underlie variation among individuals in drug response, based on individual differences in enzyme structure and

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European Union to Horizontal Cooperation Agreements, OJ 2011 C 11; Commission's Guidelines of 27 April 2004 on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements, OJ 2004 C 101, para. 167, which generally require the licensing of patents in patent pools on "fair, reasonable and non-discriminatory terms."). 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).

<sup>187</sup> Rai et al., *supra* note 8, at 17.

<sup>188</sup> *Id.* Similarly, the Biomarkers Consortium promotes multi-firm research on biomarkers of drug efficacy and safety. *Id.* at 18.

<sup>189</sup> *Id.* In contrast, the Biomarkers Consortium does not itself retain any intellectual property rights; instead, ownership is defined by the inventor's employer. Nonetheless, 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. *Id.*

<sup>190</sup> Department of Justice and Federal Trade Commission, Antitrust Guidelines for Collaborations Among Competitors § 3.32(c) (2000), available at <http://www.ftc.gov/os/2000/04/ftcdojguidelines>.

<sup>191</sup> Rai et al., *supra* note 8, at 35, citing *id.* at § 3.31(a).

<sup>192</sup> Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699 (1998).

<sup>193</sup> Reichman & Dreyfuss, *supra* note 44, at 110 (2007). For suggested alternatives, see, e.g., Hoffman, *supra* note 146 (recommending the creation of a broad experimental use exemption for patented biotechnology research tools);

function.”<sup>194</sup> 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.”<sup>195</sup> Certain empirical studies suggest that patents have not been as much of an impediment to upstream academic research as originally theorized, but that appears to be due in large part to the fact that “scientists typically ignore patents, and that for the most part, they get away with it.”<sup>196</sup> For example, respondents in a study of German 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.”<sup>197</sup> The manufacturers of generic drugs in the United States do not have that option because the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act)<sup>198</sup> requires them to certify to the Food and Drug Administration that the generic product does not violate any valid patent.<sup>199</sup>

There are currently open innovation public-private collaborations to promote genomic research. They include the SNP Consortium, 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.’”<sup>200</sup> It has amassed a database of more than 3.1 million SNPs.<sup>201</sup> A SNP, pronounced “snip,” is a single nucleotide polymorphism, that is, “a difference in a single DNA building block, called a nucleotide.”<sup>202</sup> 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.”<sup>203</sup> 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.”<sup>204</sup>

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.”<sup>205</sup> 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.

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 of biomedical drugs tailored to

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<sup>194</sup> Koch, *supra* note 30, at 264.

<sup>195</sup> Heller & Eisenberg, *supra* note 185, at 698-99.

<sup>196</sup> Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1080 (2008).

<sup>197</sup> *Id.* at 1064-65.

<sup>198</sup> Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., and 35 U.S.C.)

<sup>199</sup> 21 U.S.C. § 355(b), (c), (j).

<sup>200</sup> Koch, *supra* note 30, at 279.

<sup>201</sup> *Id.*

<sup>202</sup> National Institutes of Health, “What are single nucleotide polymorphisms (SNPs)?” in Genetics Home Reference, available at <http://ghr.nlm.nih.gov/handbook/genomicresearch/snp> (last visited July 13, 2013).

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

<sup>205</sup> Vertinsky, *supra* note 97, at 1991. See also Robert P. Merges, *A New Dynamism in the Public Domain*, 71 CHI. L. REV. 183, 188-89 (2004).

individual genomes. 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.<sup>206</sup> 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<sup>207</sup> 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.

David C. Hoffman articulated a three-prong strategy for dealing with the anticommons created by “patent thickets” and “patent stacking” in the biotechnology space,<sup>208</sup> which we would encourage regulators in both the United States and the EU to consider. First, create a broad experimental use exemption for public sector researchers that “would cover non-commercial use of any biological material, reagent, or research tool for which an equivalent substitute is not readily available biomedical research tools.”<sup>209</sup> Second, establish a compulsory licensing regime for “essential reagents and research tools” used in commercial biotechnology research administered by a collective rights organization (“CRO”) comprising representatives of the NIH, the National Science Foundation, the Biotechnology Industry Organization, (or, in the case of the EU, the analogous organizations) and public academic research institutions.<sup>210</sup> Instead of having Congress (or the Member State or the European Parliament) set uniform licensing rates by statute, the CRO would determine the licensing fees based on its assessment of “the development costs and commercial potential of new methods, reagents, and research tools.”<sup>211</sup> 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.<sup>212</sup> 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.<sup>213</sup> Third, limit the scope of biotechnological patents by requiring a more complete “enabling description” of the claimed invention in the specification that discloses an “inventive concept or principle whose precise contours are defined by the claims.”<sup>214</sup> Pursuant to the EC Biotechnology

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<sup>206</sup> *Id.* 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.”).

<sup>207</sup> As Amy 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.” Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 *BERKELEY TECH. L.J.* 1031, 1040 (2005). With regard to open source copyright licensing, see generally Robert W. Gomulkiewicz, *Enforcement of Open Source Software Licenses: The MDV 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).

<sup>208</sup> Hoffman, *supra* note 146.

<sup>209</sup> *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).

<sup>210</sup> Hoffman, *supra* note 146, at 1039-40.

<sup>211</sup> *Id.* at 1040.

<sup>212</sup> *Id.* at 1040-41.

<sup>213</sup> *Id.* at 1040.

<sup>214</sup> *Id.* at 1041-42, citing Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *COLUM. L. REV.* 839, 846 (1990).

Directive, the European Patent Office already requires DNA patent applications to set forth the “industrial applicability of the information revealed.”<sup>215</sup>

In addition, we support 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.<sup>216</sup> 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 NIH’s funding 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 NIH funding, it may be appropriate for Congress to give the NIH to retain a right to receive a small percent of the royalties generated by those inventions that are ultimately commercialized. This is tricky, however, because it is important not to distort the grant-approval process to remove funding from the type of research the private markets are most unlikely to fund, basic research. Thus, Congress might want to limit the percentage of NIH grants eligible for royalty recovery.

Finally, we argue that universities should be precluded from granting exclusive licenses for upstream inventions and research tools funded by the government. This would have avoided the Harvard oncomouse situation. If a university patents government-funded upstream inventions and research tools, it should be required either to grant nonexclusive licenses at a royalty rate not in excess of the private funding used to fund the research that led to the invention or to put the invention in a patent pool, managed by a trusted intermediary, that is open to all at a commercially reasonable rate. In addition, we support creation of a broad experimental use exemption for patented biotechnology research tools.<sup>217</sup>

Although we believe that these changes are important to ensure that the United States continues to play a leading role in emerging technologies, such as pharmacogenomics, these changes would also create an intellectual property licensing regime that would be more compatible with the norms and rules in the EU, a subject to which we turn next.

#### E. University Technology Transfer in the EU

In the EU, there has been to date poor knowledge transfer from the academic science base to industry. This is due, among other factors, to an academic culture that might prevent commercialization<sup>218</sup> and to the lack of harmonized legal rules comparable to the Bayh-Dole Act,<sup>219</sup> which creates uncertainty concerning who actually owns intellectual property

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<sup>215</sup> Reichman & Dreyfuss, *supra* note 44, at 117.

<sup>216</sup> Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS 289 (2003) (recommending that the NIH and other government agencies be given greater authority to limit the patenting of certain publicly funded research).

<sup>217</sup> Hoffman, *supra* note 146.

<sup>218</sup> 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).

stemming from government funded research.<sup>220</sup> 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.

For example, the EU gives less exclusive patent for biotechnology inventions than the United States, thereby avoiding some of the anticommons problems with the U.S. regime.<sup>221</sup> The European Directive on Biotechnology,<sup>222</sup> which all of the Member States had implemented by 2006,<sup>223</sup> treats DNA patents “as information products, whose eligibility tests should turn on the quality and industrial applicability of the information revealed.”<sup>224</sup> It also requires biotech plant patentees to give plant breeders compulsory licenses.<sup>225</sup> Although the World Intellectual Property Organization has proposed a Substantive Patent Law Treaty,<sup>226</sup> the European Patent Office cited the uncertain nature of such an effort.<sup>227</sup>

*The Economist* initially characterized Bayh-Dole as “innovation’s golden goose,”<sup>228</sup> but three years later it questioned the influence it had had on university research.<sup>229</sup> Yet, as of 2012, Austria, Denmark, Finland, Belgium, Germany, and Norway were considering or had recently passed legislation modeled at least in part on Bayh-Dole.<sup>230</sup> Although Union-wide consensus may be difficult to reach, certain Member States have generated rules to facilitate the transfer of technology from the university research lab to the marketplace.

For example, the United Kingdom, Germany, and Denmark have national rules that embody at least some of the same legal objectives as the Bayh-Dole Act.<sup>231</sup> According to the UK Patent Act of 1977,<sup>232</sup> academic researchers are employees of the university and therefore patent rights stemming from their research belong to the university. In Germany, an amendment to the German Employed Inventor’s Act provides that a university can claim inventions created by its employees on its campus using government funding. Denmark also

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<sup>219</sup> Thomas J. Siepmann, *The Global Exportation of the U.S. 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, EPC/ECFIN/01/777-EN, 34 (Jan. 22, 2002).

<sup>220</sup> Reichman & Dreyfuss, *supra* note 44, at 119 (“what 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.”).

<sup>221</sup> *Id.* at 117.

<sup>222</sup> Council Directive 98/44, Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 (EC). 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).

<sup>223</sup> See State of Play of the Implementation of Directive 98/44/EC (2007),

[http://europa.eu.int/comm/internal\\_market/indprop/docs/invent/state-of-play\\_en.pdf](http://europa.eu.int/comm/internal_market/indprop/docs/invent/state-of-play_en.pdf).

<sup>224</sup> Reichman & Dreyfuss, *supra* note 44, at 117, citing Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 255, arts. 52-53, 57, which states that an invention must have an “industrial application” to be eligible for a patent.

<sup>225</sup> Reichman & Dreyfuss, *supra* note 44, at 117. In contrast, the U.S. Supreme Court ruled in *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1766 (2013), that a farmer who initially purchased genetically altered soybean seeds patented by Monsanto may not reproduce the patented seeds through planting and harvesting without the patent holder’s express or implied permission.

<sup>226</sup> World Intellectual Property Organization, Standing Committee on the Law of Patents, Draft Substantive Patent Law Treaty, WIPO Doc. SCP/10/2 (Sept. 30, 2003), criticized in Reichman & Dreyfuss, *supra* note 44, at 87-117.

<sup>227</sup> European Patent Office, “Scenarios for the Future—How Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?” (2007), discussed in Reichman & Dreyfuss, *supra* note 44, at 104-06.

<sup>228</sup> *Innovation’s Golden Goose*, ECONOMIST, Dec. 12, 2002, available at <http://www.economist.com/node/1456653>.

<sup>229</sup> *Bayhing for Blood or Doling Out Cash?*, ECONOMIST, Dec. 20, 2005, available at <http://www.economist.com/node/532766>.

<sup>230</sup> Vertinsky, *supra* note 97, at 1950 n. 4.

<sup>231</sup> David C. Mowery & Bhaven N. Sampai, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. TECH. TRANSFER 115 (2005).

<sup>232</sup> <http://www.ipo.gov.uk/patentsact1977.pdf>.

enacted an amendment to its patent laws<sup>233</sup> concerning ownership of property rights to inventions made in university settings to encourage the development and commercialization of scientific inventions by splitting the revenue from intellectual property contracts between the inventing researchers and the institutions.<sup>234</sup> In contrast, professors in Sweden own the rights to their inventions.<sup>235</sup>

Many EU Member States have technology transfer offices to commercialize inventions created in government laboratories. Although a number of universities in the EU have established technology transfer offices to promote commercialization and licensing patents to companies, Denmark and the other Nordic countries prohibit public universities from asserting ownership rights to government-funded inventions.<sup>236</sup> Results from an OECD report<sup>237</sup> show that there is a large diversity in the structure and organization of technology transfer offices<sup>238</sup> within and across the Member States, but the majority appears to be dedicated on-site institutions that are integrated into the university or research institution.

#### F. Another Possible Impediment to PPPs in the EU: The State Aid Directive

Another possible impediment to creating PPPs in the EU is the restriction in Article 107(1) of the Treaty of the Function of the European Union (“TFEU”)<sup>239</sup> 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.

In principle, all public funding to universities is State Aid, so universities in the EU must comply with the State Aid rules when they collaborate for economic gain with industry. Thus, any public funding that could distort (or just threatens to distort) competition by favoring certain enterprises, will be incompatible with the internal market if it affects the trade between the Member States.<sup>240</sup> That is why universities clearly separate their economic and non-economic activities. Articles 107 and 108 of TFEU and EU law in general have no uniform rules that can be applied to ensure the correct separation of economic and non-economic activities for State Aid purposes. Instead, this responsibility rests with the Member States.

Given the goals of the Innovation Union and of Horizon 2020, an exemption to the State Aid restrictions should, however, be available for pharmaceutical R&D created by a

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<sup>233</sup> See also Bekendtgørelse af lov om opfindelser ved offentlige forskningsinstitutioner, LBK nr 210 af 17/03/2009 at <https://www.retsinformation.dk/Forms/R0710.aspx?id=123680>.

<sup>234</sup> Siepmann, *supra* note 219.

<sup>235</sup> Stevens & Effort, *supra* note 173, at 98.

<sup>236</sup> Maria “Tess” Barker, Comment, *The Use of Universities’ Intellectual Property to Address Humanitarian Concerns in Developing Countries*, 19 *TRANSNAT’L L. & CONTEMPORARY PROBLEMS* 923, 938 (2011), citing Niklas Bruun, *Innovation Policy, Academia and Intellectual Property Rights*, 23 *GA. ST. U. L. REV.* 913, 915 (2007).

<sup>237</sup> OECD, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003).

<sup>238</sup> Variations include on- or off-campus offices, arm’s length intermediaries, industry sector-based technology transfer offices, and regional technology transfer offices.

<sup>239</sup> Consolidated Version of the Treaty on the Functioning of the European Union, art. 107(3)(b), March 30, 2010, 2010 O.J. EU (C 83) 47.

<sup>240</sup> See also Bernhard von Wendland, *State Aid and Public Funding for Universities and other Research Organisations*, *COMPETITION POLICY NEWSLETTER* 54, 55 (no. 2, 2010)

partnership between a university and a private enterprise pursuant to Article 107(3)(b) and 107(3)(c) of TFEU,<sup>241</sup> which provide:

The following may be considered to be compatible with the internal market:

...

(b) aid to promote the execution of an important project of common European interest or to remedy a serious disturbance in the economy of a Member State;  
(c) aid to facilitate the development of certain economic activities or of certain economic areas, where such aid does not adversely affect trading conditions to an extent contrary to the common interest . . . .

There is precedent for this in the form of the legislation for government funding of orphan drugs, which are drugs designed to treat small subsections of the population. The U.S. Congress enacted the Orphan Drug Act (“ODA”) in 1983<sup>242</sup> to provide incentives for private firms to develop (1) drugs for diseases affecting fewer than 200,000 patients in the United States or (2) drugs for diseases affecting a larger population 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 drugs.”<sup>243</sup> The ODA provides a seven-year period of marketing exclusivity for the drug, even if it would not otherwise be eligible for patenting,<sup>244</sup> federal funding through the Food and Drug Administration,<sup>245</sup> and a fifty percent tax credit for human clinical trials.<sup>246</sup> The EU adopted similar legislation in 2000,<sup>247</sup> but it limits the period of exclusivity to four years if the product is sufficiently profitable.<sup>248</sup> 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 pharmacogenomics products.<sup>249</sup> The same reasoning could be applied to other types of drug development.

## VII. Proposed Technology Licensing Regime for the EU

Although there are significant advantages to the U.S. approach to commercializing government-funded inventions, we submit that the EU should not enact legislation akin to Bayh-Dole without giving universities and public funders more discretion over both when technology must be patented to avoid having it revert to the government and 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.”<sup>250</sup> This would create a middle ground between the model of open innovation in

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<sup>241</sup> See further the Communication from the Commission, “Investing in Research: An Action Plan for Europe,” June 4, 2003, COM (2003) 226 final/2; the Communication from the Commission, “Europe 2020,” Mar. 3, 2010, COM (2010) 2020; Case 173/73 Italy v. Commission [1974] ECR 709; Case C-487/06 P, British Aggregates Association v. Commission (Dec. 22, 2008).

<sup>242</sup> 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.

<sup>243</sup> 21 U.S.C. § 360bb(a)(2).

<sup>244</sup> 21 U.S.C. § 360cc(a)(2).

<sup>245</sup> 21 U.S.C. § 360ee.

<sup>246</sup> 26 U.S.C. § 45C(a).

<sup>247</sup> Regulation on Orphan Medicinal Products, Regulation 141/2000, 2000 O.J. (L18) (EC).

<sup>248</sup> *Id.*, Art. 8.

<sup>249</sup> Nuffield Council on Bioethics, *Pharmacogenetics: Ethical Issues* (2003).

<sup>250</sup> Vertinsky, *supra* note 97, at 1949.

the IMI and the anticommons created by the current U.S. system. In addition, we encourage policy makers in the EU to consider David C. Hoffman's three-prong strategy for dealing with the anticommons created by "patent thickets" and "patent stacking" in the biotechnology space.<sup>251</sup>

Both to reduce transaction costs<sup>252</sup> 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 PPPs using pre-approved standardized licensing contracts, such as the Uniform Biological Materials Transfer Agreement. Universities are 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.<sup>253</sup> By offering a safe harbor for parties willing to accept such an agreement, regulators in the EU could help facilitate transfer of materials as well as technologies.

Because one-size rarely fits all,<sup>254</sup> the standardized contracts "blessed" by the EU regulators could provide alternative licensing terms from which the parties to the PPP 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," we would encourage policy makers in the EU 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.<sup>255</sup> 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,<sup>256</sup> 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.

## Conclusion

A comparative analysis of the U.S. and EU approaches to translational medicine shows that there are lessons to be shared. PPPs 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 PPPs in the United States, and the United States can emulate the open innovation aspects of the European IMI concept and the tighter patenting standards imposed by the European Patent Office.

Well-crafted pharmaceutical public-private partnerships combine the contractual partnership model inspired by the theory on strategic alliances with the joint optimization

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<sup>251</sup> Discussed *infra* in text accompanying note 208.

<sup>252</sup> 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.").

<sup>253</sup> Rai & Eisenberg, *supra* note 216, at 305-06.

<sup>254</sup> Beirne Roose-Snyder & Megan Doyle, *The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level*, 35 AM. J. L. & MEDICINE 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.").

<sup>255</sup> Rai & Eisenberg, *supra* note 209, at 300.

<sup>256</sup> Downie & Herder, *supra* note 141, at 34 (offering examples of instances when private firms threatened legal action if an academic published negative results or commentary).

attainable by applying game theory, including strategies for repeat coordination games. They represent a powerful legal tool, yet to be widely employed in the European pharmaceutical industry, that can both enhance competitiveness and improve societal and individual patient welfare. As a result, we argue that policymakers in the EU should encourage utilization of PPPPs and facilitate their formation and operation by clarifying the applicability of the State Aid limitations and by permitting universities to obtain patents on government-funded inventions, perhaps with a royalty-sharing arrangement akin to what Denmark has recently enacted. At the same time, the U.S. Congress should consider promoting open innovation for certain upstream research and research tools to avoid placing undue burdens on innovation.