PHARMACEUTICAL PUBLIC-PRIVATE PARTNERSHIPS: MOVING FROM THE BENCH TO THE BEDSIDE

By

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Abstract

This article provides a game theory and law-and-management analysis of for-profit pharmaceutical public-private partnerships, a complex type of legal arrangement in the highly regulated pharmaceutical industry. A pharmaceutical public-private partnership (PPPP) agreement is a legally binding contract between a private pharmaceutical enterprise and a public research university (or a private university conducting publicly funded research) to support research leading to new commercial pharmaceutical and biologic products. The key purpose of this article is to provide a theoretical explanation and a practical perspective on how properly crafted PPPP arrangements can promote innovation more efficiently than traditional self-optimizing contracts. In particular, a properly framed binding contract, coupled with respect for positive incentives, can move the parties away from an inefficient prisoners' dilemma Nash equilibrium to the Pareto Optimal Frontier and thereby increase both the overall size of the pie and the value of the share retained by each participant. 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. Thus, this article discusses how 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. 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 of pharmacological discoveries by flipping the parties' incentives as compared with a more traditional contract.

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

Introduction

Both to address unmet medical needs and to improve industry competitiveness, governments in the European Union (EU) and the United States have taken bold steps to promote the movement of medical research and

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discoveries from "bench to bedside,"[1] from the university laboratory to the patient. This "translation from the university laboratory to the healthcare sector [is facilitated by] the generation and support of start-ups, spin-offs, university-industry consortia, and other platforms."[2] For example, in 2014, the National Institutes of Health (NIH) in the United States announced the $230 million Accelerating Medicines Partnership, which will bring together scientists from ten large pharmaceutical companies, several research foundations and nonprofit organizations, and the NIH and Food and Drug Administration to collaborate on multi-year, open-source projects. These projects are designed to bridge the gap between (i) cutting-edge genomics, proteomics, imaging and other medical research, and (ii) the new drugs and diagnostics needed to fight type 2 diabetes, Alzheimer's disease, lupus, and rheumatoid arthritis.[3] Success "will require a systematic approach in which government, academia, industry, and patient groups work collaboratively to sift through the flood of disease targets and find the ones most likely to prove responsive to treatments."[4]

The launching of this "bold new venture"[5] follows the 2011 creation of the NIH's National Center for Advanced Translational Sciences (NCATS), with a fiscal year 2012 budget of $575 million.[6] NCATS' 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."[7] 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,"[8] to retain a competitive advantage in pharmaceutical innovation and "to support the progress of the present implementation of the [EU's Innova-

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[1] Rogerio Gaspar et al., *Toward a European Strategy for Medicines Research (2014-2020): The EUFEPS Position Paper on Horizon 2020*, 47 Eur. J. Pharmaceutical Sciences 979, 980 (2012).

[2] *Id.*

[3] Editorial Board, *NIH Tries a New Approach to Speed Drug Development*, Wash. Post, Feb. 8, 2014, *available at* http://www.washingtonpost.com/opinions/nih-tries-a-new-approach-to-speed-drug-development/2014/02/08/bf30ba18-8ea1-11e3-b227-12a45d109e03_story.html (last visited Apr. 4, 2014).

[4] Accelerating Medicines Partnership, National Institutes of Health, nih.gov/science/amp/index.htm (last visited Mar. 2, 2014).

[5] *Id.*

[6] *Budget*, Nat'l Center for Advancing Translational Sciences, http://www.ncats.nih.gov/about/budget/budget.html (last visited Mar. 2, 2014).

[7] *Strategic Alliances for Technology Transfer*, Nat'l Center for Advancing Translational Sciences, http://www.ncats.nih.gov/research/tech-transfer/alliances.html (last visited Mar. 2, 2014).

[8] *About*, European Federation for Pharmaceutical Sciences, http://www.eufeps.org/about (last visited Mar. 2, 2014).

tive Medicines Initiative] research agenda,"[9] Europe will need to pursue similar initiatives.

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."[10] As John C. Reed, 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 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.[11]

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[9] Gaspar et al., *supra* note 1, at 982.

[10] John C. Reed, *NCATS Could Mitigate Pharma Valley of Death*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (May 15, 2011), http://www.genengnews.com/gen-articles/ncats-could-mitigate-pharma-valley-of-death/3662/ (last visited Mar. 1, 2014); *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.").

[11] Reed, *supra* note 10. 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. *General Information,* MOLECULAR LIBRARIES INITIATIVE, https://mli.nih.gov/mli/compound-repository/mlsmr-compounds/ (last visited Apr. 4, 2014). These molecules are released into the public domain and 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 10, at 7. Unlike biologics, which are comprised of macromolecules that are expensive to produce, small molecule drugs can be mass-produced at a lower cost. *Id*. at 3.

This article focuses on pharmaceutical public-private partnerships (PPPPs)[12] involving a public university or research institute (or a private university or institute conducting 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.[13] 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."[14] The purpose of this article is to promote the use of PPPPs by providing an annotated roadmap for universities and private pharmaceutical firms.

In contrast to the for-profit PPPPs discussed in this article, there are a variety of subsidized international public-private partnerships involving the World Health Organization (WHO), including the 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.[15] For example, Pfizer, Merck Serona, and Chemtura have joined the WHO's Tropical Disease Network and allow its Special Program for Research and Training in Tropical Diseases Compound Evaluation Network "to submit targets for in-house screening against a subset of the firms' respective chemical libraries."[16] Partnerships of this sort, which are "highly integrated relationships among states, international organizations, companies, NGOs, research institutes, and/or philanthropic foundations,"[17] are designed to address the market's failure to incentivize private

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[12] 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." *Public-Private Partnerships*, 44 FALL PROCUREMENT LAW. 9, 9 (2008).

[13] Unlike Gian Luca Burci, who defines a pharmaceutical public-private partnership as a "long-term collaborative arrangement among a group of diverse stakeholders, some of which [are] 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 ORGS. L. REV. 359, 361 (2009), we define "public nature" to include public universities and research institutes, and those private universities and research institutes that receive government funding for medical research.

[14] *Public-Private Partnerships Step Up*, APPLIED CLINICAL TRIALS ONLINE (June 4, 2012) *available at* http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/Blogs/Public-Private-Partnerships-Step-Up/ArticleStandard/Article/detail/776075?contextCategoryId=49914 (last visited Apr. 4, 2014).

[15] *See* 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).

[16] Rai et al., *supra* note 10, at 30.

[17] 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).

firms to develop and market drugs that would not be profitable without government or NGO funding.[18] Although certain aspects of our analysis are applicable to NGO- and development country-related projects, there are significant differences between such arrangements and a for-profit strategic alliance between a single for-profit medical enterprise and one or more universities. Thus, except as otherwise noted, we use the term "PPPPs" to refer to the latter type of for-profit arrangements.

In Part I, we describe the pharmaceutical market. In Part II, we explain how a partnership arrangement between a public university[19] 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 PPPPs. In Part V, we suggest various add-ons to existing contracts and game-changing contract clauses for strategic alliances designed to encourage joint optimization and the efficient allocation of added value from joint medical research discoveries and commercialization. These provisions can promote not only more efficient PPPPs but also more efficient joint government-industry projects such as the Accelerating Medicines Partnership in the United States and the Innovative Medicines Initiative in the EU.

I. The Pharmaceutical Market

In 2011, worldwide expenditures on pharmaceuticals approached $1 trillion.[20] That year, France, Germany, Italy, Spain, and the United Kingdom alone spent $159 billion on medicine.[21] The United States spent $322 billion.[22] The pharmaceutical industry is a major industry in both the EU and the United States,[23] and it is highly concentrated.[24] As seen in Table 1,[25] the ten largest firms earned roughly $467 billion in 2012.

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[18] *See* 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).

[19] 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.

[20] *The Global Use of Medicines: Outlook Through 2016,* IMS Institute for Informatics 5 (2012), *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.

[21] *Id.* at 31.

[22] *Id.*

[23] Gaspar et al., *supra* note 1; European Federation of Pharmaceutical Industries and Associations [hereinafter EFPIA]; The Pharmaceutical Industry in Figures 3, referring to EFPIA member associations (official figures) - (e): efpia estimate; eurostat (eu-27 trade data 1995–2012) ("The European-based pharmaceutical industry makes a major contribution to the EU, not just in economic terms but also in terms of high-quality employment, investment in the science base and in terms of public health."). *Pharmaceuticals in Europe: facts and*

TABLE 1: TOP TEN PHARMACEUTICAL FIRMS IN 2012

	Name	Headquarters	2012 Revenues (USD billions)
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% of EU GDP in 2010[26] and nearly double that in the United States.[27] Because total healthcare expenditures are 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.[28]

figures, EUR. COMM'N, http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/importance/facts-figures_en.htm. (According to the World Trade Organization, "the global pharmaceuticals market is worth US$300 billion a year, a figure expected to rise to US$400 billion within three years. The 10 largest drugs companies control over one-third of this market, several with sales of more than US$10 billion a year and profit margins of about 30%. Six are based in the United States and four in Europe. It is predicted that North and South America, Europe and Japan will continue to account for a full 85% of the global pharmaceuticals market well into the 21st century," http://www.who.int/trade/glossary/story073/en/.).

[24] 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).

[25] *Sales Data*, *Top Pharma Companies by 2012 Revenues*, http://www.fiercepharma.com/special-reports/top-pharma-companies-2012-revenues#ixzz2ZAg0zpeW (last visited Apr. 4, 2014).

[26] *Pharmaceutical and Health Services Overview,* EUROPEAN COMMISSION, http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html (last visited Mar. 2, 2014). According to the European Commission the 9% covers the pharmaceutical sector (prescription and non-prescription medicines), medical devices, and health services.

[27] 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.

[28] EFPIA, *supra* note 23.

The development of new pharmaceuticals is both high risk[29] and high cost, with new drugs costing a billion dollars or more to bring to market.[30] The productivity challenge in the pharmaceutical industry can be explained in part by an increase in R&D costs,[31] reduced output, and depleted pipelines.[32] Innovation losses in developing new drugs are increasing across the industry.[33] Although the number of new, approved molecular entities has remained steady in the past ten years, the cost of new drug development has increased significantly in both the U.S. and the EU.[34] The pharmaceutical industry in both the U.S. and the EU are looking for new ways to sustain pharmaceutical innovation and sell new products. 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.[35] In addition, the shareholders of the major pharmaceutical firms have grown accustomed to dramatic returns from "blockbusters,"[36] which are costly to develop. Despite its wishes to the contrary, the industry anticipates change because "[t]he era of the blockbuster is ending."[37]

The national market for medicines is highly regulated. Competition and corporate behavior are shaped by national health systems, national regulatory requirements for price and product information, legal rules governing

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[29] Valerie Gutmann Koch, *Incentivizing the Utilization of Pharmacogenetics in Drug Development*, 15 HEALTH CARE L. & POL'Y 263, 274 & n.89, 276 (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% of drugs approved by the FDA are subsequently withdrawn due to negative side effects).

[30] National Institutes of Health, PhRMA Industry Profile 2011 10 (2011). As Valerie Koch notes, others dispute this calculation. Koch, *supra* note 29, at 274 n.87 (citing Donald W. Light & Rebecca Warburton, *Demythologizing the High Cost of Pharmaceutical Research*, 6 BIOSCIENCES 34, 36, 38–39 (2011)); *see also* Alfonso Gambardella, Luigi Orsenigo & Fabio Pammolli, *Global Competitiveness in Pharmaceuticals: A European Perspective* 11–13 (2000), *available at* http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/comprep_nov2000_en.pdf.

[31] U.S. Gov't Accountability Office, GAO-07-49, New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts 1 (2006) (noting that industry R&D costs increased 147% between 1993 and 2004 but that FDA submissions for new chemical molecules have generally decreased since 1995).

[32] Robert F. Service, *Surviving the Blockbuster Syndrome*, 303 SCI. 1796, 1796 (2004).

[33] Gambardella, Orsenigo & Pammolli, *supra* note 30, at 2–3 (2000).

[34] Michael Hu, Karl Schultz, Jack Sheu & Daniel Tschopp, Kellogg School of Management, *The Innovation Gap in Pharmaceutical Drug Discovery & New Models For R&D Success*, (Mar. 12, 2007), *available at* http://www.kellogg.northwestern.edu/biotech/faculty/articles/NewRDModel.pdf (last visited Aug. 3, 2013).

[35] *See* Reddi Kotha, Gerard George & Kannan Srikanth, *Bridging the Mutual Knowledge Gap: Coordination and the Commercialization of University Science*, 56 ACAD. MGMT. J. 498, 503 (2013).

[36] 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, 95 (2009). A drug is considered a blockbuster if it has annual global sales of more than $1 billion. Koch, *supra* note 29, at 273.

[37] Koch, *supra* note 29, at 273.

human trials and authorization procedures, and rules governing property rights.[38] In the EU, the European Agency for the Evaluation of Medicinal Products coordinates regulatory oversight of the pharmaceutical industry among the Member States.[39] 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 WHO.[40] In the United States, the FDA regulates the testing, approval, and marketing of pharmaceuticals as well as medical devices.[41] Other developed countries have similar regulators.[42] Competitiveness in the pharmaceutical industry is thus negatively affected by market fragmentation and different national regulatory regimes.

Patents make it possible for the pharmaceutical industry to prevent the production and sale of cheap generics and to extract rents.[43] The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) requires World Trade Organization members to grant and honor patents on pharmaceuticals.[44] Although the Doha Agreement[45] permits countries

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[38] There has been limited harmonization since 1990 involving the U.S., the EU, and Japan pursuant to the results from 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), http://www.ifpma.org/quality/regulatory-harmonization.html; *see also* David V. Eakin, *International Conference on Harmonization of Pharmaceutical Regulations: Progress or Stagnation,* 6 TULSA J. COMP. & INT'L L. 221, 221 (1998–1999).

[39] Council Regulation 2309/93, 1993 O.J. EEC (L214).

[40] *Overview of European Medicines Agency*, http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42; *European Medicines Agency, International-standard Organizations*, *available at* http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000227.jsp&mid=WC0b01ac05801df740 (last visited Apr. 23, 2014).

[41] *See generally* U.S. Food & Drug. Admin., FDA Fundamentals, *available at* http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm (last updated Feb. 12, 2014).

[42] *See generally* U.S. Food & Drug Admin., About FDA, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm236581.htm (last updated Apr. 18, 2014) (noting that the FDA meets with its counterpart agencies in, for example, Europe, Switzerland, Canada, and Australia).

[43] *See* 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).

[44] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994).

[45] World Trade Organization, Ministerial Declaration of 14 November 2001, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC2, 41 I.L.M. 755 (2002). 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 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*

"to issue compulsory licenses to meet the health needs of nations unable to produce locally needed medicines,"[46] developing countries continue to face difficulties in obtaining essential medicines at affordable prices.[47]

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,[48] and outsourcing to "drug discovery" firms.[49] 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.

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.[50] If pharmaceutical enterprises try to operate all aspects of their businesses in-house, demands on investment and the corresponding risk increase. If, instead, based upon the idea behind fixed cost and strategic alliances,[51] pharmaceutical enterprises partner with external inventors and funding sources (including the government), the risk and need for investment decrease and the cost can be shared with the partner.[52] When members of the pharmaceutical industry look for new ways to institutionalize and sustain pharmaceutical innovation and to sell new products, they now also look for university partners.[53]

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the TRIPS Agreement, 45 Harv. Int'l L.J. 443, 445 (2004). Although important, this topic is beyond the scope of this article.

[46] Reichman & Cooper Dreyfuss, *supra* note 43, at 97.

[47] *See, e.g.*, Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health,* 99 Am. J. Int'l L. 317 (2005).

[48] Arlene Weintraub, *Potential for Deals Drives a Big Surge in the Biotech Sector*, N.Y. Times DealBook, July 12, 2013, at B5, *available at* http://dealbook.nytimes.com/2013/07/11/biotech-companies-surge-as-investors-flock-to-them/ (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 plus the potential for an additional $350 million if certain research milestones are met).

[49] *See generally* Hu et al., *supra* note 34 (reviewing drug development and drug discovery outsourcing).

[50] Giulio Bottazzi, Giovanni Dosi, Marco Lippi, Fabio Pammolli & Massimo Riccaboni, *Innovation and Corporate Growth in the Evolution of the Drug Industry*, 19 Int'l J. Indus. Org. 1161, 1162 (2001).

[51] Kenichi Ohmae, *The Global Logic of Strategic Alliances*, Harv. Bus. Rev., Mar.–Apr. 1989 at 143, 143.

[52] *See id.* at 147, 151. *See generally* Yves L. Doz & Gary Hamel, Alliance Advantage: The Art of Creating Value Through Partnering (1998).

[53] *See* Cathy J. Tralau-Stewart, Colin A. Wyatt, Dominique E. Kleyn & Alex Ayad, *Drug Discovery: New Models for Industry–Academic Partnerships*, 14 Drug Discovery Today 95, 96–97 (Jan. 2009); Walter W. Powell, Kenneth W. Koput & Laurel Smith-Doerr, *Interor-*

For example, Pfizer has created multiple Centers for Therapeutic Innovation (CTI) in the United States. As of April 2013, Pfizer had partnered with twenty-one U.S. academic medical research centers[54] after receiving more than 300 applications from researchers.[55] 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."[56] The CTI 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.[57]

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 remains both limited and complex.[58] Traditionally, the pharmaceutical entities have co-financed research projects by academic researchers and, in the end, assumed 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.

A study of sixty-two American universities concluded that most university inventions "are so embryonic that further development with the active involvement by the inventor is required for any chance of commercialization."[59] As a result, "[i]n the pharmaceutical industry, firm connectedness to the academic community, such as through collaboration and coauthoring

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ganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology, 41 ADMIN. SCI. Q. 116, 118 (1996); Walter W. Powell, *Learning from Collaboration: Knowledge and Networks in the Biotechnology and Pharmaceutical Industries*, 40 CAL. MGMT. REV. 228, 233 (1998) ("In addition to research universities and both start-up and established firms, government agencies, nonprofit research institutes, and leading research 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 a wide array of alliances to gain access to different competencies and knowledge." *Id.* at 233.

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

[55] *Pfizer Centers for Therapeutic Innovation*, MOUNT SINAI INNOVATION PARTNERS, www.ip.mountsinai.org/formssm/partnering/pfizer-centers-for-therapeutic-innovation/ (last visited Feb. 27, 2014).

[56] *Translating Leading Science into the Clinic*, CENTERS FOR THERAPEUTIC INNOVATION, www.pfizer.com/files/research/partnering/cti_brochure_9x12_v12single.pdf.

[57] *Id.*

[58] Ian Cockburn & Rebecca Henderson, *Public–Private Interaction in Pharmaceutical Research*, 93 PROCEEDINGS NAT'L ACAD. SCIENCES (USA) 12725 (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 NEW ENG. J. MED. 1060 (2005).

[59] Richard Jensen & Marie Thursby, *Proofs and Prototypes for Sale: The Licensing of University Inventions*, 91 AM. ECON. REV. 240 (2001).

scientific articles, is a key determinant of successful drug discovery."[60] Forming partnerships of any sort increases coordination costs, however, including transaction costs.[61] 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, in a manner that is optimal for all parties, from a game theory perspective, to create maximum joint utility. This requires the creation of a fully collaborative team with a high level of cooperation, trust, information sharing (including open access to the books and records for all participants), and positive joint incentives.[62] 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 approach.[63] Thus, the PPPP contract should encourage the parties to collaborate with a strong fo-

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[60] Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CAL. L. REV. 1503, 1534 (2012).

[61] 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 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.").

[62] *See* Henrik Andersen, Fuguo Cao, Christina D. Tvarnø & Ping Wang, *PPP—An International Analysis from a Legal and Economic Perspective*, *available at* http://openarchive.cbs.dk/bitstream/handle/10398/8422/public-private_partnership.pdf; *See also* Matton Van den Berg & Peter Kamminga, *Optimising Contracting for Alliances in Infrastructure Projects*, 23 INT'L CONSTRUCTION L. REV. 59, 59 (2006). *See generally* Oliver Hart, *Incomplete Contracts and Public Ownership: Remarks, and an Application to Public-Private Partnerships*, 113 ECON. J. C69 (Mar. 2003).

[63] Scott E. Masten, *Transaction Costs, Mistakes, and Performance: Assessing the Importance of Governance*, 14 MANAGERIAL & DEC. ECON. 119 (1993); IAN R. MACNEIL, THE NEW SOCIAL CONTRACT: AN INQUIRY INTO MODERN CONTRACTUAL RELATIONS 90–102 (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).

cus 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. This should be reflected in the contract terms. For example, the contract should include explicit clauses obliging the parties to use reasonable efforts to achieve joint utility and rewarding the attainment of joint goals.

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's optimizing its own rewards and minimizing its own risks while allocating the cost of future breaches.

If the contract objectives are joint utility, efficiency, innovation, and commercial optimization, the fulfillment obligations must balance the needs and interests of all the parties. This includes the academic researchers, the research universities, industry participants and their shareholders, and the government or other public provider of research funding. Academics seek to create and disseminate knowledge, which requires optimization of publishing data and results in international journals. Although some academic researchers may be willing to defer publication until a patent application is filed, significant publication delays are problematic.[64] The industry players can use the resources in the public sector to fill the innovation gap and change the model of drug development, thereby developing and commercializing innovative drugs and earning an attractive return on investment in R&D for their shareholders.[65] From a societal perspective, joint utility is increased 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,

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[64] *See* Rai et al, *supra* note 10, at 25.

[65] Tralau-Stewart et al., *supra* note 53, at 96. *See generally* J. Demotes-Mainard, E. Canet & L. Segard, *Public-Private Partnership Models in France and in Europe,* 61 THÉRAPIE 325 (2006); Ismail Kola & John Landis, *Can the Pharmaceutical Industry Reduce Attrition Rates?*, 3 NATURE REV. DRUG DISCOV. 3, 711–15 (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*, NATURE 437, 491–93 (2005).

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.[66]

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. This knowledge should be derived from, for example, game theory. The understanding of joint utility and the maximization of the output, or "the size of the pie," is shown by Table 2 below. The contract clauses must prevent the inefficient prisoners' dilemma Nash equilibrium and aim for the maximum output by focusing on the transaction.

To achieve this perspective, it is critical to conduct specialized training for both the public and private researchers, administrative and managerial staff, which may include training in translational or pharmaceutical medicine covering target and drug discovery, preclinical development, clinical trials, and management.[67] 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.[68]

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.[69] 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 discuss and decide the substantive criteria for common goals, incentives, and responsibilities.[70]

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[66] *See* J.J. Myers, *Alliance Contracting: A Potpourri of Proven Techniques for Successful Contracting*, 18 Int'l Construction L. Rev. 56, 58–59 (2001). *See generally* Van den Berg & Kamminga, *supra* note 62; 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).

[67] Demotes-Mainard, Canet & Segard, *supra* note 65, at 332. Demotes-Mainard, Canet & Segard describe two public-private partnership (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.

[68] *See* Demotes-Mainard, Canet & Segard, *supra* note 65, at 332.

[69] *Id.*

[70] *See generally* Van den Berg & Kamminga, *supra* note 62; R. Scott, Partnering in Europe: Incentive-Based Alliancing for Projects (2001); B. Colledge, *Obligation of Good Faith in Partnering of UK Construction Contracts*, 17 Int'l Construction L. Rev. 175 (2000); D. Jones, *Project Alliances*, 18 Int'l Construction L. Rev. 411 (2001); Alan Crane

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,"[71] 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.[72] In short, the goal is to ensure that the parties do not return to their former traditional ways of doing business.[73] A properly framed binding contract, coupled with respect for positive social norms, can move the parties away from an inefficient prisoners' dilemma Nash equilibrium[74] to the Pareto Optimal Frontier, "the locus of achievable joint evaluations from which no joint gains are possible."[75]

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 the contractual commitments [is]

& Richard Saxon, *The Future*, *in* Partnering and Collaborative Working 55–56 (D. Jones, D. Savage & R. Westgate eds., 2003).

[71] Ian Ayers, *Playing Games with the Law*, 42 Stan. L. Rev. 1291, 1315 (1990). As Thomas Schelling explained, "[t]here are non-zero-sum games that permeate the economy that have settled into, or have been forced into, inefficient equilibria." Thomas S. Schelling, Strategies of Commitment and other Essays 151 (2006).

[72] *See* 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, "[e]ach 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.* at 64. Instead, the players' "strategies are interdependent, such that each one's choice depends on the other's." *Id.*

[73] 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." Van den Berg & Kamminga, *supra* note 62, at 59.

[74] 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 71, at 1297. Although all dominate strategy equilibria are also Nash equilibria, the converse is not true. *Id.* at 1297 n.36.

[75] 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.*

'black boxed' as binding payoffs for struck bargains."[76] In this Part and in Part V we look inside that "black box" in the context of PPPPs.

A. Avoiding the Inefficient Nash Equilibrium in the Prisoners' Dilemma

The prisoners' dilemma game,[77] which involves two individuals who have been arrested while in possession of stolen goods, demonstrates why two people 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[78] 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.

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[76] Ian Ayers, *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 evaluate 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 72, at 44 ("Experimental studies by both economists and psychologists have revealed systematic deviations from rationality across a wide array of settings.").

[77] *See* ANATOL RAPOPORT & ALBERT M. CHAMMAH, PRISONERS' DILEMMA (1965); *see also* 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." ERIC RASMUSEN, GAMES AND INFORMATION: AN INTRODUCTION TO GAME THEORY 196 (1989).

[78] "[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 71, at 1297 n.36.

TABLE 2: THE PRISONERS' DILEMMA[79]

	Keep quiet	**Confess**
Keep quiet	- ½, - ½	-4, 0
Confess	0, - 4	- 2, - 2 (the Nash equilibrium)

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) situations 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.[80] Looking at the future and envisioning repeat games enables parties to better coordinate and cooperate. In the context of PPPPs, repeat games facilitate knowledge transfer between the inventor team and the licensee, thereby reducing coordination costs.[81] Coordination costs result not only from misaligned incentives[82] but also from the "inability to synchronize joint efforts, either because of inadequate mutual knowledge or difficulty in creating such knowledge."[83]

In a pure-coordination game, the players' interests are convergent; in contrast, in a pure-conflict game, the interests are divergent.[84] 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."[85]

PPPPs are what Thomas Schelling calls mixed-motive or bargaining games because they involve both mutual dependence and conflict.[86] For example, 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.

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[79] *See* RAPOPORT & CHAMMAH, *supra* note 77, at 24–25.

[80] Ongoing relationships such as joint ventures and long-term PPPs can be seen as a precursor to more intimate cooperation as compared with short and finite activities. Long-term relationships can by themselves overcome the dilemma and achieve the optimal outcomes. *See* Ronald W. McQuaid, *The Theory of Partnership*, *in* PUBLIC-PRIVATE PARTNERSHIPS: THEORY AND PRACTICE IN INTERNATIONAL PERSPECTIVE 28–29 (Stephen P. Osborne ed., 2000).

[81] Kotha, George, & Srikanth, *supra* note 35.

[82] Bengt Holmstrom & Paul Milgrom, *The Firm as an Incentive System*, 84 AM. ECON. REV. 972 (1994).

[83] Kotha, George & Srikanth, *supra* note 35, 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 STRATEGIC MGMT. J. 109 (1996); Steven Postrel, *Multitasking Teams with Variable Complementarity: Challenges for Capability Management*, 34 ACAD. MGMT. REV. 273 (2009)).

[84] THOMAS C. SCHELLING, THE STRATEGY OF CONFLICT 86 (1980).

[85] *Id.*

[86] *Id.* at 87.

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

If both parties agree to a well-drafted binding contract and abide by relational norms, then they both have a positive utility of 5. These payoffs are arbitrary numbers whose importance is their relative value and sign. If the parties cannot agree on a contract but abide by relational norms then the joint utility (2, 2) would still be positive, that is, greater than it would be if there was no cooperation at all but lower than what would result 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, unless the other party waives its contract rights, this opportunistic behavior results in a loss to the non-breaching party (say, -2), which may be compensable at least in part by damages, and ill-gotten gain by the breaching party (say, 4).

As discussed in Part V(C), a trusted intermediary can ensure that neither party seeks to gain advantage at the expense of the other. This relation is similar to that of 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.[87]

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

As explained in the literature on incomplete contracting,[88] it is impossible, without incurring virtually unlimited transaction and monitoring costs, to devise a long-form contract that covers every contingency. Some assert that an enforceable long-term contract is inherently antithetical to trust building and other relational norms, and instead encourages opportunistic behavior.[89] However, 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, and repeated exchanges.[90]

Similarly, a study of German contracts for the purchase of software in Asia and Eastern Europe found that German companies use formal contracts "as [ ] communication document[s]," which is especially important when there are "no common sociocultural norms that could implicitly govern the exchange beyond the contract itself."[91] 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."[92] Even if a German company elects not to sue for breach of contract because the verdict could not be enforced in court, German companies can use private enforcement mechanisms to ensure contractual performance. These private enforcement mechanisms include: (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 "over-

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[87] Ayers, *supra* note 76, at 423 ("By pre-committing through joint counsel to ignorance, the prisoners can thus mitigate their incentives to fink on each other.").

[88] 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."); *see, e.g.*, Hart, *supra* note 62.

[89] *See, e.g.*, Charles W. L. Hill, *Cooperation, Opportunism, and the Invisible Hand: Implications for Transaction Cost Theory*, 15 ACAD. MGMT. REV. 500 (1990).

[90] Laura Poppo & Todd Zenger, *Do Formal Contracts and Relational Governance Function as Substitutes or Complements?*, 23 STRATEGIC MGMT. J. 707, 712 (2002).

[91] 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).

[92] *Id.*

arching reputational networks, which consist of companies, foreign trade chambers, and trade associations."[93] These techniques are also available to the participants in a PPPP.

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 prisoners' dilemma into a repeated game . . . ."[94] In a repeated game, in which the parties use the Tit-for-Tat strategy,[95] it is possible to encourage cooperation.[96] By using the above-mentioned clauses, the parties can realize benefits.

Legally astute managers partner with counsel to create shared value by remaining actively involved in the negotiation process.[97] This process allows the manager to get to know the counterparties better and clarify expectations and objectives, thereby strengthening relationships.[98] As Steve Huhn, 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."[99] In short, "[T]he goal is to create value by crafting a workable deal, not to position the company for a lawsuit."[100]

Asymmetric information can lead to inefficient contracting, even in the absence of transaction costs.[101] Open books and the sharing of all transaction-relevant information pursuant to binding agreements can mitigate[102] the risk of hold-up and defection.[103] Thus, symmetric information is needed to align incentives and obtain joint optimization.[104] The greater the volume of information exchanged, the more likely joint utility will be optimized.

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.[105] The researchers have access to Pfizer "compound

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[93] *Id.* at 54.

[94] *Id.*

[95] RAPPAPORT & CHAMMAH, *supra* note 77, at 215.

[96] R. AXELROD, THE EVOLUTION OF COOPERATION 27–69 (1984).

[97] Constance E. Bagley, *Winning Legally: The Value of Legal Astuteness*, 33 ACAD. MGMT. REV. 378 (2008).

[98] *Id.*

[99] Danny Ertel, *Getting Past Yes: Negotiating as if Implementation Mattered*, *in* HARVARD BUSINESS REVIEW ON WINNING NEGOTIATIONS 85, 108 (Harvard Business Review ed., 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).

[100] CONSTANCE E. BAGLEY, WINNING LEGALLY: HOW TO USE THE LAW TO CREATE VALUE, MARSHAL RESOURCES, AND MANAGE RISK 93 (2005).

[101] Ian Ayres, *The Possibility of Inefficient Corporate Contracts*, 60 U. CIN. L. REV. 387, 392–402 (1991).

[102] *See generally* Oliver E. Williamson, *Transaction Cost Economics: The Governance of Contractual Relations*, 22 J.L & ECON. 233, 241–42 (1979).

[103] *See, e.g.*, Srinivisan Balakrishnan & Mitchell Koza, *Information Asymmetry, Adverse Selection and Joint-Ventures—Theory and Evidence*, 20 J. ECON. BEHAV. & ORG. 99, 100 (1993).

[104] *See* Steven M. Shavell, *Contracts*, *in* THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 436 (1998).

[105] Press Release, Pfizer, *supra* note 54.

libraries, proprietary screening methods, and antibody development technologies that are directly relevant to the investigators' work."[106] Academic principal investigators (PIs), postdocs, and Pfizer scientists work jointly on research projects in both the Centers for Therapeutic Innovation laboratory and academic laboratories. This arrangement 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.

This approach is consistent with the Proactive Law approach, which began in Scandinavia and was officially embraced by the European Economic and Social Committee in 2009.[107] 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.[108]

Studies point to the win-win aspect of PPPPs 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, Solomon Nwaka[109] analyzed the development of malaria drugs in developing countries pursuant to Medicines for Malaria Venture's partnerships. In the Medicines for Malaria Venture, Win-Win Proposition-partnerships,[110] the parties must commit to

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[106] *Id.*

[107] *Opinion of the European Economic and Social Committee on 'The proactive law approach: a further step towards better regulation at EU level,'* 2009 O.J. (C 175). *See also* George Siedel & Helena Haapio, Proactive Law for Managers: A Hidden Source of Competitive Advantage 11–12 (2011).

[108] Gerlinde Berger-Walliser, Robert C. Bird & Helena Haapio, *Promoting Business Success through Contract Visualization*, 17 J.L. Bus. & Ethics 55, 61 (2011).

[109] Solomon Nwaka, *Drug Discovery and Beyond: The Role of Public-Private Partnerships in Improving Access to New Malaria Medicines*, 99 Transactions Royal Soc'y Tropical Med. & Hygiene 20 (Suppl. 1, 2005).

[110] Nwaka defines the pharmaceutical PPP as a Win-Win Proposition in which Medicines for Malaria Ventures (MMV) represents the public sector; the philanthropic donors supply funding and support; and the private sector provides background intellectual property rights, expertise from staff and its Expert Scientific Advisory Committee, and a link to the WHO's Roll Back Malaria program; *see also* Medicines for Malaria Venture (MMV)'s Partnership Network, http://www.mmv.org/partnering/mmvs-partnership-network (last visited May 12, 2014). If the PPP with the pharmaceutical industry succeeds in producing a drug to treat malaria, MMV owns (i) "the intellectual property rights relating to its use within the scope of MMV's 'field,' i.e., in the services of the project; (ii) a supply of the drug that results from the

a long-term relationship and share the risks and rights under a common understanding with joint goals.[111] Nwaka found a positive correlation between the distribution of intellectual property rights and the extent to which targets are achieved.[112] Because the Medicines for 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, these results illustrate existing alternative contractual models within the pharmaceutical industry that are based on the idea of cooperation and accordingly offer insights for other types of PPPPs.[113] Additional insights can be gleaned from public-private partnerships in the infrastructure space, both in the U.S. and the EU.

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

The construction industry has used long-term partnering and public-private partnership (PPP) contracts as a strategic tool to maximize the utilization of public and private resources and to diversify risk.[114] A traditional arm's-length contract in the construction industry is based on each party maximizing its 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.[115] As a result, construction public-private partnerships are in many respects analogous to PPPPs.

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collaboration to developing countries at cost or at preferential prices; and (iii) rights to use it in disease-endemic countries." The private pharmaceutical partner company typically will contribute chemical intellectual property rights, toxicology, management skills and know-how in exchange for the rights to the co-developed drug outside the services of the project and the public relations and human resources benefits. *Id.* at 25. "MMV has found that flexible, results-oriented approaches to dealing with IPR best serve their use as a tool to form and manage collaborations that can further MMV's public health mission." Medicines for Malaria Venture, *What Is MMV's Policy on Intellectual Property Rights?*, http://www.mmv.org/about-us/faqs/what-mmv%E2%80%99s-policy-intellectual-property-rights (last visited May 12, 2014).

[111] Nwaka, *supra* note 109.

[112] *Id.*

[113] *See also* Beatrice Stirner, *Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases*, 15 Eur. J. Health L. 391, 403–05 (2008).

[114] 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).

[115] *Id.*; *see also* Neil Alderman & Chris Ivory, *Partnering in Major Contracts: Paradox and Metaphor*, 25 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 201–19 (Grith Skovgaard Ølykke, Carina Risvig Hansen & Christina D. Tvarnø eds., 2012); Christina D. Tvarnø, Partnering

In the U.S., the concept of infrastructure partnering dates back to the 1960s, when the U.S. government developed a method of stimulating private investments in infrastructure.[116] The goal was "to protect [the] public interest while . . . bringing investment potential and added value from the private sector."[117] 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,[118] and Sir John Egan presented in this regard a report, *Rethinking Construction*,[119] in 1998. The Egan Report resulted in what is now the well-established partnering concept,[120] which includes collaboration, negotiation, and common utility. According to the Egan Report:

> [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.[121]

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.[122] It included clauses incorporating trust, cooperation, information, positive incentives, and successive negotiation.[123] The objectives of a partnering contract are to reduce cost and price, to increase quality, to reduce risk and failure, to improve coordination, and to share responsibility and capacity. Through a well-crafted partnering contract, the parties can realize additional value compared with other approaches, as long as an effective implementation structure exists and the objectives of all parties can be met within the strategic alliance.

Contracts – A Solution to the Nash Equilibrium? In a contract law and game theory perspective, Working paper series, CBS.dk, at 3, *available at* http://openarchive.cbs.dk/bitstream/handle/10398/8909/Tvarnoe.pdf?sequence=1.

[116] *See also* R. Scott Fosler, *Public-Private Partnership: New Opportunities for Meeting Social Needs by Harvey Brooks, Lance Liebman, Corinne Schelling,* 46 Pub. Admin. Rev. 364 (1986) (book review); Nutavoot Pongsiri, *Regulation and Public Private Partnerships*, 15 Int'l J. Pub. Sector Mgmt. 487 (2002).

[117] Andersen, Cao, Tvarno & Wang, *supra* note 62, at 25.

[118] Donald F. Kettl, Sharing Power, Public Governance and Private Markets (1993).

[119] The Construction Task Force, Rethinking Construction (1998).

[120] *Id.* at 22.

[121] *Id.* at 30.

[122] Ass'n of Consultant Architects, *PCC 2000: The ACA Standard Form of Contract for Project Partnering* (2008).

[123] *Id.*; *see also* Neil Alderman & Chris Ivory, *Partnering in Major Contracts: Paradox and Metaphor*, 25 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 for the construction of public buildings and infrastructure.[124] Governmental recognition of the efficiency of market mechanisms and the success of privatization efforts in several countries has led to increased governmental interest in PPPs.[125] Over time, governments have tapped private financial markets to fund higher-quality construction while reducing taxes.[126] Private companies were able to access new markets and developed new ways to compete and meet consumer demand.

A traditional PPP infrastructure project involves a longer legal relationship and addresses different public needs than a PPPP. Nevertheless, the two can be compared along the control and joint utility dimensions. Research on infrastructure PPPs has emphasized both that (1) the public party must give up some degree of control and allow the private party to realize an attractive yield on its investment and (2) the private party must possess sufficient expertise to reduce the total cost over time.[127]

The same applies to PPPPs. The pharmaceutical enterprise must give up some degree of control and set up a mutual relationship with university researchers to achieve joint utility. Opposite to the public infrastructure sector, it is the private pharmaceutical enterprise that needs the public-funded research and the skills of the academic scientists, due to its above-mentioned lack of path-breaking, in-house innovation and investment in basic science, especially across disciplines.[128] Thus, the public university party will stand in a superior negotiating position if either (1) the private party's utility is higher than the university's utility or (2) the university party has the relevant knowledge, such as resources, funding, research, and the ability to confer legal rights, that 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

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[124] In the late 1990s, national governments no longer regarded 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 80, at 135.

[125] Pongsiri, *supra* note 116.

[126] *See generally* TONY BOVAIRD, *A Brief Intellectual History of the Public-Private Partnership Movement*, *in* INTERNATIONAL HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS (Graeme A. Hodge et al. eds., 2010).

[127] JEAN-ETIENNE DE BETTIGNIES & THOMAS W. ROSS, *The Economics of Public-Private Partnerships: Some Theoretical Contributions*, *in* INTERNATIONAL HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS 145 (Graeme A. Hodge et al. eds., 2010). *See generally*, Oliver Hart, *Incomplete Contracts and Public Ownership: Remarks, and an Application to Public-Private Partnerships*, 113 ECON. J. C69 (Mar. 2003); CHRISTINA D. TVARNØ, *Law and Regulatory Aspects of PPP's*, *in* INTERNATIONAL HANDBOOK ON PUBLIC-PRIVATE PARTNERSHIPS 227 (Graeme A. Hodge et al. eds., 2010).

[128] Private firms also need an appropriate 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.

joint positive utility. In the next part, we identify specific contract terms that enhance joint optimization.

V. Crafting an Efficient PPPP Agreement

The prisoners' dilemma shows that the parties, acting alone, will self-optimize. A well-crafted and fully enforceable PPPP contract can help prevent self-optimization and instead promote joint optimization and efficient allocation of added value.

A. "Add-On" Contract Clauses

Certain "add-on" contract clauses promote long-term, Pareto optimal collaborations between pharmaceutical companies and universities in the research discovery phase, the stage in the value chain at which a strategic alliance can create benefits for both the university and the pharmaceutical business. For example, positive incentive clauses ensure that both parties have an incentive to add value for each other. They create a bigger pie and a more efficient allocation of the slices through the articulation of common goals, shared value creation, and joint optimization.

Examples of clauses aimed at joint optimization include the following:[129]

1. The parties shall together pursue a strategic alliance by joint initiatives and optimization for the benefit of the transaction. The parties recognize that the benefit of joint optimization requires specific legal clauses.
2. The parties agree to fulfill their obligations within the agreed binding clauses in respect to common goals and the value added by joint optimization.
3. The parties agree to work and conduct research together in the spirit of the project, openness, trust, and collaboration.
4. The contract shall stay on the table in the lab. The parties shall use the contract on a daily basis and educate the involved staff, researchers, and legal back office in a joint optimization spirit. The parties acknowledge that the contract is the tool to create added value.
5. The parties shall take the steps necessary to optimize the transaction. Accordingly, all parties have the obligation to warn each other of any error, omission or discrepancy of

[129] Christina Tvarnø, Vækst og værdiskabelse via nye former for innovationssamarbejder og partnerskaber 232–63 (Christina Tvarnø et al. eds., 2013), *available at* http://openarchive.cbs.dk/handle/10398/8848. A summary of the content in English is available at pages 1–5.

which they become aware and shall immediately propose solutions designed to jointly optimize the transaction.

6. It is a requirement that all relevant information be made available to all parties because it generates transparency, trust, and confidence. Accordingly, all parties shall open up the books and calculations concerning the transaction.
7. The parties must ensure each other a healthy business case and optimal research conditions and recognize that they have different economic yields from the project.
8. Due to the above clauses, the parties shall establish, develop, and implement a strategic alliance relationship in the lab with the objectives of achieving:
   - Mutual cooperation
   - Joint research
   - Common goals
   - An understanding of each other's values and the joint value of the transaction
   - Innovation
   - Improved efficiency
   - Delivery in accordance with Key Performance Indicators (KPIs) and timetables.
9. Any research, added value, risk, pain and gain identified by the parties shall be subject to incentive payments.
10. The parties shall investigate all possible positive incentives to fulfill the value added transaction. The parties shall be awarded for and encouraged to maximize their effort for the benefit of the transaction and to allocate the added value in accordance with the key factors in paragraphs 8 and 9.
11. Any dispute shall be resolved as soon as possible and the parties shall apply the specific strategic alliance guideline:
    When a problem arises, the first responsible director shall gather the parties and, based on the following objectives, launch a procedure to solve the problem:
    - Common goals
    - Optimization of the transaction
    - Trust and cooperation
    - Openness, open books and calculations

    If the problem persists, the next director in the hierarchy shall be given responsibility for the problem, then a mediator and finally an arbitrator. At every stage, the above points shall be observed. All parties recognize that even when they experience conflict, common goals and optimization lead to added value for the transaction.

B. The IP Distribution in the PPPP Contract—A Delicate Matter

"Only about 50 percent of all patented inventions (including those arising from university research) ultimately achieve commercialization."[130] Thus, effective "university technology transfer," the process by which a university transfers discoveries to the private sector for commercialization, is a priority for the pharmaceutical industry. In the U.S., this can be done both informally through scientific publications and presentations and formally through research contracts, consulting engagements, licenses, and patent agreements.[131]

Universities typically license their discoveries to private firms for commercialization.[132] 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.[133]

To deal with the complex issues involved in patenting and licensing inventions, many research universities in the U.S. have established technology transfer offices (TTOs) or technology licensing offices (TLOs) that function as "central clearinghouses for university generated inventions."[134] These offices, which tend to deal with formal transfers, ensure compliance with the commercialization requirements of the Bayh-Dole Act[135] "by collecting invention disclosures, coordinating patent prosecution, and negotiating licenses with firms."[136] The parties to a PPPP should consider the role

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[130] Lee, *supra* note 60, at 1507. *See generally* 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(2004) (proposing a broad experimental use exemption for university inventions licensed to private industry).

[131] Lee, *supra* note 60, at 1507–08.

[132] *See generally* Hafiz Aziz ur Rehman, *Equitable Licensing and Publicly Funded Research: A Working Model for India?*, 16 SW. J. INT'L L. 75–78 (2010).

[133] Robert M. Yeh, *The Public Paid for the Invention: Who Owns It?*, 27 BERKELEY TECH. L.J. 453, 470 (2012). *See generally* Thomas P. Stossel, *Regulating Academic-Industrial Research Relationships—Solving Problems or Stifling Progress?*, 353 NEW ENG. J. MED. 1060 (2005).

[134] Yeh, *supra* note 133, at 473.

[135] Pub. L. No. 96–517, 94 Stat. 3015 (codified as amended at 35 U.S.C. § 200–12). *See generally* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research,* 82 VA. L. REV. 1663 (1996); *cf.* Hoffman, *supra* note 130, at 997.

[136] Lee, *supra* note 60, at 1514.

and function of the university's TTO when drafting the PPPP agreement to avoid the inefficiency of a traditional licensing game.

As an example, Pfizer's Centers for Therapeutic Innovation PPPPs are governed by an agreement that provides that all shared inventions will be jointly owned, with Pfizer's holding an exclusive option to license a drug after proof of mechanism.[137] In the event Pfizer exercises its option, any jointly developed enabling intellectual property (IP) will be licensed from the academic institution.[138] If Pfizer declines, the IP and other joint assets revert to the institution.[139]

When crafting contract clauses allocating the IP rights between the parties, one must recognize that the parties have different utility functions. The private pharmaceutical company is driven by a shareholder focus, while the university focuses primarily on research and patients. When parties have different utility functions, the party with the higher utility will invest more, even when a disproportionate share of the benefits accrues to the other party.[140] This can be seen in the game theory example of the "Odd Couple."[141] Two persons live in the same apartment but they value having a clean place to live differently. It takes twelve hours to clean the apartment per week. The players have three, six, or nine hours of cleaning as the possible strategies. As seen in Table 4, if Person A derives the greatest utility from a clean apartment, then (1, 2) is the equilibrium and solution of the game.

TABLE 4[142]

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

If the utility function of the parties in a PPPP is input into the above game, the pharmaceutical company acts similarly to Person A because its utility function from commercialization is larger than that of the university (Person B). This game shows how, in a contractual context, the various utility functions affect the allocation of the added value attainable by commercialization. Thus, the pharmaceutical company may, for contractual purposes, be ready to generate more utility for the university through the

[137] *See* Mark Ratner, *Pfizer Reaches Out to Academia—Again*, 29 NATURE BIOTECHNOLOGY, Jan. 10, 2011, at 3–4, *available at* http://www.nature.com/nbt/journal/v29/n1/full/nbt0111-3.html.

[138] *See id.*

[139] *See id.*

[140] PRAJIT K. DUTTA, STRATEGIES AND GAMES: THEORY AND PRACTICE 52–53 (1999).

[141] *Id.*

[142] *Id.*

allocation of the added value than what the university would be willing to pay to attain that value if it were acting alone. This suggests, for example, that a pharmaceutical firm may be willing to give the university the right to retain use of the upstream research tools (or even permit their use by other universities) as long as the pharmaceutical firm retains an option to retain exclusive ownership of the downstream inventions.[143]

C. Other Applications

The tools explained above, including the use of legal clauses and relational governance techniques to promote joint utility, could promote the objectives of not only the Accelerating Medicines Partnership (AMP) in the United States but also the Innovative Medicines Initiative (IMI) in the EU. The IMI is a joint initiative between the EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA), a pharmaceutical industry association with a €2 billion budget. The IMI acts as a neutral third party supporting open-source, public-private research projects in the EU involving large biopharmaceutical companies that are members of the EFPIA, small and medium enterprises, patients' organizations, universities, other research organizations, hospitals, and regulatory agencies with the aim of improving drug development. The IMI is governed by Council Regulation (EC) No. 73/2008 on the establishment of the IMI Joint Undertaking (IMI-JU),[144] the IMIJU financial rules, as well as other European Community and European Union law. The IMI grant agreement of 2011 comprises eleven articles and several appendices concerning the parties, research management, the scope and duration of the project, reports, budget and financial contribution, communication, applicable law and the competent court of jurisdiction.[145] The grant agreement allows introduction of special clauses but does not itself include clauses promoting joint utility.[146] Thus, the add-on legal clauses designed to further joint optimization in PPPPs could be added to the existing IMI Grant Agreement to enhance the ability of competing pharmaceutical companies, academia, hospitals, patients and regulatory agencies to fruitfully collaborate.

The European Commission announced a proposed next phase of IMI, called IMI 2, on July 10, 2013.[147] The goal is to develop next-generation

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[143] *Cf.* Hoffman, *supra* note 130, at 997–98.

[144] Council Regulation 73/2008, Setting Up the Joint Undertaking for the Implementation of the Joint Technology Initiative on Innovative Medicines, 2008 O.J. (L 30) 38.

[145] *IMI Joint Undertaking Model Grant Agreement Core*; http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/IMI_Grant_Agreement_rev2011_Core.pdf.

[146] *IMI Joint Undertaking Model Grant Agreement Core* at 4, http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/IMI_Grant_Agreement_rev2011_Core.pdf.

[147] *Proposal for a Council Regulation on the Innovative Medicines Initiative 2 Joint Undertaking*, COM (2013) 495 final (July 10, 2013).

vaccines, medicines and treatments, including new antibiotics, through collaborative projects designed both to tackle Europe's growing health challenges and to "safeguard the future international competitiveness" of Europe's pharmaceutical industry.[148] IMI 2 will open new commercial possibilities for new services and products thereby promoting value creation and capture by academia, industry, and the societal sectors involved. As with IMI and AMP, the above described joint optimization add-on legal clauses and relational governance techniques would promote both cooperation and knowledge sharing.

Conclusion

In this article, we have presented a combined game-theoretical and law-and-management perspective on creating efficient PPPPs. In particular, we have shown how the parties can both increase their joint utility and their own share by combining long-form contracting and relational governance to align incentives, promote cooperation, and allocate risk and reward. In short, we explain from both a theoretical and a practical perspective how pharmaceutical firms and universities and their researchers can move from an inefficient prisoners' dilemma Nash equilibrium to the Pareto Optimal Frontier.

[148] *Id*. at 2.