Joel West, "Standardization and Coopetition: A Study of Pharmaceutical Industry Consortia," in Kai Jakobs, Anne Mione, Anne-Françoise Cutting-Decelle and Sophe Mignon, eds., EURAS Proceedings 2016, Montpelier (June 2016), 437-454. ISBN: 978-3-95886-103-9

Standardization and Coopetition: A Study of Pharmaceutical Industry Consortia[1]

Joel West

Keck Graduate Institute, KGI@joelwest.org

Abstract: *This study examines coopetition in multi-firm consortia organized in the pharmaceutical industry. From a sample of 87 consortia related to biomedical research, it identifies 34 that are substantially or entirely involved in standardization activities. From these 34, it offers a taxonomic classification into six categories of standardization efforts: Information and Communications Technology standards, open source ICT implementations, standardized inputs, data standards (and standardized data), process standards and quality standards. From this, it examines the cooperative and competitive aspects of these standardization efforts and the role they play in firm advantage, contrasting them to the better-known examples of ICT standardization.*

1 Introduction

Voluntary cooperative standardization creates a shared good that both benefits the broader society and the private interests of those involved in standardization (Kindleberger, 1983; Leiponen, 2008). By combining both cooperative and competing motives, the creation and use of shared standards corresponds to Brandenberger and Nalebuff's (1996) definition of coopetition (Gnyawali & Park, 2011). Today, many industrywide product compatibility standards are created through the formation of a consortium of multiple firms, a special-purpose organization supported by member fees and governed by mutually agreed-upon rules (Weiss & Cargill, 1992; Blind & Gauch, 2008). Such multilateral cooperation also represents an important form of open innovation, in that firms share knowledge to create value while combining shared and private knowledge to capture value (Simcoe, 2006; West 2014a).

Open collaboration through standardization consortia is most often associated with the Information and Communications Technology (ICT) industries (David & Steinmueller, 1994; Blind & Gauch, 2008). Examples include mobile telecommunications (Bekkers et al, 2002), smartphones (West & Wood, 2013), the Internet (Waguespack & Fleming, 2009) and open source software (West, 2003). Such consortia create standards that are usually public goods (Kindleberger, 1983; Weiss & Cargill, 1992) and are non-rivalrous in consumption (Liebowitz and Margolis, 1992). Created through voluntary collective action (Simcoe, 2012), these consortia and their standards create an alternate form of non-market governance (Hallström, 2004). Such cooperative standardization fits the definition of coopetition, in that cooperation by competing firms (Leiponen, 2008) create standards that can create new markets or even industries (e.g., Keil, 2002). Such standardization activities may be more or less open, to the degree that they allow participation by a wide range of stakeholders, including customers, complementors, and direct competitors (West, 2007).

However, one industry not typically known for such cooperation has been the pharmaceutical industry. In this industry, multinational firms spend more than $100 million in R&D costs to bring a single new compound to market on the basis of a patent on that compound

[1] Data collection for this project was funded by the Science of Science Policy program of the National Science Foundation, grant #1538799. Jenifer Krass, Ryan Segur and Karen Sun provided helpful research assistance.

(Grabowski, 2002; DiMasi et al, 2003; Pisano, 2006). Their willingness to make risky investments in R&D and other costs of bringing a new technology to market (and their business models more generally) thus depends on the certainty of strong appropriability provided by the patent's temporary monopoly on that technology (cf. Arrow, 1962; Teece, 1986; Cohen et al, 2000). These firms have also enjoyed high margins and large cash flow that allowed them to pursue go-it-alone strategies, building vertically integrated firms that include their own R&D, manufacturing, sales and distribution (Temin, 1979).

Such vertical integration and high dependence on patent-based business models meant that open collaboration was uncharacteristic of pharmaceutical firms, until they began to form and join their own R&D consortia in the late 1990s (West & Olk, 2016). The shift towards openness came as the leading pharmaceutical firms faced a decade of increasing R&D costs and failure rates for R&D, bringing decreasing returns to R&D and declining profit margins (Munos, 2009; Scannell et al, 2012). In response, pharmaceutical companies have begun to cooperate through dozens of consortia that share the cost of R&D and other responsibilities.

While these efforts are patterned on Sematech and other traditional industrial R&D consortia of the 1980s and 1990s (cf. Evan & Olk, 1990; Mowery, Oxley & Silverman, 1996), there appear to be crucial differences. Compared to the earlier consortia, these pharma consortia are more open in that the knowledge created spills over to the entire industry and society at large, meaning that there are weaker incentives for firms to provide financial support for these consortia (West & Gallagher, 2006; West & Olk, 2016).

Some of these pharmaceutical consortia are involved in creating cooperative industry standards. This study offers the first comparison of such standardization efforts in the pharmaceutical industry. Here I identify 34 consortia that fit into six categories: ICT standards, open source ICT implementations, other standardized inputs, data standards, process standards, and quality standards.

Using this data, the remainder of this paper offers preliminary observations as to how such standardization differs from the oft-studied examples in the ICT industry, particularly in terms of the nature of the public good and the role that the standard plays in the firm's business model. It concludes with suggestions for future research.

2 Theoretical Background

Research has identified that an important form of multi-lateral firm cooperation is the R&D consortium, particularly after 1984 legislation in the United States that relaxed antitrust restrictions for certain forms of cooperation (Ring, Doz & Olk, 2000). Such consortial collaboration corresponds to a particular form of network collaboration within open innovation, in that member firms in a consortium generate, share and receive knowledge flows across a network of collaborations (West, 2014a, 2014b). Numerous examples of such collaborations can be found in the standardization consortia used to generate voluntary industrywide standards (Simcoe, 2012; Xia et al, 2012).

A crucial tension in the operation of such consortia is managing the conflict expectations of the participating firms, between the shared interest of the members in creating value, and the private interests of members in capturing value (Simcoe, 2006). This corresponds to what Brandenburger & Nalebuff (1996) term as "coopetition," in which a group of two or more firms both cooperate and compete in the same market or industry. Creating, evolving, supporting and implementing compatibility standards provides an important example of such coopetition, in that the cooperation of participating firms creates value through their shared

standard, while the firms continue to compete to capture value through their respective products (Simcoe, 2006; Gnyawali & Park, 2011).

2.1 R&D Consortia

R&D consortia are an inter-organizational form to allow coordination between firms and other organizations. These consortia pool the financial and other resources the member organizations to achieve a shared organizational purpose, while at the same time allowing these organizations to achieve their private interests. Cooperation is made more difficult by the heterogeneity of member firms, their goals and approaches towards achieving those goals both inside and outside the consortium (Olk, 1999; 2002; Ring et al, 2005).

These consortia are created to develop new product or process standards, new technology, or to address changing regulatory requirements upon the industry. One example of the latter is the International Pharmaceutical Aerosol Consortium, the first known example of a multi-firm consortium in the pharmaceutical industry that was formed in 1987 to develop a new aerosol for asthma inhalers after the previous formulation was banned by international treaties (IPAC, 1999).

However, the pharmaceutical consortia studied here add a third level beyond the firm and the consortium: spillover benefits to non-members. Firms, organizations, competitors and other entities not part of the collaboration may achieve clear benefits from the efforts of the consortium: the collaboration between member companies thus functions as an open system (Chesbrough, 2006; West & Gallagher, 2006). For a variety of reasons discussed later, most (thought not all) pharma consortia encourage such spillovers and the dissemination of this knowledge as a public good. These spillovers create potential conflicts between the shared goals of the consortia (and broader public) and the private interests of the member firms providing the resources to support the consortia (West, 2007).

2.2 Open Innovation, Standardization and Coopetition

A special form of consortium is one that produces interfirm standards. Such standards can be classified into two categories: compatibility and quality (Hemenway, 1975). The first form assure compatibility between products from varying sources (West, 2007), allowing for interoperability and modularity in the division of labor within an industry (Baldwin & Clark, 2000; Keil, 2002). The second form reduce coordination costs by providing a common definition of product (or process) quality for firms within an industry (Hallström, 2004).

Open innovation is by definition how firms allow intentional knowledge inflows and outflows to advance their innovation strategies. In open innovation, such knowledge flows must be aligned to the firm's business model, and in particular its ability to create value for customers and capture value to support its private financial interests. (Chesbrough, 2006). While research on open innovation has emphasized bilateral alliances between two firms, an important form of open innovation strategy is through network cooperation (West, 2014b). Standardization is thus an important example of open innovation (Simcoe, 2006).

These network forms include most forms of standards cooperation, including platform ecosystems and standardization consortia (West, 2014a). Such consortia often include direct competitors (Weiss & Cargill, 1992; Leiponen, 2008). In some cases, these consortial collaborations benefit the member companies preferentially to other firms (Keil, 2002). But in other cases, such as open source software consortia, the benefits of the consortia spillover to non-members (West & Gallagher, 2006).

Open innovation is particularly evident in telecommunications standardization, where all firms face a common need for anticipatory standardization, because interoperability is an inherent requirement for such communications products (David and Steinmueller, 1994). Participating firms cooperate both to define a standard that each firm will implement and win adoption of the standard by a wide range of stakeholders, which may include hardware makers, software developers, telecommunications network operators, dealers, and end customers (Dittrich & Duysters, 2007; West & Wood 2013).

Such cooperation by directly competing firms (Leiponen, 2008) fits the definition of coopetition (Brandenburger & Nalebuff, 1996), in that competing firms gain through cooperation in producing a shared good. This shared good comprises an external innovation that provides an input to the open innovation strategies of the firms (West, 2014a). At the same time, cooperative standardization among direct competitors exposes the multiple tensions inherent in coopetition. Both individually — and as a group — the members face a tension between maximizing both the value created through cooperation and the private value they capture as competitors (Simcoe, 2006). The process of cooperation slows down as the competitive stakes increase, as Simcoe (2012) demonstrated using data from the Internet Engineering Task Force.

A seemingly intractable problem comes when strong intellectual property rights (i.e. patents) are an integral part of a firm's business model. The presence of such IPR increase the private value captured by one or more member companies while increasing the costs (and decreasing the value capture) of other standards users; for example, the W-CDMA mobile telecommunication standards were written to overlap lower-quality IPR of key member companies (Bekkers & West, 2009). The proliferation of (often unsuccessful) consortia policies to constrain such opportunism (Ring et al, 2000) is a testament to the difficulty of balancing cooperation and competition when the potential value capture is large.

Thus we expect tensions of coopetition for any industry standardization when the cooperation involves large multinational firms and a heavy reliance on intellectual property. Such a description describes well the industry dynamics of the pharmaceutical industry.

3 Context: Private and Cooperative Pharmaceutical R&D

3.1 Big Pharma's Traditional R&D Model

The traditional pharmaceutical R&D model is based on vertically integrated drug discovery and development over a decade or more. Starting from the discovery of a candidate drug, it takes an average of 12 years and $150-200 million to bring a new drug to market, with most of the time and cost associated with running human clinical trials. However, those estimates need to be increased sixfold to cover the costs of those drugs that fail prior to regulatory approval (DiMasi et al, 2003; DiMasi & Grabowski, 2007; Pammolli et al, 2011).

Given these factors, it is not surprising that the industry is highly dependent on patents (Cohen et al, 2000; Grabowski, 2002). It also has a very high R&D intensity. The world's 50 largest pharma companies achieved combined sales of more than $600 billion in pharmaceutical revenues in 2014, and spent more than $100 billion of that on pharmaceutical R&D (Swanick et al, 2015). Of these, the top 20 accounted for $482 billion in revenues and nearly $82 billion in R&D, with $48 billion of that R&D performed by U.S.-based firms and $43 billion by European firms (see Table 1).

Table 1: Leading Global Pharmaceutical Companies in 2014

Rank	Company	Country	Drug Sales	Pharma R&D Spending	R&D intensity
1	**Novartis**	Switz.	$46.13 B	$9.30 B	20.2%
2	**Pfizer**	U.S.	$44.51 B	$7.15 B	16.1%
3	**Roche**	Switz.	$40.09 B	$8.61 B	21.5%
4	**Sanofi**	France	$38.22 B	$6.20 B	16.2%
5	**Merck & Co.**	U.S.	$36.61 B	$6.53 B	17.8%
6	**Johnson & Johnson**	U.S.	$30.73 B	$6.03 B	19.6%
7	**GlaxoSmithKline**	U.K.	$30.30 B	$4.87 B	16.1%
8	**AstraZeneca**	U.K.	$25.69 B	$4.94 B	19.2%
9	Gilead Sciences†	U.S.	$24.47 B	$2.74 B	11.2%
10	**AbbVie**	U.S.	$19.88 B	$3.25 B	16.4%
11	Amgen†	U.S.	$19.33 B	$4.12 B	21.3%
12	Teva††	Israel	$17.47 B	$1.49 B	8.5%
13	**Bayer**	Germany	$16.35 B	$2.50 B	15.3%
14	**Eli Lilly**	U.S.	$16.35 B	$4.38 B	26.8%
15	**Novo Nordisk**	Denmark	$15.83 B	$2.45 B	15.5%
16	**Boehringer Ingelheim**	Germany	$13.90 B	$3.15 B	22.7%
17	**Takeda**	Japan	$13.04 B	$3.18 B	24.4%
18	**Bristol-Myers Squibb**	U.S.	$11.97 B	$3.91 B	32.7%
19	Actavis††	Switz.	$11.13 B	$1.09 B	9.8%
20	**Astellas Pharma**	Japan	$10.42 B	$1.86 B	17.8%

Source: Swanick et al (2015). **Bold** indicates incumbent "big pharma" firm
† Dedicated Biotech Firm †† Manufacturer of off-patent drugs

More recently, the large incumbent pharmaceutical companies have faced two major challenges. The first has been the emergence of dedicated biotechnology firms (DBFs) that entered the market since the 1980s, using a new scientific paradigm that devalued big pharma's traditional chemistry-based competencies; to access these new competencies, incumbent pharma firms partnered with or acquired the DBFs (Galambos and Sturchio, 1998; Pisano, 2006). The second factor has been declining R&D productivity — particularly for the largest firms — due to high R&D spending and fewer approved drugs (Munos, 2009; Paul et al, 2010; Pammolli et al, 2011). One major reason has been the "Better than the Beatles" challenge (Scannell et al (2012): new drugs must compete with former blockbuster drugs that (after expiration of their patents) are available as lower-cost generic pharmaceuticals. In fact, the older DBFs are larger, vertically integrated, and face many of the same R&D challenges (DiMasi & Grabowski, 2007). Thus both big pharma and larger DBFs are seeking new approaches to improve the effectiveness or reduce the costs of R&D.

3.2 Open Innovation and Open R&D Consortia

In response to these pressures, pharmaceutical companies have embraced open innovation to harness external sources of knowledge to accelerate internal R&D and increase the efficiency and effectiveness of their innovation efforts (Hunter and Stephens, 2010; Bianchi et al, 2011; Salah and McCulloch, 2011). One form of such open innovation has been bilateral cooperation with universities (Melese et al, 2009; Ratner, 2011).

Another approach (adopted by some but not all firms) has brought an unprecedented level of collaboration between previously proprietary rivals, often in conjunction with government, university or other nonprofit entities. This has led to the creation of consortia that pool existing firm knowledge, engage in pre-competitive R&D, define standards and roadmaps for

key enabling technologies, and engage in post-approval activities such as monitoring the safety of released products. Such collaborations are the subject of the proposed study.

In this regard, the range of organizational forms more closely resembles corporate funded open source software (cf. West & O'Mahony, 2008) than R&D consortia organized under the National Cooperative Research Act of 1984 or the National Cooperative Research and Production Act of 1993 (cf. Olk & Young, 1997). However, it is difficult to generalize the characteristics of these consortia without a comparative study of multiple consortia and their member interactions (comparable to the aforementioned studies of open source software and R&D consortia). Such a comparison is one of the goals of this study.

3.3 Research Design

This paper is part of a larger multi-year project studying consortia in the global pharmaceutical industry. The project is compiling a variety of data on each consortium, including history, mission, purposes, activities, governance, and corporate and nonprofit sponsoring organizations. The data have included information from the current company website, previous versions of the website (from Archive.org), published articles in scientific journals and industry magazines, supplemented by a small number of interviews with consortia participants (which are still in progress).

To develop our list of consortia, scholarly and press articles were searched to identify R&D consortia, as well as related forms of inter-organizational cooperation related to pharmaceutical development. Our initial search for consortia identified 87 consortia. Half included "consortium" in their title, and most appeared headquartered in the US or Europe. Two of the earliest and most influential consortia appear to be the NIH-organized Biomarkers Consortium and the international Structural Genomics Consortium (which was studied by Perkmann & Schildt, 2015). From the 87, using secondary data I identified 34 as being entirely or primarily related to one or more approaches to standardization.

4 Standardization in Pharmaceutical Consortia

The 34 standardization-related consortia can be subdivided into six categories: ICT standards, open source ICT implementations, standardized inputs, data standards (and standardized data), process standards, and quality standards (Table 2).

4.1 ICT Standards

The most recognizable example of standardization among the pharmaceutical consortia are those consortia that develop ICT compatibility standards. As biomedical research has become increasingly automated — and increasingly dependent on large databases related to therapeutic compounds, genetic data and other aspects of human health, pharmaceutical companies have chosen to become more directly involved in industry-specific ICT standardization (cf. Markus et al, 2006).

However, the organization and control of these efforts represent a subset of the full range of structures and openness that have been reported in ICT standardization (cf. West, 2007). All are performing industry-controlled multi-firm standardization similar to industry-sponsored standards setting organizations (e.g. Keil, 2002). At one extreme, they exclude the government-developed (US Department of Defense, 1983) or government sanctioned (Bekkers et al, 2002) open standardization efforts. At the other extreme, they exclude the single-firm proprietary standards that were common for many years in computing (Langlois, 1992; Bresnahan & Greenstein, 1999), or the firm-dominated open communities more recently used in open source software development (West & Lakhani, 2008).

Table 2: Classification of Standardization-related Pharmaceutical Consortia

Category	Goal	Com-patibility	Qual-ity	Imple-mentation	Num-ber	Examples
ICT Standards	ICT standards	X			5	Allotrope, BioMedBridges
Open Source ICT Implementations	ICT system	X		X	3	TransCelerate, tranSMART
Other Standardized Inputs	Make inputs to firm products	X		X	3	Infectious Disease Research Institute
Data Standards and Standardized Data	Representation of biomedical research or clinical data	X	X	*some*	15	Biomarkers Consortium, ICGC, International Serious Adverse Event Consortium
Process Standards	Processes for pharmaceutical research, production or use		X	*some*	6	Predictive Safety Testing Consortium, Rx-360, TransCelerate
Other Quality Standards	Standards for product or process quality		X		3	International Pharmaceutical Privacy Consortium, IQ Consortium
Totals					34†	

† One consortium covers two categories

Perhaps the clearest example is the Allotrope Foundation, founded in 2012 as a spinoff of the IQ Consortium. The goal of Allotrope is to develop and win adoption of standards for analytical instruments, so that biomedical researchers (both in academia and industry) can mix and match data collection from various vendors and easily import that data into their research databases. The consortium includes both participation by pharma companies (that are among the customers for these instruments) and the vendors that make these instruments.

4.2 Open Source ICT Implementations

Open source software (OSS) forms a special case of standards openness. Under standard open source licenses, the technology and architecture are fully open to standardization participants and non-participants alike (West & O'Mahony, 2008). While standardization efforts have often provided for prototype implementations to test for standards completeness (Russell, 2006) or interoperability between vendors (Manninen, 2002), participating firms historically competed on implementations (Garud et al, 2003). However, unlike a typical open standard, an OSS project can both define a standard and also provide a shared implementation freely available to any firm — thus enabling entry by small firms that do not have the resources to develop their own implementations (West, 2003). An example of this can be seen with the adoption of Linux, an open source offshoot of Unix that — because it was freely available — displaced the established Unix standard at the end of the 20th century.

Like other 21st century IT professionals, the IT professionals of the pharma industry are both aware of the successes of open source software and aware of its potential impact on their work (e.g. Ince et al, 2012). Pharma companies have only recently begun to recognize that many previously proprietary activities do not generate competitive advantage — leading to the rise of many of these pharmaceutical consortia (West & Olk, 2016). Thus, it is not surprising that some pharma firms and their IT managers would choose to embrace creating consortia that both create ICT standards and create a common implementation that can become shared infrastructure for the entire industry.

One example of a pharma OSS project is TransCelerate Biopharma, founded in 2012. The consortium engages in a range of standardization efforts, including process standards (discussed below). However, one of its major initiatives is the Shared Investigator Platform, an online system for managing clinical trials. Biomedical products for human health require lengthy (and usually extensive) clinical trials to demonstrate safety and efficacy. Such trials are typically conducted by dozens of local research hospitals under contract to pharma companies, with hospitals often working on multiple trials (with multiple companies) simultaneously. Much as an open Internet email architecture of the commercial Internet supplanted the need to maintain e-mail accounts in multiple proprietary e-mail systems (cf. Greenstein, 2015), TransCelerate sponsors hope that clinical trial sites and sponsoring firms can communicate results using a single IT infrastructure.

4.3 Other Standardized Inputs

Standardization has important benefits of providing inputs for the design of complex modular products (Hemenway, 1975; Ulrich, 1995). For many standardized technologies — particularly low-technology components such as screw threads or connectors — the specific of the standard enables entry by multiple competing suppliers.

However, in the heavily regulated biomedical sector, the cost of regulatory compliance may discourage the provision of inputs. In other cases, proprietary intellectual property (typically patents) will provide a temporary monopoly in the provision of these inputs.Two related consortia — BioBricks and iGEM — are organized to encourage the donation of synthetic biology building blocks that are made available via open source. Both are explicitly modeled on the ideas of modularity and sharing for open source software, but thus far have had more of an impact on teaching than on pharmaceutical development.

A third consortium, the Infectious Diseases Research Institute, is working to accelerate the development of diagnostics, therapeutics, and vaccines funded by a range of public (European Commission; US Army, DoD, National Institutes of Health), foundation (Allen, Gates, Wellcome), and industry (Eli Lilly, Novartis, Sanofi). It is developing molecules that can be used for diagnostics and adjuvants that enhance the performance of vaccines.

4.4 Standardized Data

The sequencing of the human genome — and the rapid decline in the cost of sequencing the genome of individual patients — has brought a deluge of genomic data and predictions of a revolution in biomedical research (Collins, 2010). However, the usefulness of compiling and sharing this data — between biomedical firms, health providers, academic researchers, and others — requires standardizing both the syntax and the semantics of the representation of this data. Many of the issues reporting genomic (and transcriptomic, proteomic, and other "-omic") data did not exist before this genomic revolution. Representing and sharing this data thus requires standardizing the content, annotation, syntax, and semantics of data relevant to the specific biomedical problem being solved (Field & Sansone, 2006).

Given the exponential growth in the supply of genomic data, the new content being represented, and the increasing emphasis of academic and industry scientists in utilizing such data, it is thus not surprising that many consortia have been formed to compile such biomedical data, define standards for storing the data and creating online databases for publicly disseminating this data. In fact, this is by far the most popular of the categories in our sample, accounting for almost half of the consortia involved in standardization.

These consortia define a standard format for representing such data in electronic form. In many cases, this standardization is merely a first step for gathering such data – create data,

collect, curate, and combine data into a single shared database (i.e. public good) available to all. The process of scientific research is highly dependent on such standardized knowledge platforms that serves as inputs to the scientific enterprise (Fehder et al, 2014).

In the 21st century, this data provides a common infrastructure of scientific knowledge to support genomic-based biomedical research — both basic research by academic scientists and product-oriented applied research by industry scientists. Given the application to basic research — and the public good nature of this information — many of these projects are funded through public/private partnerships or (in some cases) entirely by government and/or foundation support.

In the U.S., the largest and best known of such consortia is the Biomarkers Consortium, established in 2006 as a public-private sponsorship between the U.S. National Institutes of Health and leading drug companies. The goal of the consortium is to sponsor (usually university) studies to identify and validate biomarkers, which are sought as efficient and inexpensive genetic or cellular (e.g. blood test) proxies for more complex medical states (such as organ failure or the successful treatment of cancer).

A data effort with a more direct impact on discovering new drugs is the International Cancer Genome Consortium (ICGC). This international collaboration is gathering genomic and other data on more than 25,000 tumors across a wide range of cancers. It is funded by national cancer agencies from the EU and more than 10 countries, plus a small number of foundations (such as the Wellcome Trust) and research institutes. However, those data are primarily being used by university, clinical and nonprofit researchers. The consortium lists 223 projects where researchers received access to confidential data (ICGC); of these, only 10% (22) of the projects involved corporations, including two projects from major pharma companies (AstraZeneca, Roche) and two from publicly traded DBFs (Cellgene, Regeneron).

4.5 Process Standards

Because of the potential impact of biomedical products on human health, the process for research, production and distribution must meet specific quality standards to win regulatory approval (Yu, 2008). While — depending on the regulator and context — industry may have little or no impact on the formal standards, firms develop internally standardized processes to assure compliance with these regulations. As with other activities, the pharmaceutical industry has concluded that such separately developed processes are not source of competitive advantage, and thus have been working to standardize best practices that are both shared by various competitors and also sanctioned (officially or implicitly) by the relevant regulators. In some cases, the standardization of these practices also includes an implementation of such practices (such as a quality audit).

The most dramatic example is Rx-360, formed in 2009 to assure supply chain quality for pharmaceutical companies and their suppliers. The consortium was founded in response to the dozens of deaths in 2008 from adulterated Heparin, when the manufacturer Baxter International was unable to detect counterfeit suppliers of an essential ingredient (West & Olk, 2016). The consortium both developed standardized processes for auditing such suppliers, and also helps Rx-360 member companies contract for shared supplier audits that are conducted by the British Standards Institution.

4.6 Other Quality Standards

Consistent with other research on quality standardization (Hemenway, 1975; Hallström, 2004), the pharmaceutical industry seeks standards for the quality of its outputs, and also the

processes used to create such outputs. (Unlike the previous category, such quality standards do not create the process but are only a way by which such processes may be measured).

For example, the International Pharmaceutical Privacy Consortium (founded in 2010) is focused on efforts to protect the privacy and security of data regarding the privacy of data related to clinical research; because their data will be used for regulatory filings (and often journal publications), patients in these trials face different privacy issues than ordinary patients (whose privacy in the U.S. is covered by the Health Insurance Portability and Accountability Act). The consortium has developed white papers and worked with regulators to refine standards intended to protect and safeguard the privacy of such patient data.

5 Discussion

The paper describes the preliminary results of a study of standardization consortia in the pharmaceutical industry as examples of coopetition that creates inputs enabling open innovation. It provides another example of industry-specific standardization (cf. Markus et al, 2006), and thus extends our understanding of standardization beyond the oft-studied computing and communications industries.

In particular, it provides an insight into voluntary collaborative industry standardization in a sector not usually thought of as being an active participant or supporter of such activities. The identification of 34 standardization-related consortia (out of a broader sample of 87 biomedical consortia) suggests the importance of such standardization in this sector.

The paper uses these 34 consortia to offer a taxonomy of six different categories. Using Hemenway's (1975) bifurcation of compatibility vs. quality, I identify three categories for compatibility: two for quality and one for both. Not surprisingly, three of the four compatibility categories relate directly to standards for information technology or information interoperability: ICT standards, open source ICT implementation, and data standardization. Perhaps also not surprisingly, two other categories relate to quality standardization in an industry heavily regulated for quality and safety — those that create standardized processes, and those that judge the quality of products or processes. Finally, the most unusual category is the creation of standardized inputs for biomedical production, a consortium business model that is unproven and perhaps unsustainable.

5.1 Standardization as Coopetition

As noted earlier, by their nature standardization (and other) consortia involving competitors correspond to the principles of coopetition, in which firms balance the tension between cooperative outcomes that benefit all parties and competitive outcomes which advantage one party over another (cf. Brandenburger & Nalebuff, 1996).

The benefits of standardization consortia accrue both to specific firms and an industry (or economy) as a whole. The cooperative production of broadly shared standards provide shared benefits such as interoperability (Hemenway, 1975; Weiss & Cargill, 1992). Firms participating in standardization may also gain access to firm-specific benefits from that effort, such as access to tacit knowledge related to the standard or its underlying technology (West, 2007) or steering a standard in a way that directly benefits the firm (Bekkers & West, 2009). Finally, firms may gain indirect benefits such as strengthening industry ties (Rosenkopf et al, 2001) or favorable publicity (Blind & Gauch, 2008). These firm-specific benefits can potentially provide competitive advantage over non-participating firms, or even preferential advantages over other participants.

At the same time, firms incur costs of participating in standardization consortia that may vary by firm (Weiss & Cargill, 1992). The direct costs include cash payments (e.g. membership fees), as well as the use of employee time and other resources (West & Gallagher, 2006). Firms also worry about indirect costs of participation, notably the leakage of proprietary information to the common effort and to direct competitors, particularly the leakage of (hard to identify and control) tacit knowledge held by a firm's representatives to standardization (Blind, 2006). Firms face a tension between sharing knowledge that's relevant to the creation of the standard (or other cooperative outcome) and protecting knowledge that provides competitive advantage (Ritala & Hurmelinna-Laukkanen, 2009).

For many of the 34 pharma standardization consortia, the donated labor was the largest cost. Interviews suggested that volunteers might spend 10-20% of their annual labor on consortia business, which for VP-level pharma execs could exceed $50k per employee. For some standardized data compilation projects (e.g. the International HapMap Project), the donated labor of scientists comprised the entire cost of participation.

The direct costs of participation vary dramatically. Many consortia offer nonprofit or associate membership at free or reduced rates. As with ICT standardization, most consortia appear to use variable dues to maximize revenues from large firms, utilizing a sliding scale based on the total firm employment (Clinical Data Interchange Standards Consortium), revenues (Rx-360) or even R&D expenditures (Biomarkers Consortium, TransCelerate). Some distinguish by the member firm's industry, with higher dues for pharma companies (Pistoia). Although not all consortia publicly report their membership policies, the annual dues charged for the largest firms (for those that charge dues) range from $18,000 to more than $150,000; in an interview, one participant said their consortium charged large firms $500,000 annually, but that number was not publicly reported.

Such direct and indirect costs pale compared to the pharma industry's available resources. The industry has high gross and net profit margins, particularly for those blockbuster drugs generating more than $1 billion in annual revenues. The industry is increasingly dependent on such blockbuster drugs, and thus even a day's delay in bringing a drug to market can cost firms millions of dollars by reducing the window to sell proprietary compounds prior to patent expiration (cf. Cutler, 2007; Paul et al, 2010). At the same time, these high margins meant that firms were unwilling to cooperate until they faced increasing pressures from declining R&D productivity and financial performance (West & Olk, 2016).

5.2 Open vs. Oligopolistic Benefits

How does collaborating in cooperative standardization[2] impact a firm's competitive position? Prior research suggests at least three possible outcomes:

Public Goods. First, the benefits of standardization may be freely available to all; in economic terms, this corresponds to standards as a pure public good that is non-excludable and non-rivalrous in use; in these cases, the benefits of standardization accrue to active participants and free riders alike (Kindleberger, 1983). However, this risk of free-riders can lead to under-investment by private sources (Cargill & Bolin, 2007).

Club Goods. The second case is when standardization participants gain significant benefits — such as access to tacit knowledge — often as a central aspect of the business model of the standardization consortium to convince firms to provide financial, human, and other

[2] Because our focus is on multi-firm consortia, here we exclude the case of single-firm proprietary standards, which are both sponsored and implemented by a single firm (Eisenmann et al, 2011).

resources to support the consortium's effort (West, 2007). In these cases, standards correspond to a form of impure public good sometimes referred to as a "club good" (Prakash, 2000)[3]. However, in those cases — as is common with industry consortia —where club membership is open to qualified members, firms outside the consortium may not choose to join if the incremental benefits of becoming a club member (rather than being a non-member free rider) are less than the cost of joining and participating in the consortium (Zhao et al, 2007). In addition, the preferential access to scarce knowledge may confer only a temporary advantage until such knowledge is codified and widely diffused — both inherent goals of such standardization (Blind, 2006).

Oligopolistic Cooperation. In some forms of standardization activities, member firms may overtly seek to create a standard that serves their own interests, both relative to other consortium members and non-members alike. A common flashpoint in recent practice (and thus research) has been over the impact of intellectual property (usually patents) upon the creation and use of standards. For example, member firms may choose to design a standard that requires a license to their own IP (Bekkers et al, 2002; Bekkers & West, 2009). Conversely, the consortium members may act as oligopsonistic buyers that impose restrictive terms on potential suppliers of such IP (Sidak, 2009).

In this study, the results of most standardization efforts are public goods widely available to domestic and foreign competitors, for at least three reasons. One is the normative effect of openness — both from within and outside the biomedical sector — that both motivated some of these collaborations and established an ethos of openness within them (Barnes et al, 2009; West & Olk, 2016). Although we lack direct evidence, it appears that the same industry pressures and shift in culture that prompted firms to cooperate also discouraged some firms (or firm representatives) from seeking direct competitive advantage from such cooperation.

Second, interviews showed that certain consortia — particularly public-private partnerships producing standardized data — are closely aligned to the principles of open science. In these consortia, the private (and public) money is used to fund research by academic scientists that (as such scientists are wont to do) will be published in the open scientific literature. For examples, several consortia were formed to catalog and disseminate genomic data that might suggest specific approaches to therapeutic medicine. One was the Biomarkers Consortium, in which industry, academic, nonprofit, and government scientists prioritize funding academic research into biomarkers that predict clinical outcomes such as cardiac health or liver damage (Interviews, 27 July 2015). Another was GAIN, which sought to establish standardized processes for conducting Genome-Wide Association Studies and was funded almost entirely by Pfizer (Interview, 14 Mar 2016).

Finally, open science has been the seed corn of pharma firms for decades (Cockburn & Henderson, 1998) and thus it is not surprising that that firms accepted (and government and academic scientists expected) that the results of such research would be disseminated using the norms of open science. However, the sharing of raw data by pre-competitive consortia goes *beyond* the norms of open science:

---

[3] Some have argued that from a theoretical standpoint, firm-developed cooperative standards should be considered club goods. In reality, years of standardization research suggest that the existence of such excludability benefits is an open empirical question for any given consortium (see for example Baron et al, 2014). If these benefits are small or temporary, this suggest that the steady state allocation of benefits may be more accurately represented as a public good than as a club good. As a practical matter, competition (aka antitrust) laws restrict the degree to which consortia can impose membership restrictions that reduce competition (Anton and Yao, 1995) — effectively setting limits on the creation of a club good.

> Open data partnerships provide universal and free access to research outputs including results, data and sometimes materials…. The open data approach is in contrast not only to commercial emphasis on intellectual property rights, but even to classic open science in which only the final outputs are shared. (Perkmann & Schildt, 2015: 1134).

There are some exceptions. As with ICT standardization efforts (West, 2007), some consortia provide preferential access to members (i.e. club goods) to support their own revenue model by incentivizing firm membership. For example, Rx-360 will sell its member companies a supply chain audit service, utilizing the standardized processes that it developed. ELSIE provides access to its database on potential packaging-therapeutic compound interactions (such as plastic leaching from packaging to a pill) only to paying member companies.

5.3 Standardization, Value Creation and Competitive Advantage

With its focus on coopetition, this study highlights the differences in the ways that standardization provides value and provides a firm an opportunity to gain competitive advantage and capture value. At the same time, it suggests some differences between the ICT and other standardization efforts.

Standardization is clearly central to industry dynamics in the ICT sector. Years of research on anticipatory ICT standardization has shown how firms either create value by enabling diffusion of products, or how firms gain competitive advantage by influencing such standardization — or both (e.g. Langlois, 1992; Bresnahan & Greenstein, 1999; Garud et al, 2002; Keil, 2002; Russell, 2006; Simcoe, 2006; Leiponen, 2008). Standards are a requirement to sell certain ICT products, either to allow interoperability of communication (David & Steinmueller 1994) — or obtain a supply of specialized complementary assets (Teece, 1986; Bresnahan & Greenstein, 1999). In some product markets, standards also provide the opportunity to generate patent royalties (and thus increased profits) for firms owning patents required for implementing a standard — thus creating an incentive for firms to influence standardization to serve their private interests (Bekkers & West, 2009).

In other cases the ICT standard is essential to firm sales, but member firms gain only a temporary advantage until knowledge is widely disseminated. In these cases, firms compete not on the basis of such advantage but on more durable resources (cf. Sirmon et al, 2010).

However, in other industries standardization is important, but not central to the firm's value creation and value capture (Markus et al, 2006). This was true for most of the 34 biomedical consortia. In these cases, the impact of firm competitive advantage (or lack thereof) upon firm success will be less (Table 3).

Table 3: Alignment of Standardization to Firm Value Creation

		Centrality of Standard to Firm Business Model	
		Low *Complementary to value creation*	High *Central to value creation*
Opportunity for Sustained Advantage	High *Unique resources or competencies*	ISO-9000	Mobile phones Web browsers PostScript printers
	Low *Commodity implementations*	USB **Allotrope (customers)** **Rx-360**	MP3, Blu-ray players **Allotrope (vendors)** **ICGC**

5.4 Future Research

This study suggests several important opportunities for researching standards beyond the ICT sector. First, the nature of standardization cooperation (and competition) has tended to be studied in industry based on engineering-based industries such as software and electronics, rather than industries organized around open science from academic research. This study suggests that the nature of how firms utilize standardization will be different in these cases.

Secondly, standardization may be more complementary (rather than central) to the value creation activities of a firm or industry. While this study suggest possible implications of such differences, the nature of biomedical (particularly pharmaceutical) competition is so unusual that additional research is needed to test these implications in other industries.

More generally, Markus and her colleagues noted a decade ago (Markus et al, 2006), further research is needed on industry-specific standardization, and how the interaction between industry structure, value creation and other dynamics shapes the creation, adoption, adaptation and use of such standards.

6 References

Anton, James J., and Dennis A. Yao. "Standard-setting consortia, antitrust, and high-technology industries." *Antitrust Law Journal* 64, 1 (1995): 247-265.

Arrow, Kenneth J. "Economic welfare and the allocation of resources for invention," in Richard R. Nelson (ed.), *The Rate and Direction of Inventive Activity.* Princeton Univ. Press, New York (1962): 609-624.

Baldwin, Carliss Young, and Kim B. Clark. *Design rules: The power of modularity.* Vol. 1. Cambridge, Mass.: MIT Press, 2000.

Barnes, Michael R., Lee Harland, Steven M. Foord, Matthew D. Hall, Ian Dix, Scott Thomas, Bryn I. Williams-Jones, and Cory R. Brouwer. "Lowering industry firewalls: pre-competitive informatics initiatives in drug discovery." *Nature Reviews Drug Discovery* 8, 9 (2009): 701-708.

Baron, Justus, Yann Ménière, and Tim Pohlmann. "Standards, consortia, and innovation." *International Journal of Industrial Organization* 36 (2014): 22-35.

Bekkers, Rudi, Geert Duysters, and Bart Verspagen, "Intellectual Property Rights, Strategic Technology Agreements and Market Structure: The Case of GSM," *Research Policy* 31, 7 (2002): 1141-1161.

Bekkers, Rudi, and Joel West. "The limits to IPR standardization policies as evidenced by strategic patenting in UMTS." *Telecommunications Policy* 33, 1 (2009): 80-97.

Bianchi, Mattia, Alberto Cavaliere, Davide Chiaroni, Federico Frattini, and Vittorio Chiesa. "Organisational modes for Open Innovation in the bio-pharmaceutical industry: An exploratory analysis," *Technovation* 31, 1 (2011): 22-33.

Blind, Knut. "Explanatory factors for participation in formal standardisation processes: Empirical evidence at firm level." *Economics of Innovation and New Technology* 15, 2 (2006): 157-170.

Blind, Knut, and Stephan Gauch. "Trends in ICT standards: The relationship between European standardisation bodies and standards consortia." *Telecommunications Policy* 32, 7 (2008): 503-513.

Brandenburger, Adam M., and Barry J. Nalebuff. *Co-opetition*. New York: Doubleday, 1996.

Bresnahan, Timothy F., and Shane Greenstein. "Technological competition and the structure of the computer industry." *Journal of Industrial Economics* 47, 1 (1999): 1-40.

Cargill, Carl, and Sherrie Bolin. “Standardization: a failing paradigm.” In Shane Greenstein and Victor Stango, eds. *Standards and Public Policy*. Cambridge, UK: Cambridge University Press (2007): 296-328.

Chesbrough, Henry, “Open innovation: a new paradigm for understanding industrial innovation,” In Henry Chesbrough, Wim Vanhaverbeke, and Joel West (eds.). *Open Innovation: Researching a New Paradigm*. Oxford: Oxford University Press (2006): 1-12.

Cockburn, Iain M., and Rebecca M. Henderson. “Absorptive capacity, coauthoring behavior, and the organization of research in drug discovery.” *The Journal of Industrial Economics* 46, 2 (1998): 157-182.

Cohen, Wesley M., Richard R. Nelson, and John P. Walsh. “Protecting their intellectual assets: Appropriability conditions and why US manufacturing firms patent (or not),” Working paper W7552, National Bureau of Economic Research, Feb. 2000.

Collins, Francis. “Has the revolution arrived?” *Nature* 464, 7289 (2010): 674-675.

Cutler, David M. “The demise of the blockbuster?” *New England Journal of Medicine* 356, 13 (2007): 1292-1293.

David, Paul A., and W. Edward Steinmueller. “Economics of compatibility standards and competition in telecommunication networks.” *Information Economics and Policy* 6, 3 (1994): 217-241.

DiMasi, Joseph A., and Henry G. Grabowski. “The cost of biopharmaceutical R&D: is biotech different?” *Managerial and Decision Economics* 28, 4-5 (2007): 469-479.

DiMasi, Joseph A., Ronald W. Hansen, and Henry G. Grabowski. “The price of innovation: new estimates of drug development costs,” *Journal of Health Economics* 22, 2 (2003): 151-185.

Dittrich, Koen, and Geert Duysters. “Networking as a means to strategy change: the case of open innovation in mobile telephony.” *Journal of Product Innovation Management* 24, 6 (2007): 510-521.

Eisenmann, Thomas R., Geoffrey Parker, and Marshall Van Alstyne. “Opening platforms: how, when and why?” In Annabelle Gawer (ed.), *Platforms, Markets and Innovation*, Elgar: Cheltenham, UK (2011): 131-162.

Evan, William M., and Paul Olk. “R&D consortia: A new US organizational form,” *Sloan Management Review* 31, 3 (1990): 37-46.

Fehder, Daniel C., Fiona Murray, and Scott Stern. “Intellectual property rights and the evolution of scientific journals as knowledge platforms.” *International Journal of Industrial Organization* 36 (2014): 83-94.

Field, Dawn, and Susanna-Assunta Sansone. “A special issue on data standards.” *OMICS: a Journal of integrative Biology* 10, 2 (2006): 84-93.

Galambos, Louis, and Jeffrey L. Sturchio. “Pharmaceutical firms and the transition to biotechnology: A study in strategic innovation,” *Business History Review* 72, 2 (1998): 250-278.

Garud, Raghu, Sanjay Jain, and Arun Kumaraswamy. “Institutional entrepreneurship in the sponsorship of common technological standards: The case of Sun Microsystems and Java.” *Academy of Management Journal* 45, 1 (2002): 196-214.

Gnyawali, Devi R., and Byung-Jin Robert Park. “Co-opetition between giants: Collaboration with competitors for technological innovation.” *Research Policy* 40, 5 (2011): 650-663.

Grabowski, Henry. “Patents, innovation and access to new pharmaceuticals,” *Journal of International Economic Law* 5, 4 (2002): 849-860.

Greenstein, Shane. *How the Internet Became Commercial: Innovation, Privatization, and the Birth of a New Network*. Princeton University Press, 2015.

Hallström, Kristina T., 2004. *Organizing International Standardization: ISO and the IASC in Quest of Authority.* Edward Elgar, Cheltenham, UK.

Hemenway, David. *Industrywide Voluntary Product Standards*. Ballinger Publishing Company, 1975.

Hunter, Jackie, and Susie Stephens. "Is open innovation the way forward for big pharma?" *Nature Reviews Drug Discovery* 9, 2 (2010): 87-88.

ICGC, "DACO Approved Projects," International Cancer Genome Consortium, accessed April 25, 2016, URL: https://icgc.org/daco/approved-projects

Ince, Darrel C., Leslie Hatton, and John Graham-Cumming. "The case for open computer programs." *Nature* 482, 7386 (2012): 485-488.

IPAC. "Ensuring Patient Care—The Role of the HFC MDI," 2nd edition, International Pharmaceutical Aerosol Consortium, Washington, DC (1999).

Keil, Thomas. "De-Facto Standardization through Alliances—Lessons from Bluetooth," *Telecommunications Policy* 26, 3 (2002), 205-213.

Kindleberger, Charles P. "Standards as public, collective and private goods." *Kyklos* 36, 3 (1983): 377-396.

Langlois, Richard N. "External economies and economic progress: The case of the microcomputer industry." *Business history review* 66, 1 (1992): 1-50.

Leiponen, Aija Elina. "Competing through cooperation: The organization of standard setting in wireless telecommunications." *Management Science* 54, 11 (2008): 1904-1919.

Liebowitz, Stan J., and Stephen E. Margolis. "Network externality: An uncommon tragedy." *The Journal of Economic Perspectives* 8, 2 (1994): 133-150.

Lundeby-Grepstad, D.Tordrup, T. Craig and D. Taylor. "Patients' Needs, Medicines Innovation and the Global Public's Interests," working paper, GlobalHealthProgress.org, January 28, 2014. URL: http://www.patentdocs.org/2014/02/patenting-necessary-for-continued-innovation-in-biotechpharma-industries-academics-conclude.html

Manninen, Ari T. "Elaboration of NMT and GSM Standards." *From Idea to Market, Studia Historica Jyväskyläensia* 60, Jyväskylä, Finland: University of Jyväskylä (2002).

Markus, M. Lynne, Charles W. Steinfield, and Rolf T. Wigand. "Industry-wide information systems standardization as collective action: the case of the US residential mortgage industry." *MIS Quarterly* 30 (2006): 439-465.

Melese, Teri, Salima M. Lin, Julia L. Chang, and Neal H. Cohen. "Open innovation networks between academia and industry: an imperative for breakthrough therapies," *Nature Medicine* 15, 5 (2009): 502-507.

Mowery, David C., Joanne E. Oxley, and Brian S. Silverman. "Strategic alliances and interfirm knowledge transfer," *Strategic Management Journal* 17, S2 (1996): 77-91.

Munos, Bernard. "Lessons from 60 years of pharmaceutical innovation," *Nature Reviews Drug Discovery* 8, 12 (2009): 959-968.

Olk, Paul. "Explaining a member organization's influence in an R&D consortium: A joint test of the dimensions of task characteristics and organizing routines and of the level of analysis," *Journal of High Technology Management Research* 10, 1 (1999): 123-146.

Olk, Paul. "Evaluating strategic alliance performance," in Farok J. Contractor and Peter Lorange (eds.), *Cooperative Strategies and Alliances*. London: Elsevier Press (2002): 119-143.

Olk, Paul and Candace Young. "Why members stay in or leave an R&D consortium: performance and conditions of membership as determinants of continuity," *Strategic Management Journal* 18, 11 (1997): 855-877.

Pammolli, Fabio, Laura Magazzini, and Massimo Riccaboni. "The productivity crisis in pharmaceutical R&D," *Nature Reviews Drug Discovery* 10, 6 (2011): 428-438.

Paul, Steven M., Daniel S. Mytelka, Christopher T. Dunwiddie, Charles C. Persinger, Bernard H. Munos, Stacy R. Lindborg, and Aaron L. Schacht. "How to improve R&D productivity: the pharmaceutical industry's grand challenge." *Nature Reviews Drug Discovery* 9, 3 (2010): 203-214.

Perkmann, Markus, and Henri Schildt. "Open data partnerships between firms and universities: The role of boundary organizations," *Research Policy* 44, 5 (2015): 1133-1143.

Pisano, Gary, P. *Science Business: The Promise, The Reality, and The Future of Biotech*. Harvard Business School Press, 2006.

Prakash, Aseem. "Responsible care: An assessment." *Business & Society* 39, 2 (2000): 183-209.

Ratner, Mark. "Pfizer reaches out to academia— again," *Nature Biotechnology* 29, 1 (2011): 3-4.

Ring, Peter Smith, Yves Doz and Paul Olk. "Managing formation processes in R&D consortia," *California Management Review* 47, 4 (2005): 137-156.

Ritala, Paavo, and Pia Hurmelinna-Laukkanen. "What's in it for me? Creating and appropriating value in innovation-related coopetition." *Technovation* 29, 12 (2009): 819-828.

Rosenkopf, Lori, Anca Metiu, and Varghese P. George. "From the bottom up? Technical committee activity and alliance formation." *Administrative Science Quarterly* 46, 4 (2001): 748-772.

Russell, Andrew L. "'Rough consensus and running code' and the internet-OSI standards war." *IEEE Annals of the History of Computing* 28, 3 (2006): 48-61.

Salah, Hadi and John McCulloch. "New Models of Innovation in Life Sciences," white paper, April 2011, MaRS Discovery District, www.MarsDD.com.

Scannell, Jack W., Alex Blanckley, Helen Boldon, and Brian Warrington. "Diagnosing the decline in pharmaceutical R&D efficiency," *Nature Reviews Drug Discovery* 11, 3 (2012): 191-200.

Sidak, J. Gregory. "Patent Holdup and Oligopsonistic Collusion in Standard-Setting Organizations." *Journal of Competition Law and Economics* 5, 1 (2009): 123-188.

Simcoe, Timothy S. "Open Standards and Intellectual Property Rights," in Henry Chesbrough, Wim Vanhaverbeke, and Joel West (eds.), *Open Innovation: Researching a New Paradigm*. Oxford: Oxford University Press (2006): 161-183.

Simcoe, Timothy. "Standard setting committees: Consensus governance for shared technology platforms." *American Economic Review* 102, 1 (2012): 305-336.

Sirmon, David G., Michael A. Hitt, and R. Duane Ireland. "Managing firm resources in dynamic environments to create value: Looking inside the black box." *Academy of Management Review* 32, 1 (2007): 273-292.

Swanick, Michael, David Hole and Ben Comer. "Taking Flight: Pharm Exec's Top 50 Pharma Companies," *Pharmaceutical Executive,* July 14, 2015. URL: http://www.pharmexec.com/print/293826

Teece, David J. “Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy,” *Research Policy* 15, 6 (1986): 285-305.

Temin, Peter. “Technology, regulation, and market structure in the modern pharmaceutical industry.” *Bell Journal of Economics* 10, 2(1979): 429-446.

Ulrich, Karl. “The role of product architecture in the manufacturing firm.” *Research Policy* 24, 3 (1995): 419-440.

US Department of Defense, *Reference Manual for the Ada Programming Language, ANSI/MIL-STD-1815A-1983,* New York: Springer-Verlag, 1983

Waguespack, David M., and Lee Fleming. “Scanning the commons? Evidence on the benefits to startups participating in open standards development.” *Management Science* 55, 2 (2009): 210-223.

Weiss, Martin, and Carl Cargill. “Consortia in the standards development process.” *Journal of the American Society for Information Science* 43, 8 (1992): 559.

West, Joel. “How open is open enough? Melding proprietary and open source platform strategies,” *Research Policy* 32, 7 (2003): 1259-1285.

West, Joel. “The Economic Realities of Open Standards: Black, White and Many Shades of Gray,” in Shane Greenstein and Victor Stango (eds.), *Standards and Public Policy,* Cambridge: Cambridge University Press (2007): 87-122.

West, Joel. “Challenges of Funding Open Innovation Platforms: Lessons from Symbian Ltd.,” in Henry Chesbrough, Wim Vanhaverbeke and Joel West, eds., *New Frontiers in Open Innovation,* Oxford: Oxford University Press, (2014a): 71-93.

West, Joel. “Open Innovation: Learning from Alliance Research,” in Refik Culpan, ed., *Open Innovation Through Strategic Alliances,* New York: Palgrave MacMillan (2014b): 1-16.

West, Joel, and Scott Gallagher. “Challenges of open innovation: the paradox of firm investment in open-source software,” *R&D Management* 36, 3 (2006): 319-331.

West, Joel, and Paul Olk. “Collaboration vs. Competitive Advantage Across the Value Chain: A Study of Pharmaceutical Consortia,” Academy of Management Annual Meeting, Anaheim, Calif., August 7, 2016.

West, Joel and Siobhán O’Mahony. “The role of participation architecture in growing sponsored open source communities,” *Industry and Innovation* 15, 2 (2008): 145-168.

West, Joel and David Wood, “Evolving an Open Ecosystem: The Rise and Fall of the Symbian Platform,” in Ron Adner, Joanne Oxley and Brian Silverman, eds., *Advances in Strategic Management,* 30 (2013): 27-68.

Xia, Mu, Kexin Zhao, and Joseph T. Mahoney. “Enhancing value via cooperation: firms’ process benefits from participation in a standard consortium.” *Industrial and Corporate Change* 21, 3 (2012): 699-729.

Yu, Lawrence, X. “Pharmaceutical quality by design: product and process development, understanding, and control.” *Pharmaceutical Research* 25, 4 (2008): 781-791.

Zhao, Kexin, Mu Xia, and Michael J. Shaw. “An integrated model of consortium-based e-business standardization: Collaborative development and adoption with network externalities.” *Journal of Management Information Systems* 23, 4 (2007): 247-271.