

AN ORIGINAL INSTITUTIONALIST APPROACH TO THE STRUCTURE, CONDUCT, AND
PERFORMANCE OF THE PHARMACEUTICAL INDUSTRY:
THE IMPORTANCE OF INTANGIBLE ASSETS

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AN INSTITUTIONALIST APPROACH TO STRUCTURE, CONDUCT, AND PERFORMANCE
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THE IMPORTANCE OF INTANGIBLE ASSETS

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ABSTRACT

This dissertation presents an examination of the pharmaceutical industry with a primary focus on the importance of intangible assets from the original institutional economics perspective. This is done in three main chapters. The first main chapter examines the importance of intangible assets within the context of the heterodox theory of the business enterprise. It is argued that in the early stage of the going concern – where production is separate from consumption – intangible assets necessitate the creation of monetary bargaining transactions. In industrial capitalism – with the internal separation of the enterprise into industrial and pecuniary divisions – intangible assets take the form of rationing transactions, limiting the number of sellers of a particular product. As the enterprise then evolves into its modern joint-stock form in money manager capitalism, intangible assets become the basis for capitalization, upon which incorporeal property may be issued, increasing the return to shareholders.

The second main chapter discusses the structure and performance of the pharmaceutical industry. Based on the concept of centralized private sector planning

and Alfred Chandler's theory of learned organizational capabilities, I develop a core-nexus understanding of pharmaceutical industry activity. The core is seen as made up of 15 firms who dictate the direction and evolution of the industry as a whole. I then examine the performance of this core using measurements of financial ratios. Measuring performance in this way is consistent with the stated motives of the business enterprise under money manager capitalism, which embodies the dominance of pecuniary habits of thought over industrial ones.

The third main chapter combines the first two, examining one specific member of the core – the Pfizer Corporation – and examines the importance of intangible assets on its activity. Over time, it is shown that Pfizer has become more reliant on intangible assets as an overall portion of total assets, its net tangible assets – the book value of the company – has become negative, and Pfizer relies more heavily on drugs obtained through acquisition, rather than internal development.

Money manager capitalism, as a regime of accumulation, rewards enterprises that take on an intangible characteristic. In the pharmaceutical industry, this is done with the aid of mergers and acquisitions due to accounting rules for intangible items such as goodwill and the division of labor between the core and nexus. Dominant pharmaceutical firms, then, should be seen as rent-collecting institutions, as opposed to productive entities.

The faculty listed below, appointed by the Dean of the School of Graduate Studies, have examined the dissertation titled “An Original Institutionalist Approach to the Structure, Conduct, and Performance of the Pharmaceutical Industry: The Importance of Intangible Assets” presented by Avraham Izhar Baranes, candidate for the Doctor of Philosophy degree, and certify that in their opinion it is worthy of acceptance.

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For Sabba

CHAPTER 1

INTRODUCTION

This dissertation extends the heterodox tradition, particularly the Veblenian institutionalist path, by examining the nature and role of intangible assets in the organization of the pharmaceutical industry. Based on insights from heterodox economics, the standard structure-conduct-performance model is modified to reflect enterprises as going concerns, whose management is primarily concerned with pecuniary returns to shareholders, which are considered separately from economic efficiency, as is claimed by neoclassical agency theories of industrial organization. Using the Pfizer Corporation as a case study and examining its merger and acquisition history, intangible assets are shown to be at the root of its conduct and performance, and the acquisition of such assets performs an important function in the structure of the pharmaceutical industry as a whole. Money manager capitalism, as a regime of accumulation, rewards enterprises that take on an intangible characteristic. In the pharmaceutical industry, this is done with the aid of mergers and acquisitions due to accounting rules for intangible items such as goodwill and the division of labor between the core and nexus. Dominant pharmaceutical firms, then, should be seen as rent-collecting institutions, as opposed to productive entities.

Industrial organization deals with how production and distribution are organized, and in that sense covers all aspects of the provisioning process. An important feature of industrial organization and the provisioning system in a capitalist economy is private property rights. Property rights proscribe the ways in which

community members gain access to the provisioning system; those who own are able to withhold from those who do not. Property rights include not only rights over physical, tangible objects, but within also rights over intangible and immaterial things. Important sources of intangible property rights include patents, copyrights, franchises, and trademarks. These largely determine who may use certain ideas and produce certain products. In this sense, intangible property – and intangible assets as a whole – represent income streams for the owner not because of productivity, but because they grant control over different forms of social relations¹.

Heterodox economics has focused on the significance of intangible assets within the system of social provisioning. Marx's explanation of fictitious capital in Volume III of *Capital* can be – and in this dissertation, is – viewed as a result of intangible assets² (Marx 1894; Hilferding 1910). Veblen specifically focuses on the importance of intangible assets in influencing the behavior of enterprises, particularly once industrial activities have been separated from business activities (Veblen 1904, 1908a, 1908b). In the Post Keynesian tradition, the valuation of assets – both tangible and intangible –

¹ While intangible property rights can be seen as emerging out of innovative activity, I would hesitate to claim that they *cause* such activity. This topic will be revisited later in this chapter.

² Marx considers the capitalized value of the enterprise to be the sum of its productive capital, or capital in use, and what he calls “fictitious capital”, or the value of stocks and debts that the enterprise has issued. While these two values may be related, as Marx claims that the value of capital in use is related to the value of fictitious capital, the value of fictitious capital depends upon the expected earning capacity of the enterprise, which depends upon its assets. Intangible assets swell the value of the asset based used in capitalization, thus increasing the ability for the enterprise to issue fictitious capital (Marx 1894).

under a monetary and credit economy are seen as a source of instability. When assets are re-valued at lower or higher rates, the ability of the company to meet its outstanding obligations is changed, creating variously panic, economic downturn, speculation, and increased expectations of future returns (Keynes 1936; Minsky 1975, 1986; Wray 2007, 2009). I endeavor to add to this tradition by specifically examining the way in which *intangible* assets are used to gain a differential advantage within the pharmaceutical industry and specifically to the role of mergers and acquisitions in this process.

The Pharmaceutical Industry

Life expectancy in the United States has increased over the course of the last half-century. In 1950, life expectancy at birth was 65.6 years for men and 71.1 years for women. In 2011, those numbers had increased to 76.3 years for men and 81.1 years for women, with death rates from cardiovascular disease, cancer, and HIV/AIDS in decline (Pharmaceutical Research and Manufacturers of America 2013a). Several factors are associated with this change, but one important factor has been access to pharmaceutical products. Lichtenberg (2007) found that the launch of new medicines accounted for nearly 40% of the increases in life expectancy during the 1980s and 1990s. Hence, in the modern era, the ability to provide for the growth and maintenance of the community is mitigated by its access to pharmaceuticals. Understanding the environment within which pharmaceutical products are invented, developed, manufactured, and distributed is important in understanding the continuation of the life process.

In this section, I review research regarding two areas that influence the way in which industry activity is undertaken. First is a brief summary of the benefits and costs of patents, as well as a review of the literature surrounding this topic. While this is not the primary focus of this dissertation, it is useful because such issues are inseparable from the issues surrounding the pharmaceutical industry. Second is a review of the role that mergers and acquisitions have played in shaping the industry. Of interest here is the network-type of relationships between large pharmaceutical firms and the smaller firms that compose the supporting nexus.

Pharmaceutical Research and Patent Debates

Many of the questions regarding the pharmaceutical industry revolves around the nature of intellectual property rights. Patent defenders claim that for enterprises to take on the high costs of pharmaceutical research, there must be a way to recoup costs. Without property rights to protect the innovation, no firm will create new, beneficial pharmaceuticals. Patent opponents, on the other hand, claim that patent rights do not incentivize innovation, but promote rent-seeking behavior. Further, patents work to prevent innovation by prohibiting knowledge spillovers and increasing the cost of innovation through licensing fees once a patent has been issued.

Costs of Pharmaceutical Research

Pharmaceutical research is costly to the enterprise³. However, there are disagreements as to how costly the research actually is. In 2006, the Congressional

³ For a more detailed description of what pharmaceutical research and the pharmaceutical approval process entails, see Appendix A.

Budget Office, based on research by DiMasi, Hansen, and Grabowski (2003) found the cost of developing a new drug to be approximately \$800 million, with annual total spending on pharmaceutical research reaching \$40 billion. Since then, these estimates have continued to increase. In 2007, DiMasi and Grabowski found that it cost \$1.2 billion over a 10 to 15 year period to develop and approve a new drug (see also Zhong 2012). On the high end, industry reports claim the average cost of developing a new drug is \$1.38 billion, with firms spending nearly \$135 billion on R&D per year (International Federation of Pharmaceutical Manufacturers & Associations 2012). More recently, the Tufts Center for the Study of Drug Development has estimated that new drugs cost \$2.56 billion to take from discovery to marketing approval (2014).

Gagnon (2015) questions the accuracy of these estimates, while GlaxoSmithKline CEO, Andrew Witty, stated that the reasons costs were so high were due to failed candidates being included in the measurements (Hirschler 2013). Further, Light and Lexchin (2012), in breaking down the report of \$1.2 billion, found a number of questionable methodologies. “Half that total comes from estimating how much profit would have been made if the money had been invested in an index fund of pharmaceutical companies that increased 11%, compounded over 15 years.” (p. 23) Further, they find that a quarter of the funds, or approximately \$330 million, were paid for by tax credits and deductions, and that the only drugs that were considered were the most costly quintile, which were “3.44 times more costly than the average.” (p. 23) Another study by Morgan, Grootendorst, Lexchin, Cunningham, and Greyson (2011) found that cost estimates vary wildly, depending on a number of factors such as how

the data was collected – e.g., publicly available or privately through confidential surveys – and the types of treatments included. Their conclusion was that “no published estimate of the cost of developing a new drug can be considered a gold standard.” (Morgan et. Al 2011, p. 11)

The importance of patents can be seen as two-fold: the first question is whether or not such intellectual property rights over-compensate the company. High costs of drug development would require an ability to recover those costs, which would be impossible due to the ease of copying in the pharmaceutical industry (May 2007). Patent protection would offer the monopoly power necessary to prevent copying. The second question emphasizes the nature of the patent system – *how* do patents induce innovation; and is it successful in so doing?

The Nature and Function of Patents in Innovation

Mazzoleni and Nelson (1998) describe four features of the patent system with regard to its role in incentivizing innovative activity: invention motivation, invention dissemination, commercialization, and broadening prospects. In this section, each of the four is examined.

The most common argument in favor of patents is invention motivation. Due to the costs and difficulty of inventing a new and useful product, the inventor requires a guaranteed monetary reward if they are successful. In this way the invention motivation theory states that patents are what drive individuals to create new things that may be of service to the community (Mazzoleni & Nelson 1998). The most common critique of this theory is that an inventor will receive a benefit through the first-mover

advantage by being the first to invent (Boldrin & Levine 2008, 2012). Rather than rely on patents to protect the invention, it is possible for the inventor to rely on trade secrecy⁴. This leads to the second defense of the patent system, invention dissemination. Patents, under this theory, provide an incentive for the inventor to make public the knowledge necessary for the creation of the product – information that would otherwise be kept secret. “In certain industries firms customarily engage in general cross licensing of process technology, a sharing of technology that likely would be much more difficult if patents were not available on process technology.” (Mazzoleni & Nelson 1998, p. 1039) Indeed, in the pharmaceutical industry, licensing of patents and products play an important part of drug development. Baumol (2002) and Chisum *et al.* (2004) show another benefit to patents based on the information dissemination theory. According to this research patents do not cover a very wide breadth of information, and thus there is room to invent around the patent. This leads to what Lichtenberg and Philipson (2002) call “between-patent competition” (p. 643). Disseminating information contained in a patent leads other firms to create products that are imperfect substitutes. In the pharmaceutical industry, this may have important benefits as different patients with the same disease may require different treatments. The information dissemination function of a patent helps these different treatments to be produced.

The third theory discussed by Mazzoleni & Nelson (1998) reflects the idea that while invention is the creation of knowledge, it is not until that knowledge is

⁴ Trade secrecy is difficult for pharmaceutical and chemical companies, due to advances in technology in those fields, as pointed out by May (200

transformed into a commercial product that it can generate welfare. This theory, supported by Teece (1981, 1989), Baumol (1990, 2002), Chisum *et al.* (2004), and Swann (2009) posits that invention is only a part of the product development process. There are costs involved with developing a raw invention to the point where it may be released as a product; patents do not induce only *invention*, but more importantly, *innovation* – the commercialization of new knowledge. Protection through marketing exclusivity in this theory is deemed necessary to incentivize enterprises to undergo the costly development process required to bring a product to market⁵. This theory was the basis for the Bayh-Dole Act in 1980; an Act that allowed research conducted with public funds – i.e., research done at little cost to the private enterprise – to be patented. Chisum *et al.* (2004) claim that prior to the Bayh-Dole Act, much biological research conducted at universities using government grants were not being commercialized. It was only after the act that such discoveries were developed into biopharmaceutical products, helping to create the biotechnology industry.

The fourth theory discussed by Mazzoleni & Nelson addresses the idea that patents allow for the exploration of different possibilities once invention occurs; this is known as prospect theory (Kitch 1977). The base for this theory is knowledge spillovers. “The prospect theory views an initial discovery or invention as opening up a whole range of follow-on developments or inventions.” (Mazzoleni & Nelson 1998, p.

⁵ In the pharmaceutical industry, this would include the cost of clinical trials and FDA approval. We can see a relationship, then, between the invention dissemination and the commercialization theories of patents. The high costs of product development may lead to smaller companies partnering with larger companies through licensing agreements, while larger companies are only willing to finance late-stage, more expensive clinical trials because of the marketing exclusivity.

1042) Patents allow the enterprise to explore different paths of research using the invention by reducing the transaction costs required to investigate these different prospects. Kitch (1977) points out that patents have several functions, including signaling to others what information is already available, thus reducing the cost of maintaining control over the knowledge generated. Further, a patent signals to other firms the seriousness of the holder in creating the product, making it easier to find development partners willing to provide finance (Lacetera 2001; Levitas & McFayden 2009).

Based on this research, patents can be seen as having an important effect in the pharmaceutical industry by 1) incentivizing companies to take newly discovered compounds and continue to develop them to the point where they become socially beneficial drugs and 2) by creating economies of scale through a division of labor between the core of the industry focused on late-stage development and marketing and a supporting nexus that focuses on discovery and early development (Arora, Gambardella, & Rullani 1997). Further, if the purpose of a patent is to ensure that the enterprise will remain viable, despite high R&D costs, they are also successful, as Gagnon (2009, 2015) has demonstrated, in regards to rising prices for pharmaceutical products.

The issue at the center of the patent debate is whether or not patents – based on the theories above – over-compensate the holder and whether they are actually

innovation inducing. If innovation is seen as a cumulative process⁶, then it is possible that patents reduce the amount of innovation in an economy by preventing such processes from taking place. Denicolò (2007) found that within the context of sequential innovation – each innovation being based on prior innovations – strong patent protection leads to reductions in firms’ incentives to share information. This research supports earlier results found by Helpman (1993), which showed that with tighter intellectual property rights, the long-run rate of innovation actually declines: while innovative behavior increases initially, it subsequently falls once patents have been established. This supports the idea that patents prevent the cumulative processes necessary for innovation to occur.

The idea of patents decreasing innovation by preventing cumulative knowledge creation is tied to what Heller and Eisenberg (1998) call the “tragedy of the anticommons.” (p. 698) Patents, rather than incentivizing innovation, function to create tollbooths to innovative behavior. An innovator must pull knowledge from many different fields in order to create; for innovation to be successful, knowledge from one field must be able to spillover into other fields. However, if an innovator must pay a licensing fee to enter each field and gain access to that knowledge, it increases the cost of innovating. This explains Helpman’s result that stronger intellectual property rights lead to short-term increases in innovation, but long-term decreases. Prior to the erection of patent “tollbooths”, innovation increases as firms and inventors try to be the first to obtain the patent. Once property rights have been allocated, however, future

⁶ As is the case with many heterodox theories of innovation, such as those promoted by Veblen (1908a, 1908b), Ayres (1944), Foster (1981b), and Alperovitz and Daly (2008).

innovators may be unable to obtain the licenses necessary for the patented knowledge; they are unable to pay the toll. From a Schumpeterian standpoint, intellectual property rights prevent the creative destruction process from occurring because they prevent or forestall the entrants necessary for the destruction of entrenched monopolies (Schumpeter 1942).

The Swedish Growth School, based on the tragedy of the anticommons and Schumpeter's theory of creative destruction, developed a theory of entrepreneurship based on knowledge spillovers (Acs *et al.* 2004; Acs & Sanders 2008; Acs *et al.* 2009). In this theory, the entrepreneur is an individual acting as the central node in a network that is able to pull from different fields when developing new products. The knowledge spillover function of innovation – the concept that the creation of knowledge in one fields leads to further knowledge creation in other fields – is vital for entrepreneurship as this is how the entrepreneur obtains the necessary tools to create. This network is consolidated into what are called “technological innovation systems”, which represent a set of interrelated networks linked through the diffusion of knowledge. The end result of such a system is an increase in opportunities for product creation, the reduction of uncertainty through knowledge dissemination, and the continual course of cumulative innovation. When taken together, the Swedish Growth School sees knowledge spillovers as the primary cause of endogenous growth and social wellbeing (Carlsson & Stankiewicz 1991; Carlsson & Eliasson 2003; Hekkert *et al.* 2007; Bergeck *et al.* 2008).

In order for an innovation system to form, entry barriers must be low or non-existent, or else they prevent the knowledge spillover process. Acs and Audretsch

(1987) found that, once barriers to entry are taken into account, network effects are generated that give large, entrenched firms the ability to exploit gains from innovation; rather than seeing their market shares erode, larger firms find themselves in a stronger position when innovative activity occurs. Findings by Arora, Gambardella, and Rullani (1997) and Orsenigo, Pammolli, and Riccaboni (2001) support the concept that innovation in industries with high barriers to entry end up favoring dominant firms. Arora, Gambardella, and Rullani found that patents, when held by dominant firms, helped maintain existing market shares in the face of new entrants; when held by smaller firms, they induced licensing agreements between the smaller and larger firms for the purpose of avoiding costly litigation. Additionally, Orsenigo, Pammolli, and Riccaboni found that in the pharmaceutical industry, new entrants caused the network of firms to become broader, but centrality measures for dominant firms to become stronger. In other words, new entrants caused the industry to expand, but strengthened, rather than diminished, the position of dominant firms.

The implication is that, rather than promote innovation, patents function to maintain the pre-existing industrial relations by generating rent payments. The patent holder receives an income stream, not necessarily because they are productive, but due to the differential advantage bestowed by this type of ownership. Access to the market, then, is dictated by the patent holder who may choose whether or not to license the knowledge to other producers. This is the main argument made by Boldrin and Levine (2012), who support the finding that in mature industries, patents function to reduce

innovation. In fact, they find that patents actually inhibit innovation by increasing the amount of rent extraction:

Being not a 'property' right but rather a 'monopoly' right, patent processors will automatically leverage whatever initial rents their monopoly provides them with in order to increase their monopoly power until all potential rents are extracted and, probably dissipated by the associated lobbying and transaction costs. (p. 11)

Patents, then, are important to dominant firms because they generate rent payments. In this way, once an industry has become organized with a dominant core in place, patents no longer serve their purpose as innovation inducers, but rather function to generate rent payments through monopoly rights⁷.

When examining the pharmaceutical industry it is important to recognize the ways in which patents – and intangible assets in general – help shape the industry and the relations between enterprises in the industry. One effect is a division of labor between enterprises that conduct early stage research and discovery and those that license patents from these nexus companies for the purpose of development and distribution. In the examination of the Pfizer Corporation's merger and acquisition history in Chapter 4, this division of labor is seen clearly in the types of companies Pfizer has acquired or engaged with in strategic alliances. Understanding mergers, acquisitions, and strategic alliances, therefore, is an important feature in understanding

⁷ While not discussed here, another important result of patents is the creation of "patent trolls", or companies that acquire patents for the purpose of engaging in litigation. These companies have no interest in production and simply earn an income through settlements or licensing agreements with producing enterprises; this is the most extreme version of rent extraction due to the patent privilege. For more on this topic, see Choi (2003), Chein (2008, 2012), and Dean (2013).

the effect that patents and other intangible assets have on industrial conduct and performance. Though this topic will be investigated in more detail in Chapter 4, a brief introduction to the literature with a focus on the pharmaceutical industry is given here.

Mergers and Acquisitions: The Changing Pharmaceutical Industry

Chandler (2005) and Gagnon (2009) argue that the supply side of the pharmaceutical industry depends upon relationships between the industry core and the supporting nexus. Legislation in the early 1980s affecting patent rights and marketing exclusivity – particularly the Bayh-Dole Act in 1980, the Orphan Drug Act in 1983, and the Hatch-Waxman Act in 1984 – further strengthened the idea that interactions between the core and nexus were necessary for the discovery, development, and marketing of pharmaceuticals.

Cockburn (2004) showed that pharmaceutical research in the 1980s was dictated by downstream concerns – the larger, core pharmaceutical companies. He finds that, as market values drove out academic values⁸, there began to be more communication between upstream and downstream enterprises. Biotechnology companies – which themselves had spun out of university research departments – developed technologies that could be used for early screening and discovery, which were then licensed to larger pharmaceutical companies. First movers in the biotechnologies used these funds to develop their own compounds, which then led to

⁸ Cockburn notes: “Historically, academic research has been driven by social norms and resource allocation procedures that ignored market signals and commercial concerns.” (2004, p. 20) Key changes to the legal structure during the early 1980s were made to induce the commercialization of research being done by academics, leading to the creation of the biotechnology sector (Chandler 2005; Gagnon 2009).

another form of interaction – biotechnology companies joining with larger pharmaceutical companies to get the product through FDA approval and take advantage of the manufacturing capabilities, sales network, and marketing ability of large companies (Chandler 2005). The modern process of pharmaceutical product development – and the industry itself – is built on the relationships between the industry core and the supporting nexus.

Danzon, Nicholson, and Pereira (2003) examined these relationships and found that products developed using an alliance between small and large companies were more likely to succeed than products developed by one company. “The [small] firms often develop drug leads⁹ and then out-license these leads to large pharmaceutical firms, who then take the drug candidates through lead optimization, development and clinical trials, and ultimately regulatory approval.” (p. 5) These technologies and compounds are protected by patents, but the small firms do not have the capabilities to bring them to market¹⁰; they require assistance from large firms for development. Further, they, like DiMasi (2001) and Arora, Gambardella, Pommolli, and Riccaboni (2000), found that “large firms have higher success rates on compounds that they in-license than on compounds that they originate in-house.” (Danzon, Nicholson, & Pereira 2003, p. 5) In other words, not only are such alliances helpful for biotech companies as

⁹ A drug lead is a new compound that may eventually be developed into a commercialized pharmaceutical product.

¹⁰ While they may have the ability to discover a product, and in some cases, the ability to get the drug through approval, such firms do not have the capabilities to manufacture, market, and distribute the product globally. For this reason, they partner with the larger firms. This will be revisited in Chapter 3.

a source of funding, they are also helpful to large companies that obtain the marketing rights to products with a higher probability of being approved.

Following this research, Danzon, Epstein, and Nicholson (2004) attempt to explain why this division of labor works for small and large pharmaceutical companies. They find that small firms benefit from the experience of larger firms when it comes to late stage clinical trials and dealing with FDA requests during the approval process. Large firms, on the other hand, benefit from dealing with small firms because it gives them a way to fill gaps in their product pipeline. Evidence for this excess capacity hypothesis was also provided by Ravenscraft and Long (2000), who focused on the merger between Glaxo and Wellcome, showing that the key factor in this merger was the ability for Glaxo to replenish its pipeline. However, Danzon, Epstein, and Nicholson (2004) also found that while a merger might provide benefits in the short period, it does not provide a long-term solution to supply line problems.

Previous research in the pharmaceutical industry has shown that mergers and acquisitions are sought with an eye towards short-term effects, rather than long-term. From the standpoint of product development this is clear if mergers are a way for the company to refill its product line. The long-term effect of acquiring an enterprise for the purpose of obtaining rights to a particular product are negligible, as the product will eventually go off-patent and compete with generic entrants. Further, from the perspective of maximizing shareholder value, mergers and acquisitions are a way of increasing stock values in the short run, satisfying the needs of absentee owners without focusing on long run productivity. Black (2000) and Alexandridis, Mavrovitis,

and Travlos (2012), focusing on the fifth and sixth merger waves, found that the primary goal for enterprises that enter into merger agreements was increasing market capitalization. This topic will be discussed in more detail in the next chapter.

Methodology

The above review depicts this industry in which the ability for an enterprise to be a going concern depends upon the ability for it to obtain patent and marketing rights to pharmaceutical products. From a heterodox perspective, this reflects the separation of industry and business – the ability to engage in profitable transactions with the aid of a differential advantage such as monopoly rights garnered from intangible property. This separation, and the importance of patent rights in this separation, generates a particularly industry structure and conduct in which a core group of enterprises may dictate the course of action for the industry as a whole. Further, the conduct of enterprises in this industry, because of the core-nexus structure, revolves around upstream and downstream deliveries of research and monopoly rights through mergers, acquisitions, and licensing agreements. This section describes the approach taken in this dissertation to understand the nature of intangible assets within the pharmaceutical industry

Institutional Foundations of Industrial Organization

The institutionalist perspective is concerned primarily with the nature of social relationships – both the presence and absence – that transform inputs to outputs (Tauheed 2013b). These relationships both determine the structure of and are determined by the institutional setting within which they take place. In this sense, there

is a feedback between institutional relations and institutional constraints that causes social evolution to be a never-ending process; so long as there are agents within a social system interacting, the system will alter in response to their actions and in turn, change the way in which they act (Foster 1981a; Bush 1987; Tool 2001). From this standpoint, an institution can be seen in one of three ways. From the Veblenian perspective, an institution represents “settled habits of thought common to the generality of men... [by which] men order their lives.” (1909, p. 626) The second part of this definition states that an institution is engrained within a given social structure that determines the nature of relationships between the members of a community. The first part reflects the emergent characteristic of institutions; they are created through historical process by the ongoing relationships of those within the social setting.

From the Commons perspective, institutions represent “collective action in control, liberation, and expansion of individual action.” (1934, p. 648) The notion of collective action refers to the rules and regulations that emerge out of interactions and transactions between members of a community. In turn, these rules function to define an action space within which members of the community can engage. Further, the idea that such collective action not only controls, but also liberates and expands individual action implies that the main purpose of an institution is to create a space within which community members can have some sense of certainty with regards to how their actions, interactions, and transactions will be conducted. For example, in a capitalist

economy, the institutions of private property and free contracting seek to ensure that individuals are able to engage in trade without fear of coercion or being cheated¹¹.

John Fagg Foster defines an institution as “prescribed patterns of correlated human behavior.” (1981e, p. 940) The concept of “prescribed patterns” refers to a value structure that governs the behavior of individuals within a community. The “correlated human behavior”, then, refers to the way in which people interact, given the value structure of the institution. Hayden (1982) and Bush (1983) expand upon both parts of this definition, showing that there exists a feedback between the interactions of individuals, the development of new technologies, and the value structure of an institution, culminating in a process of institutional adjustment that leads to continual changes in prescribed value structure (Foster 1981c; Bush 1987; Tool 2000, 2001).

Tauheed (2013a, 2013b), from a critical institutionalist perspective reconciles these three views of institutions by showing them to be the same definition, but operating at different levels of analysis. As Neale (1987, p. 1182, emphasis in original) states:

An institution is defined by three characteristics. First, there are a number of people doing. Second, there are rules giving the activities repetition, stability, predictable order. Third, there are folkviews – most certainly what Walton Hamilton meant by a “bundle of intellectual usages” – explaining or justifying the activities and rules.

From this perspective, the “*people doing*” represents Foster’s prescribed patterns of correlated behavior. They represent people acting in accordance with a particular value structure. This value structure, then, is derived through Commons’ collective action,

¹¹ In an ideal exchange situation.

which represents the rules and norms regulating the individuals' actions, interactions, and transactions. Lastly, "by 'habits of thought' Veblen did not mean behaviors, but propensities and predispositions to engage in certain behaviors." (Tauheed 2013a, p. 154; see also Hodgson 2004) These propensities, then, are the social norms out of which collective action is developed – what Neale refers to as "folkviews". Over time, as the way in which community members act, interact, and transact changes due to, e.g., a technological development, the social norms will change as well.

The institutional structure influences the agency of the individual, while the individuals' agency simultaneously influences the structure of the institution. Veblen identifies two sets of instincts at the core of individual action, out of which an institutional structure develops. On the one hand, individuals possess an instinct of workmanship, which represents the desire to create and solve problems through the process of scientific inquiry, allowing for the continuation of the communal life process. These instincts give rise to an industrial or instrumental habit of thought, by which the focus is on the promotion of the productive use of resources and incorporating technological change that promotes the continuity of social life (Veblen 1914). On the other hand, individuals are also motivated by an instinct of predation, which represents the desire to differentiate oneself from others based on status, wealth, and power. This instinct gives rise to a ceremonial habit of thought and results in actions based on moneymaking and wasteful spending that may threaten the community as a viable concern (Veblen 1899b). Based on these two instincts, Veblen develops a dichotomy

between industrial and business activities, reflecting the instinct of workmanship and the instinct of predation, respectively (Waller 1982).

Dean (2013), based on this dichotomy, develops a theory of the business enterprise from a heterodox perspective. He states “heterodox theory would recognize the business enterprise as a point of agency, capable of instrumental, or useful, behavior as well as ceremonial or wasteful, behavior.” (p. 19) From this standpoint, the focus of industrial organization is on the effect that the feedback loops between industry structure and enterprise conduct have on performance from the standpoint of the industrial-business dichotomy. This requires an alteration to the standard structure-conduct-performance framework or model.

The Structure-Conduct-Performance Paradigm

One of the main traditional methods of industrial organization has been the structure-conduct-performance model (SCP). In this model, structure refers to the environment within which business act, typically defined as the nature of competition, the number of buyers and sellers, the degree of product differentiation, barriers to entry, and cost structures. Conduct refers to the actions of individual enterprises from a managerial decision standpoint, focused usually on pricing strategy, product development decisions, and research and development choices, sometimes through a form of game theoretical model. Finally, performance refers primarily to the productive and allocative efficiency of the enterprise and the industry as a whole. The key feature to an SCP model is the feedback among the three features while basic market conditions – the nature of supply and demand – are treated as external to the industry, focusing on

a competitive static methodology rather than a dynamic one (Modigliani 1958; Sylos-Labinin 1969; Chandler 1962, 1977; Greer 1992; Mansfield 2000; Church & Ware 2000; Waldman & Jensen 2013). The research strategy for the standard SCP model is to identify whether, given the existing market conditions, the industrial outcomes meet the standards of efficiency. If the industry is inefficient, policy can alter the industry structure by, e.g., breaking up monopolies or trusts, or it can alter industry conduct by influencing the payoff matrix enterprises face in their game. However, the goal of industrial organization research and industrial policy is to determine and produce efficient outcomes.

From a heterodox perspective, this is problematic for a number of reasons. First, viewing market conditions as exogenous ignores the ways in which enterprises work to formulate and manipulate those conditions. For example, advertising is designed to alter the structure of demand, meaning consumers are not completely sovereign in their decisions (Galbraith 1958). Advertising not only influences performance, but also influences a basic condition. Further, structure occurs within a given network of social relations. Rather than attempt to classify a market as competitive, noncompetitive, or workably competitive, market structure may be seen as emerging out of relationships between enterprises, similar to the way in which institutions emerge out of relations between individuals. Examining social relations in this way allows development of a more wholistic understanding of the environment within which enterprises act, interact, and transact.

Moreover, conduct may be better understood through agency decisions of enterprises emerging out of the nature of the industry structure, rather than within a game theoretic concept. The relationship between structure and agency within industry may be seen as a feedback loop, where structure influences decision-making, which in turn influences structure, and so on. In game theoretic models, the payoff matrix ignores the emergent properties of enterprises and industrial conduct, meaning it imposes a particular structure on industrial relations (Connor 1998). When dealing with conduct variables such as pricing behavior, this implies that “In the end, one cannot be sure whether the observed gap [between prices and marginal costs] is a consequence of the imposed *a priori* structure, or stems from measurement of misspecification problems.” (Azzam & Anderson 1966, p. 44) From the standpoint of the going concern, games would be indefinitely lived and no form of equilibrium could be reached due to continual changes in the payoff matrix¹². Examining industry conduct through a dynamic form of analysis using an historical approach grounds conduct in empirical reality and further emphasizes the relationships between enterprises that compose the industry structure (Granovetter 2005).

Finally, and perhaps most importantly, industry performance cannot be limited to identifying efficiency or inefficiency. Performance includes the motives of the going concern and how well the going concern can meet these goals. From an institutionalist perspective, following Dean (2013), the performance of an industry is defined within

¹² A better approach, discussed by Sen (1982), Weibull (1995), and Martins (2015), would be a form of evolutionary game theory in which enterprise conduct is seen as picking the social structure in which they will engage, rather than conduct options from a given structure.

the framework of the dichotomy – it can be measured based on instrumental and ceremonial means. Efficiency in production and allocation refers primarily to instrumental measures, emphasizing the ability for the enterprise to produce output and the way in which that output is distributed within the general community. However, from a business standpoint, the end goal for an enterprise as a going concern within a monetary production economy is the ability to generate earning capacity. Enterprise activity may be better understood by examining the means to achieve these ends, which, among other things, include ceremonial activities such as rent extraction through patents and intellectual property rights, stock price manipulation, and the maintenance of core-nexus relationships based on these property rights. If enterprise and industry performance are judged from the perspective of the going concern, then it becomes easier to understand, for example, mergers that do not provide for long term gain, or why enterprises needing quick cash flow sell productive capacity but maintain their monopoly rights over products (Chirstensen 2011; Denning 2011).

In this dissertation, the traditional use of the SCP model is modified to account for the issues raised above. Industry structure is examined from the standpoint of the relationship between the industry core and supporting nexus, while conduct emphasizes how these relationships are maintained through mergers and acquisitions. Performance is measured through the lens of shareholder return; as will be discussed further in the next chapter, the primary function of a business enterprise in the modern economy is to ensure a return to its absentee owners, regardless of whether such actions will harm the long term viability of the concern (Veblen 1923; Jo & Henry 2015).

Therefore, using measurements of interest to shareholders will reflect the ability for the enterprise to meet the standards of ceremonial adequacy set by its owners and other interested parties, which will allow the industry to remain viable with an economic framework that reinforces ceremonial business motives over instrumental industrial ones¹³.

Outline and Conclusion

This dissertation is divided into three main chapters. In chapter two, I examine the evolution of the use of intangible assets in the provisioning system using Dean's (2013) heterodox theory of the business enterprise in conjunction with Lazonick's (2008) New Economy Business Model and Serfati's (2009) theory of the transnational corporation. Of primary interest is how the use of intangible assets has changed through the degrees of separation. The findings from this chapter show that as the enterprise evolves, so too does the way in which intangible assets are used to generate earning capacity. Initially, they represent the ability for the enterprise to control the nature of the relationship between buyer and seller and the relationship between the community and its joint stock of knowledge. With the separation of business activities and industrial activities, intangible assets come to represent a form of rationing transaction, limiting the number of sellers of a particular product so as to generate an earning capacity through monopoly power. With the separation of ownership and

¹³ Differentiating between instrumental and ceremonial efficiency means that, unlike agency theories of industrial organization that see maximizing returns to shareholders as representing efficient use of resources (Lazonick & O'Sullivan 2000), I emphasize the ceremonial means used to achieve these ceremonially efficient outcomes and make no claims as to the instrumental efficiency of enterprise activity.

control, then, intangible assets function to increase earning capacity by increasing the capitalized value of the enterprise, which functions to increase the value of ownership; under money manager capitalism, this becomes the primary focus of management, whose interests have been brought in line with the absentee owners through, e.g., stock based compensation. They form a key part of the asset base for the enterprise out of which incorporeal property may be issued and distributed. Further, they aid the enterprise in obtaining external financing by acting as collateral and signaling mechanisms. Finally, through their function as property rights, they help the enterprise manage its subsidiaries by defining property rights along the value chain in terms of who has the right to develop, manufacture, and sell output.

In chapter three, a structural analysis of the pharmaceutical industry is developed. It focuses on the separation between the core of the industry, which is able to direct the course of industrial evolution, and the supporting nexus, which provides the activities necessary for the core to reproduce itself¹⁴. This chapter is grounded in previous work done by Alfred Chandler (2005) and Marc-Andre Gagnon (2009), emphasizing the importance of learned organizational capabilities – the technological, functional, and managerial abilities of an enterprise to develop, produce, and sell multiple products while maintaining itself as a going concern. The primary purpose is to update Gagnon’s (2009) description of the industry’s core based on more recent developments. I find similar results, with a few new enterprises that have managed ton

¹⁴ The core/nexus concept bears a relationship to be center/periphery concept described by Averitt (1968, 1987), but has some important differences more suitable to the pharmaceutical industry, in particular the importance of intangible assets.

entrench themselves as core enterprises and a few that have left the core via merger. On the whole, however, the dominance of the core remains unchanged, with the 15 enterprises controlling 65% to 70% of industry activity. I then examine the performance of the core based on five different measurements, each related to the differing degrees of separation. Regardless of measurement, results show a similar pattern: during the 1990s, returns are relatively high, but fall in the early and mid-2000s, with a valley around 2004. However, profits begin to rise again in the late 2000s and early 2010s, peaking in 2009.

Based on these results, chapter four analyzes the Pfizer Corporation to understand how a pattern like this may emerge. Based on the importance of mergers and acquisitions in acquiring intangible assets and maintaining a position in the core, I examine Pfizer's merger, acquisition, and strategic alliance history from 1985 through 2014. Results here show a shift in business strategy from 1990s to the 2000s and the 2010s. Initially, Pfizer is focused on the discovery of new compounds, allying itself with nexus enterprises that emphasize screening technologies for pre-clinical testing. In the early and mid-2000s, Pfizer's strategy shifts to the acquisition of companies with drugs in later stages of clinical testing. In the late 2000s, Pfizer's strategy shifts yet again, with a focus on acquiring companies with products at the end of the approval process or already developed. During these later stages, Pfizer also began to sell tangible assets, reflecting both cost-cutting procedures and the outsourcing of manufacturing processes as described in the modular production network framework by Sturgeon (2002). I also find that in this later development that intangible assets makeup an increasingly

greater portion of Pfizer's total asset base, with a substantial majority of its 2014 revenue being generated by acquired drugs, rather than internally developed drugs.

The final chapter concludes this dissertation with a review of the results and paths for future research. Of interest are more research into the merger, acquisition, and strategic alliance activities of pharmaceutical enterprises to see if their strategies match that of Pfizer. Based on the research in this dissertation and the work done by Côte and Keating (2012) and Gagnon (2015), I am inclined to think it will, but further data is required. Another important path of research this dissertation opens is policy work, particularly with regards to the Orphan Drug Act and how it may be updated in response to changing technologies, such as pharmacogenics.

Pharmaceuticals are important in maintaining the community as a going concern by increasing the lifespan and life expectancy of its members. Consequently, the performance of the pharmaceutical industry is important to the ability to deliver products with life enhancing capabilities. However, as will be shown in this dissertation, the structure and conduct of the pharmaceutical industry has been organized and operated primarily to satisfy ceremonial motives, with performance – measured in terms of return to absentee owners – following suit. Intangible assets in the form of patent rights and goodwill have been the primary contributors in creating this institutional setting. Therefore, to understand the pharmaceutical industry as a whole, it is necessary to understand the nature of intangible assets within the provisioning system. To this I now turn.

CHAPTER 2

INTANGIBLE ASSETS AND THE BUSINESS ENTERPRISE: UNDERSTANDING CORPORATE CONTROL OVER SOCIAL RELATIONS

Introduction

Within a human economy, knowledge constitutes the productive core of economic activity. In the modern so called free enterprise system, this knowledge is appropriated by private individuals and companies in the form of capital, and it is from this appropriated knowledge that differential earnings are obtained (Veblen 1908a, 1908b; Gagnon 2007, 2009; Nitzan & Bichler 2009). This chapter examines the importance of the business enterprise insofar as knowledge is appropriated, with an emphasis on the use of intangible assets as the means for knowledge appropriation. Of primary focus is the separation between the productive capacity and the earning capacity of the enterprise (Veblen 1904; Dean 2013). I develop this framework more fully so that it can be used to examine the activity of the Pfizer Corporation. As will be shown, intangible assets generally function as a way for the enterprise to generate earning capacity separate from productive capacity. In this chapter, I examine how intangible assets perform this function over the course of the evolution of the business enterprise.

This chapter is comprised of three sections. First, I examine the theoretical foundations of intangible assets within the concept of the knowledge-based economy. Gagnon (2009), in line with Ayres (1952) and Foster (1981b), argues that the driving force of economic growth is technological change. Following this argument leads to an examination of the relationship between technology and intangible assets. In the second

section, I synthesize Veblen and Commons with regards to their approach to intangible assets. While Veblen's approach is grounded in the business-industry separation and Commons' approach is rooted in law, both see intangible assets offering a differential advantage through the generation of pecuniary earnings above the industry average. The final section builds off this synthesis to examine the function of intangible assets in the modern economy. Informed by Hilferd (1910), Lazonick (2005, 2010a, 2010b), Serfatti (2008, 2009), and Jo and Henry (2015), I discuss how intangible assets come into their own as the basis for capitalization with the separation of ownership and control.

Theoretical Foundations of Intangible Assets: The Joint Stock of Knowledge

Knowledge is composed of what Veblen (1908a) refers to as the community's joint stock of knowledge. This "information and proficiency in the ways and means of life" (p. 518) is created, possessed, and maintained by the community as a whole, and in this manner, forms the base for the provisioning system. As a social creation, the joint stock of knowledge encompasses both the relationship of members of society to the physical world and relations between people (Dean 2013). In the former, the joint stock of knowledge refers to the ability of a community to develop its material means of life¹. The community does not organize itself around resources of technology, but through its knowledge of ways and means organizes the natural world around itself (DeGregori

¹ This includes not only the development of tools, but also the creation of new resources. "Resources are not fixed and finite because they are not natural. They are a product of human ingenuity resulting from the creation of technology and science." (DeGregori 1987)

1987, 2002). The joint stock of knowledge, then, can be seen as defining the parameters of possible action (Foster 1981b)². This knowledge, further, is embodied physically in the tools and tangible assets used by the community to provision itself.

The limits imposed on a community by the joint stock of knowledge are the *technological* limits of social activity. Ayres (1953) discussed technology within this social context, stating “[t]echnology is doing – a mode of doing, perhaps, but one that runs through the whole gamut of human activities.” (p. 282) For Ayres, technology is not a thing, but a learned behavior (Ayres 1952); it is the knowledge of some type of skill, which allows one to act. These skills are culturally organized, acquired, and conditioned – the skills one learns depends heavily upon the community in which they live. The knowledge manifested in skills is also embodied in tools, and it is this combination of tools and skills that compose technology:

It is necessary to bear in mind at all times that technology is the sum of human skills, and in doing so to recognize that modern man is not less skilled but infinitely more skilled than his primitive forebears. But technology is also the sum of human tools. Thus we must recognize that skill is conceivable only in relation to tools. Skill is tool-behavior it is always and wholly that. (Ayres 1952, p. 52)

² It follows that the expansion of the joint stock of knowledge also expands the technological limits of the community. This is done in two ways: first, through diffusion or assimilation, whereby a greater portion of the community becomes more adept at utilizing the current stock of knowledge; and second, through invention, whereby additions are made to the joint stock of knowledge (Veblen 1908a). These processes are not separate; simply increasing the level of complexity of existing technology is not enough to greatly improve the quality of life of the community. Not only must the new knowledge be created, it must also be assimilated.

Technology is a set of tool-skill combinations (Munkirs 1988). The development of tools depends upon the size and accessibility of the joint stock of knowledge, while the skills that will be nurtured depend further upon the value structure of the underlying institutions in society³. Technology is embedded within the institutional structure – it is a cultural concept. The ability for a community to provision itself, then, depends upon access to and use of the joint stock of knowledge (Veblen 1908a; Ayres 1952; Lower 1987; McCormick 2002).

Within a capitalist economy, access is defined through property rights over both material and immaterial things. Ownership over material things reflects ownership over the tools developed from the joint stock of knowledge. Ownership over immaterial things, on the other hand, reflects the ability to control the nature of the social relationships embedded within society, be they relations in production or relations in sale. In the next section, I examine Veblen’s theory of intangible assets and Commons’ theory of intangible property within the context of the business enterprise. The principal finding is that the earning capacity depends not only on the enterprise’s ability to produce output for sale, but also its ability to control these relations in production and sale. Further, as the enterprise evolves, the ability to control such relations becomes the primary way in which earning capacity is generated.

³ Two things should be noted here. First, it is impossible to have tools without skills, or skills without tools. An airplane without a pilot is simply a pile of metal, whereas a pilot without an airplane cannot fly anywhere. This leads to the second point, which is that technology, from the standpoint of tool-skill combinations, is intrinsically value-lade. The tool itself does not dictate its use, and the skills that will be taught emerge out of an institutional setting. The plane does not dictate whether it is filled with bombs or medicine before being sent to a war-torn area; the community in which the tool resides makes these decisions, and the skills nurtured reflect its value structure.

Veblen, Commons, and Intangible Assets: A Synthesis

The purpose of this section is to compare Veblen and Commons' position on intangible assets and provide a synthesis to form a more cohesive theoretical understanding of the way in which they are used by the business enterprise in the modern economy. Both Veblen and Commons start with the concept of the going concern – that the purpose of business activity is to reproduce itself and its relations through time. However, due to the dynamic nature of capitalism, what it means for an enterprise to be a going concern changes. Initially, profit through the sale of output may have been the dominant focus, but later stages of capitalism – particularly industrial capitalism, when the ability to produce enough output is no longer in question – require the enterprise to obtain control over market relations. Intangible assets, then, become an increasingly important strategic tool for the enterprise, as they come to form the basis upon which output may be sold *and* confer a differential advantage through monopoly rights. Therefore, in a discussion of the business enterprise *qua* going concern, the role of intangible assets is a primary focus.

This section is divided into five subsections. In the first, I examine the origins of intangible assets, based on accounting and legal history. The purpose here is to develop an understanding of how such assets came to be and how they are traditionally thought of in business. The second section briefly examines Veblen and Commons' perspectives on tangible assets and tangible property. The emphasis here is on the way in which these property relationships emerge and what is exactly meant by “tangible property.” This provides a base for the next section in which I discuss the importance of intangible

assets in the first degree of separation. Within this stage of business development, intangible assets are used to create and maintain bargaining transactions. As production shifts from handicraft to industrial, intangible assets come to take on the character of market equities, creating rationing transactions that limit the number of sellers of a particular product; this is the focus of the fourth section. The final subsection concludes by examining the common threads between Veblen and Commons with regards to intangible assets in the business enterprise.

The Emergence of Intangible Assets

Intangible assets are important tools in ensuring the reproduction of the business enterprise. Their origins may be found in both legal and accounting history. The term “intangible asset” encompasses a wide range of things, such as “brand names, copyrights, corporate culture, covenants not to compete, franchises, future interests, licenses, operating rights, patents, record masters, secret processes, supplier relationships, trademarks, and trade names.” (Dean 2013, p. 82; see also Hendrickson & van Breda 1992; King 2006) These types of intangible assets function as rights to exclude others from producing and selling a given good. Indeed, this is the function of the patent system in general, as a patent, at its core, is a right to exclude (Chisum et al. 2004). In the 1852 case *Bloomer v. McQuewan*, Chief Justice Taney ruled that “the franchise which the patent grants consists altogether in the right to exclude everyone from making, using, or vending the thing patented without the permission of the patentee. That is all he obtains by a patent.” (*Bloomer v. McQuewan* 1852, p. 542) The right to exclude, rather than the right to produce, is what gives the intangible asset the

locking out characteristic, meaning they grant the holder a differential advantage through the ability to set prices (Veblen 1904; Commons 1924). The enterprise who owns the patent, copyright, or trademark is under no obligation to use it within the context of output production⁴.

One of the earliest examples for this type of intangible asset comes from ancient Greece. In Sybaris, if a cook or confectioner had created a new and excellent dish, the inventor was entitled to all profits derived from that dish, and no other chef was permitted to serve it for one year (Anthon 1841). Apart from this however, the ancient Greeks and ancient Romans did not recognize property rights over intangible goods; rather, the working rules during these times emphasized the knowledge itself as opposed to the application or use of the knowledge (Chisum et al. 2004). Put another way, the expression of the knowledge – the material object – was important insofar as it reflected use-value, or the culmination of society’s joint stock of knowledge as a means to reproduce the communal life process. The individual doing the expressing was less important than the knowledge itself.

The first patent was granted in Florence during the Italian Renaissance in 1421 to the architect and engineer Filippo Brunelleschi; Brunelleschi received monopoly rights for his ship, which transported Carrarn marble to be used in the building of the dome of the Florence Cathedral (Chisum et al. 2004). This event marked a shift away

⁴ This has led to a class of enterprises called “non-producing enterprises” whose main business is patent litigation. A non-producing enterprise, or “patent troll”, functions first by building a large patent portfolio and then suing companies that may infringe on those patents. Income is earned either through damages received or licensing agreements with companies that wish to use the knowledge to produce (Chein 2008).

from the traditional method of protecting knowledge through the use of guild monopolies; prior to Brunelleschi's patent, much of the knowledge creation was conducted within the context of guilds, which used rigid hierarchies and collective protection to keep their secrets. Individuals within the guild were responsible for developing new techniques or new product extensions; they received protection not from government monopoly, but from the guild leaders (May 2007). The granting of the patent brought with it a shift in the philosophical landscape. May points out that the development of intellectual property standards requires three different social forces coming together: technological forces that change the way in which production and distribution utilized knowledge; legal forces, which refers to the way in which property is defined and valued; and most importantly, philosophical, or the development of the notion of the sovereign knowledge producer (May & Sell 2005; May 2007).

The technological and legal forces had been dominated by guilds. Innovation and invention was conducted under guild protection, and the guilds did not distribute the new knowledge to the general public. As a result, commerce was controlled by the guilds, as they were the ones with the technical know-how to produce output. Through the use of trade secrets, charters, and mutual agreements, the guilds were able to create monopolies through cartel-like arrangements to protect their knowledge and lock out the general population. With the development of patents, however, innovation philosophy shifted to view the process as an individual, rather than communal, one. The guild was not necessary, and became viewed as an inhibitor to knowledge creation

(Walford 1888; Gross 1890; Ballard 1913; Pirenne 1937; Holmes 1962; Richardson 2001; May 2007).

This shift was reflected in the first patent statute enacted by the Venetian government on March 19th, 1474, the goal of which was to incentivize technological advancement through the issuance of private grants and import licenses. The statute included many rules that would become staples of later patent statutes. For example

grants were not recognized where there was prior knowledge within the territory of the Republic of the supposed innovation or invention (*newness*); there was a requirement for utility (or *usefulness*); a limited term of grant (*time limits* for protection); rights were transferable (*alienability*); there was a rudimentary working requirement, in that patent grants were forfeited by the failure to use them within a certain term, and the state retained a right to compulsory license. (May 2007, p. 3; see also Mandich 1948)

The notions of newness and usefulness formed the basis for the United States Patent Act of 1790, which authorized the issuance of patents for “any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used.” (Chisum et al. 2004, p. 19) In 1850, this act was expanded to include a requirement for “nonobviousness”, meaning that the three main requirements obtaining a patent in the United States became novelty, or the invention had to be new; utility, or the invention had to be useful; and nonobviousness, meaning the invention had to be something that a reasonable person could not come up with on their own. These three requirements are primarily grounded in the philosophical foundation of the sovereign inventor.

Stemming from Locke's theory of property⁵, it is argued that knowledge may be viewed as a commons and that the inventor mixes his or her labor with the commons when developing new ideas. Because knowledge is non-rivalrous, ideas may be appropriated from the common knowledge without devaluing or exhausting the overall stock. Further, by offering these rights, it incentivizes people to further develop the joint stock of knowledge, which, due to the cumulative nature of innovation, leads to exponential increases in productivity (Solow 1957; Hettinger 1989; Waldron 1993).

At its core, this class of intangible asset – the monopoly right – functions as a means to prevent the greater community from accessing the joint stock of knowledge. This knowledge, from an institutionalist perspective, is not *given* to the community as in Lockean justifications, but is *created* by the community through its life process. An individual who mixes his or her labor with the joint stock of knowledge is not utilizing a naturally occurring resource; they are utilizing a social creation (Ayres 1944). The primary function of the monopoly type of intangible asset, initially, is to grant an income stream based on the ability of the owner to control the community's access to its knowledge stock. Another form of intangible asset is “goodwill⁶”, which has been a

⁵ The key point to this theory are that the commons were given to humanity by God, and that when a person mixes their labor with the commons, they make the result their property. So long as the person does not take more than they can make use of, and does not destroy the commons, they have a natural right to what they can mix their labor with (Locke 1960).

⁶ See Table 2.1 for a breakdown of the different ways of defining goodwill discussed in this chapter. For a more complete history of the way in which accountants have dealt with the topic, see Courtis (1983).

Table 2.1: Definitions of Goodwill, Lord Eldon to John Commons

Author	Year	Definition
Lord Eldon	1810	Nothing more than the probability that old customers will resort to the old place. (<i>ves.</i> 356)
Vice-Chancellor Page-Wood	1859	That good disposition which customers entertain towards his particular shop or house of business, and which may induce them to continue their custom with it. (Ch. 841)
H.D. Macleod	1875	[A property right that] only exists to receive some <i>uncertain</i> profit, but no certain person is bound to make that payment and there is only the expectation that someone will, this is called <i>emptio spei</i> , or the <i>emptio rei speratae</i> in Roman Law: this Species of Property may be called Rights of Expectation. (p. 218-219)
R. Bithell	1882	The advantage connected with an established business of good repute. A well-established business presents an expectation of profits to any one entering upon it, and is worth paying for. (p. 142)
J.H. Bourne	1888	The benefit and advantage accruing to an existing business from the regard that its customers entertain towards it, and from the likelihood of their continued patronage and support. (p. 107)
A.G. Roby	1892	The advantage or benefit which is acquired by an establishment or a man beyond the mere value of the capital, stock, funds, or property employed therein, or by him, in consequence of the general public patronage and encouragement which it or he receives from constant or habitual customers, clients, or patients, on account of its or his local position, or common celebrity, or reputation for skill, or affluence, or punctuality, or accidental circumstances, or necessities, or even from partialities or prejudices. (p. 289)

Table 2.1, Continued

Author	Year	Definition
L.R. Dicksee	1897	The value of that reputation which a business has acquired during its continuance, which induces the confidence or expectation that the same, or an increasing patronage will continue to be extended so long as the business is conducted in the same place upon the same principles. (p. 40)
E. Guthrie	1898	The value in pecuniary terms of this intangible thing is the difference between the value of the normal results of the working of any business or profession which may be established by and worked by any person in any place, and the results of working any individual business of a similar character. (p. 425)
W. Hunter	1901	Goodwill exists as a benefit or advantage accruing to the firm, in addition to the value of its property, derived from its reputation for promptness, fidelity and integrity in its transactions, from its mode of doing business, and other incidental circumstances, in consequence of which it acquires general patronage from constant and habitual customers. (p. 351)
T.B. Veblen	1904	Goodwill taken in its wider meaning comprises such things as established customary business relations, reputation for upright dealing, franchises and privileges, trade-marks, brands, patent rights, copyrights, exclusive use of special processes guarded by law or by secrecy, exclusive control of particular sources of materials. All these items give a differential advantage to their owner, but they are of no aggregate advantage to the community. They are wealth to the individuals concerned – differential wealth; but they make no part of the wealth of nations. (p. 139-140).

Table 2.1, Continued

Author	Year	Definition
P.D. Leake	1914	The privilege, granted by the seller of a business to the purchaser, of trading as his recognized successor; the possession of a ready-formed “connexion” of customers, considered as an element in the saleable value of a business, additional to the value of the plant, stock-in-trade, book debts, etc. Goodwill, in its commercial sense, is the present value of the right to receive expected future super-profits. (p. 81)
W.A. Paton	1922	Goodwill may be defined as the capitalized value of the excess income which a particular enterprise is able to earn over the income of a representative competitor – a “normal” business – having the same capital investment, the rate used in capitalizing being the rate realized by the representative concern. (p. 313)
J.R. Commons	1924	Goodwill in business is liberty to go elsewhere. In proportion as alternatives diminish, goodwill diminishes, until with the disappearance of all alternatives, goodwill disappears in the loyalty of vassal or slave. (p. 272)

Source: Compiled from books and articles attributed to the listed authors.

source of confusion for economists and accountants alike⁷ (Courtis 1983). Initially, goodwill had been defined in terms of “Rights of Expectation” (Macleod 1875, p. 219) or “the advantage connected with an established business of good repute.” (Bithell 1882, p. 638) This type of definition, though vague, became the standard (Bourne 1888; Dicksee 1897; Guthrie 1898; Dicksee & Tillyard 1906; Leake 1914, 1921; Enders 1985). Goodwill, therefore, primarily refers to the differential advantage granted to an enterprise over the representative enterprise “having the same capital investment, the rate used in capitalizing be the rate realized by the representative concern.” (Paton 1922, p. 313) The concept of goodwill recognizes that there is a difference between the productive capacity of an enterprise and the earning capacity. While the two may be related, the reputation of a business will increase the earning capacity without directly affecting productive capacity⁸. Goodwill, then, is pure earning capacity that offers some level of guarantee that the enterprise will be a going concern (Hunter 1901; Kaner 1938; Walker 1953).

This earning capacity may be obtained in several ways. The good reputation of a business may refer to a number of different relations. Wixon and Kell (1962) describe

⁷ Some of this confusion may be related to the confusion as to how to account for assets in general, and whether they reflect property rights that may be exchanged for cash or whether they reflect some abstract future benefit. For a more detailed description of how accountants have treated assets, see Williams (2003).

⁸ H.E. Seed (1937) expands upon this notion that goodwill represents a differential advantage. For Seed, goodwill refers to “the advantage which arises from the good name, reputation, and connection of a business; alternatively, the benefit which accrues to the owner of a business from the likelihood that such business will earn, in the future, profits in excess of those required to an economic rate of remuneration for the capital and labor employed therein.” (p. 8) In other words, goodwill represents not only actual earning capacity, but *expected* earning capacity as well.

four different categories of goodwill showing that prestige may be derived from both production and distribution:

Commercial goodwill results from such factors as customers' attitudes, superior products, pleasing surroundings and desirable location. Industrial goodwill is acquired through satisfactory employee relations, including stable employment, high wages, and numerous fringe benefits. Financial goodwill reflects the favourable attitudes of credit institutions, investors, and trade creators. Public goodwill arises from the general reputation of the company. (p. 14)

Goodwill emerges from the relationship between members of the community, or more specifically, the transactions between members. Commercial goodwill, for example, arises out of the bargaining transactions between buyers and sellers, while industrial goodwill arises out of the interactions between managers and workers.

This idea of customary relations as the foundation for goodwill is also seen in court decisions regarding the subject. As Lord Eldon in *Crutwell v. Lye* stated, "The goodwill which had been the subject of sale was nothing more than the probability that old customers will resort to the old place." (1810) This implies that the customary relationship between buyer and seller includes not only the reputation of the business, but the location, name, and monopoly power⁹. Another key implication of this decision is the transferability of goodwill. Vice-Chancellor Page-Wood emphasized this point in *Churton v. Douglas*, stating that "When a person parts with the Goodwill of the business, he means to part with all that good disposition which customers entertain towards his

⁹ Lord Cransworth in *Austen v. Boys* agreed with this definition, stating "When a trade is established, the Goodwill of that trade means nothing more than the sum of money which any person would be willing to give for the chance of being able to keep the trade connected with the place where it had carried on." (1858)

particular shop or house of business, and which may induce them to continue their custom with it.” (1859) The differential advantage granted by customary relations, then, are *transferable* from one party to another¹⁰. Accountants have dealt with this fact by considering the goodwill of a business to be valued at the difference between the acquisition value and book value of a company during acquisition (APB 1970; Andrews Jr. 1981; FASB 2001)¹¹.

From the preceding discussion we may conclude that goodwill is an asset that is engrained within business activity and emerges from the customary, beneficial relations between buyer and seller or the relations within production. At its core, goodwill grants an income stream to the enterprise and the right to the income stream may be transferred when the company is bought and sold. Further, while monopoly intangible assets represent control over relations between the community and its joint stock of knowledge with regards to production of output, goodwill represents an income stream due to relations involved in both the production and distribution of output.

Before discussing the way in which these intangible assets confer a differential advantage to the business enterprise as the enterprise evolves, a brief discussion of the

¹⁰ Later court cases reinforced both the customary origins of goodwill and its transferability. See *Trego v. Hunt* (1896) and *Commissioner’s of Inland Revenue v. Muller Ltd* (1901) for more.

¹¹ It should be noted that goodwill, as an accounting term, can increase *only* during acquisition. When a company is acquired, its current goodwill is written to zero during the acquisition. Then, the difference between the acquisition value and the book value goes onto the acquiring firm’s balance sheet as goodwill. This reinforces the importance of mergers and acquisitions, as it is the only way a company can increase the goodwill line on their balance sheet (APB 1970; FASB 2001).

nature of the tangible side is warranted. The reproduction of the community *qua* going concern requires the production of serviceable output, which itself requires tangible assets. Control over these tangible assets in a capitalist economy is granted through a system of property rights, and understanding the emergence of such rights is integral to understanding the emergence and evolution of the business enterprise. It is to this I now turn, with a focus on synthesizing Veblen and Commons¹².

Tangible Assets and Tangible Property

One of the conclusions drawn from Veblen and Commons' theory of assets and property in general is the lack of a "natural rights" theory of property, as found in classical liberal philosophy (Lock 1690). Veblen discusses the nature of tangible assets in two footnotes in his "On the Nature of Capital" (1908a). In one, he defines assets as "serviceable capital goods considered as valuable possessions yielding income to their owner." (p. 539 *fn* 1) In an earlier footnote, he addresses the property relation that appears to be embedded in tangible assets:

The term [asset] properly covers a pecuniary concept, not an industrial (technological) one, and it connotes ownership as well as value... In the present connection, it is used figuratively, for want of a better term, to convey the connotation of value and serviceability without thereby implying ownership. (p. 518, *fn* 1)

¹² While the topic of property rights is an important feature of both heterodox and mainstream economics alike, my focus here is on expanding the understanding of the business enterprise *qua* going concern from the institutionalist standpoint. For this reason, I focus solely on Veblen and Commons' discussion of the emergence of property rights. For discussions covering other branches of economics, please see Sweezy (1942) or Ellerman (1992) for a Marxian view and Todd (2009) for a mainstream/libertarian view.

A tangible asset has a dual nature. It provides a serviceable component to the community, while simultaneously generating an income stream that may be appropriated by the asset's owner. However, these assets are developed from the community's joint stock of knowledge, which requires the community as a whole for upkeep (Veblen 1908a; Ayres 1944). When understanding the joint stock of knowledge in the context of cumulative innovation, as described by Ayres (1952, 1967), Alperovitz and Daly (2008), and Lazonick and Mazzucato (2013), it becomes clear that the invention and innovation process is a communal one, and the income stream derived from the creation of tangible asset is, too, a social creation. Private property refers, then, to an emergent institutional structure that grants the right to the income stream to an individual; there are no natural rights to property (Veblen 1899a).

Commons, too, identifies a dual nature in tangible property. Based on the concepts of transactions¹³ and the theory of reasonable value¹⁴, he identifies how

¹³ Commons identifies three types of transactions: bargaining, which occur between agents of a social system absent any hierarchical structure; managerial, which are command-like that occur between a legal superior and a legal inferior; and rationing, which occur between the collective action – be it the state, the law, or any other type of accepted social rules – and members of the collective. To quote Commons: “Bargaining transactions *transfer ownership* of wealth by voluntary agreement between legal equals. Managerial transactions *create wealth* by commands of legal superiors. Rationing transactions apportion the burdens and benefits of wealth creation by the *dictation* of legal superiors.” (1934, p. 68)

¹⁴ Reasonable value emerges out of the decisions made by a third party – hereafter referred to as the court – when settling disputes by members involved in transactions. It is an evolutionary idea that depends upon the political, moral, and economic circumstances of the time (Ramstad 1995). Two quotes from Commons should be sufficient to explain the concept:

decisions made by the courts have led to a change in what is considered “property” from use-value to exchange-value. The 1872 Slaughterhouse Cases judged, given the pre-existing working rules, that property was valued based on the serviceability to the community – the use-value. Over time, however, this definition changed to incorporate exchange-value. The 1890 Minnesota Rate Case considered property as “the *expected earning power* of those things... and property is taken from the owner, not merely under the power of *eminent domain* which takes the *title* and *possession*, but also under the police power which takes its *exchange* value.”¹⁵ (Commons 1924/2007, p. 16) When referring to tangible property, then, the courts ruled that the main concern is what may be got in exchange for the item, not just the productivity of the item in use. The transformation from property-as-use-value to property-as-exchange-value is neither spontaneous nor exogenous; it occurs through the decisions of the courts based on the doctrine of reasonableness.

Two similarities between Veblen’s description of tangible assets and Commons’ description of tangible property may be noted. First, both describe tangible

“Reasonable value, in the United States, is what the constituted Court decides is reasonable, by mere fiat, not what individuals think is reasonable... It is not a matter of subjective or individual opinion; it is the constitutional structure of the American judicial system that decides.” (1936, p. 245)

“When we investigate reasonable value, we are investigating the unwritten constitution. When we investigate the evolution of reasonable value, we are investigating the Court’s changes in meanings of such fundamental economic terms as property, liberty, person, money, due process. Each change in meaning is a judicial amendment to the constitution.” (1936, p. 249)

¹⁵ For a more complete description of this change, see the first section of chapter two in Commons’ *Legal Foundations of Capitalism* (1924).

assets/property as having a dual nature, incorporating both the serviceable use-value and the pecuniary exchange-value. This is clearly seen in Commons' discussion of property initially being considered a use-value to being considered an exchange-value. The important note here is that, while the item in question may be valued based on what may be got for it, it does have some serviceable component to it separate from the exchange-value. Veblen recognizes the serviceable aspect to assets arising out of the joint stock of knowledge, implying that they impose an instrumental value on society. However, within a given social system that recognizes private property rights, the income stream generated from these assets simultaneously implies an exchange-value embedded within them. This emerges out of the pecuniary relationships between owners and non-owners, and depends upon the working rules of society, i.e., the reasonable value process. What is important for Veblen and Commons, then, is the relationship of this use-value to exchange-value, and how the property relationship emerges out of the working rules of society (Veblen 1904, 1908a; Commons 1924, 1936).

This leads to the second similarity. Unlike classical liberal philosophy in the Lockean tradition, there are no natural rights to property in either theory. For Veblen, tangible assets arise out of communal knowledge, and their use-value originates within the community. It is only under a given set of social relations that grant property rights to individuals that a single person may claim ownership. For Commons, the same is true: property rights emerge out of the working rules of society, and as these rules change, so too does what is deemed "property." In both cases private ownership is

emergent and depends upon the nature of social relationships within a given community.

Intangible Assets in the First Degree of Separation

The first degree of separation refers to a locking-out process that occurs with the development of private property and the handicraft and early industrial mode of production. With the development of the surplus, it becomes possible for certain members of the community to live off the work done by others. Those in positions of power or status are able to appropriate this surplus for their own use by appropriating parts of the joint stock of knowledge. This separates the community into those who own and are able to provision themselves, and those who do not and must first gain access to the joint stock of knowledge through the sale of labor (Marx 1867; Veblen 1899a, 1899b; Resnick & Wolff 1989; Lee & Jo 2011; Bowles 2013). Production, in this first degree of separation, is not for use, but for sale. “The separation of consumption and production reflects an economic system organized according to the interests of one party to an industrial process over another as evidenced by the interaction of producing and consuming positions.” (Dean 2013, p. 64) Those with ownership rights over the joint stock of knowledge – the producing positions – are able to require those without ownership rights to engage in continual bargaining transactions to gain access – the consuming positions. Production in this stage is organized around the going plant¹⁶, which has ownership rights over the tangible assets of the community. The community does not dictate the use of these assets; their interaction with the knowledge stock is

¹⁶ For more on the make-up of the going plant, see chapter two of Dean (2013).

limited to bargaining transactions with the going plant, while the plant *qua* going concern requires continual monetary bargaining transactions to reproduce itself. If these transactions are not sufficient to maintain the enterprise as a viable entity, the plant shuts down (Dean 2013; Lee 2013).

From a Veblenian perspective, intangible assets are initially important because they endow certain enterprises the ability to earn an income stream through the control of social relationships. When production becomes motivated by sale, the ability for an enterprise to reproduce itself as a going concern depends upon the salability of its output. Those enterprises with ownership of intangible assets are better able to do so, despite the fact that they provide no greater social benefit¹⁷. Through the privatization of the knowledge base, the enterprise is able to require those who do not own to engage in bargaining transactions to provision themselves. Thus, the joint stock of knowledge becomes the vehicle for the Veblenian form of exploitation: owners earn an income not solely because they produce output, but because they have successfully appropriated the knowledge base. The intangible asset represents an income stream due to the control over access to the joint stock of knowledge, much in the same way a tollbooth operator controls accesses to a road (Heller & Eisenberg 1998).

Goodwill in the form of customary relationships is also an integral part of the survival of the business enterprise in the first degree of separation. The way in which the enterprise is able to continue as a going concern in handicraft production is through

¹⁷ Veblen (1904) explains that the items included in goodwill “give a differential advantage to their owner, but they are of no aggregate advantage to the community. They are wealth to the individuals concerned – differential wealth; but they make no part of the wealth of nations.” (p. 139-140)

the price system. Prices must be set at a level to ensure the reproduction of the enterprise and the continuation of bargaining transactions (Lee 1986, 1996, 1998; Downward 2000; Gu 2012). The customary relations between buyer and seller grant the enterprise a differential advantage by making easier the continuation of the necessary bargaining transactions. An enterprise with goodwill is able to ensure ongoing monetary transactions in a more stable or greater capacity than the normal enterprise might expect (Roby 1892; Guthrie 1898; Patton 1922; Veblen 1904, 1908b; Commons 1924).

Finally, we may reiterate that intangible assets may be transferable and thus fully function as assets:

When property rights fall into definite shape and the price system comes in... differential advantages take on something of the character of intangible assets. They come to have a pecuniary value and rating, whether they are transferable or not; and if they are transferable, if they can be sold and delivered, they become assets in a fairly clear and full sense of the term. (Veblen 1908b, p. 113)

Intangible assets are genuinely an ownership right, and these rights are transferrable. In the case of monopoly rights, this is seen through the licensing of patents, either compulsory or otherwise, and the ability for enterprises to acquire brands and trademarks from other companies. In the case of goodwill and customary relationships, this is seen when an enterprise acquires another at a price above the book value of the firm – what has been acquired is the perceived value of the pre-existing relationships of the acquired company.

For Veblen, intangible assets represent control over social relationships that emerge out of the separation of the community from its joint stock of knowledge *qua* private property; like tangible assets, this control may be transferred through purchase and sale. For Commons intangible assets arise out of the transactions between different members of the community. Goodwill is seen as the ability to control access to the market through controlling the market supply

The mere ownership of land, physical capital, or commodities has no significance for a business economy unless accompanied by access to a market, and access to a market has no significance without power to control the supply and fix the price of things offered on that market (Commons 1924, p. 268)

Goodwill, in both theories, is the ability for an enterprise to control market price, generated through the establishment of customary relations. Commons further identifies three types of goodwill – personal, business, and location; the first two emerge out of the customary relations between buyers and sellers, while location goodwill refers to Lord Eldon’s statement regarding the probability that customers will continue to return to the old location.

The primary difference between Veblen and Commons with regards to intangible assets is the effect control over social relations has on social stability. For Veblen, intangible assets are extortionary, resulting from private appropriation of social relations for the purpose of pecuniary gain, leading to market power (Veblen 1904, 1908a, 1908b; Enders 1985; Atkinson 1987). Commons, however, describes intangible assets from a harmonizing perspective. “Goodwill, in Commons’ schema, is an intangible phenomenon which harmonizes opposing interests in market exchange. It is the social

psychology of the market.” (Enders 1985, p. 683) Buyers and sellers involved in market exchange seek to reduce uncertainty – for sellers, it is the uncertainty that they will not be able to sell output at a going concern price whereas for buyers it is the uncertainty as to the quality of the product they receive. Goodwill – and to a larger extent, intangible assets in general – “is liberty to go elsewhere.” (Commons 1924, p. 272) In true bargaining transactions, with multiple buyers and sellers, goodwill reflects the fact that consumers choose not to shop elsewhere, despite the higher price. Unlike Veblen’s theory, Commons’ theory of intangible assets is not exploitative, but arises out of the customary relations that give security to the buyers in terms of quality and the seller in terms of a consumer base.

In the first degree of separation, intangible assets serve two important functions. First, as explained by Veblen, they lock the community out from using its socially created joint stock of knowledge. This forces those who do not own to engage in bargaining transactions with those who do. Within handicraft and early industrial modes of production, when the survival of the going plant depends upon ongoing monetary production, patents, goodwill, and trademarks deriving from ownership over portions of the joint stock of knowledge are necessary for the creation of these bargaining transactions.

Second, goodwill in the form of customary relations between buyers and sellers are integral in allowing the enterprise to maintain such transactions. By forming these relations, the going concern is able to engage in economic activity with some degree of certainty as to the ability to reproduce itself. It does not need to seek out a consumer

base; it has one ready-made. Further, by virtue of good repute or good location, the enterprise is able to charge a higher price; buyers are willing to pay this price for the certainty of a particular quality and ease of obtaining the product.

Intangible assets in the first degree of separation influence the distribution of output, with the owners of such assets having a greater claim on the social surplus than those who do not. This is true regardless of social class – a capitalist with goodwill is able to appropriate a greater portion of output than one without it (Resnick & Wolff 1989). This is different in the second degree of separation where intangible assets come to influence economic activity by affecting the overall supply of output; they create rationing transactions that limit the number of sellers of a given product.

Intangible Assets in the Second Degree of Separation

For the going plant to survive, it must engage in ongoing monetary transactions *via* the going business side of the going concern. In the first degree of separation, intangible assets are used to satisfy this need through control over bargaining transactions. As industrial production grows larger and the ability to produce enough output to satisfy all members of society is no longer in question, the business enterprise's main concern is ensuring the price paid for output is sufficient to allow the enterprise to reproduce itself (Veblen 1921). Thus, the activities of the enterprise emphasizing the generation and maintenance of these monetary transactions become separated into their own unit apart from the going plant. This separation between the

going business and the going plant constitutes the second degree of separation¹⁸ (Dean 2013). With this separation, the methods through which the enterprise maintains itself as a going concern change. Goodwill, patents, copyrights, brand names, production secrets, and the like now represent the ability for the enterprise to prevent competing producers from engaging in bargaining transactions with consumers.

While intangible assets in the first degree of separation give enterprises a differential advantage through their control over bargaining transactions, the additional advantage in the second degree is control over who may access a market. Put another way, while monopoly rights in the first degree of separation mandated the creation of bargaining transactions, in the second degree they reduce the number of sellers of a given product. Accordingly, they are what Hamilton (1943) termed “market equities.” A market equity is simply a right to access a market in which to sell output. Enterprise use intangible assets as a means to erect barriers to entry, thereby rationing the number of sellers.

Enterprises in the second degree of separation use intangible assets as a way to create rationing transactions with the community. Commons defines rationing transactions as “the negotiations of reaching an agreement among several participants who have the authority to apportion the benefits and burdens to members of a joint enterprise.” (Commons 1934, p. 68) Rationing transactions incorporate concepts from

¹⁸ In the second degree of separation, the going plant is composed of the physical embodiments of the community’s joint stock of knowledge while the going business is composed of the assets – both tangible and intangible – that give the enterprise ownership rights and claims to income streams. The going business interact with the going plant through managerial transactions, and therefore determines what will be produced and in what quantity (Commons 1924).

both managerial and bargaining transactions; they involve relations between legal superiors and legal inferiors while influencing the sphere of distribution (Atkinson 1987). The legal superior in a rationing transaction is able to dictate terms that specify an action space within which the legal inferior must remain. For example, market governance organizations may dictate a range of prices members of the organization must maintain for their output¹⁹ (Fligstein 2001; Lee 2013). The primary purpose of a rationing transaction is to define the parameters within which bargaining and managerial transactions may take place. In so doing, they shape the way in which output is distributed, given those parameters.

Intangible assets create rationing transactions in the second degree of separation by creating barriers to entry that limit the number of sellers of a particular product. These barriers may be customary or legal. Customary barriers to entry in the form of goodwill make it difficult for new companies to capture market share²⁰. An established company obtains a differential advantage not only because it has a guaranteed consumer base with whom they can continually engage in bargaining

¹⁹ This is an example of price rationing, a form of rationing transaction that leaves the output decision at the will of the seller, but the price decision is made by the authority. The reverse of this – output rationing – occurs when the quantity sold by a seller or group of sellers is defined, but the price may fluctuate (Commons 1934).

²⁰ Such relationships include both the relationship between buyers and sellers and relationships among the supply chain that create a set of network relations, making production easier for incumbents (Munkirs 1985).

transactions, but also because they do not fear these consumers leaving when new entrants arise²¹.

Legal barriers to entry take the form of patents, trademarks, brand names, copyrights, and government licenses, as well as other forms of legally binding agreements that limit the number of producers for a given market. Prices, output, and access to the market become the decisions of those who have the legal right to produce. For example, an enterprise with a patent that grants the exclusive right to produce a product becomes the gatekeeper of the market for that product. Those who wish to enter must first get permission in the form of a license from the patent holder, and those who produce without the license are vulnerable to lawsuits and other forms of legal action (Lichtenberg & Philipson 2002; Chein 2008-2009, 2010). This offers several advantages not granted to those enterprises without intangible assets. First, by reducing competition, owners of the intangible asset are able to enjoy a monopoly position and the advantages in production and distribution that come with it (Denicolo 2007); this is the primary effect of the rationing transaction created by intangible assets. The secondary effect, however, is that through licenses, owners of patents and copyrights are able to earn an extra income stream (Shapiro 2001; Bessen 2003; Choi 2003).

²¹ Veblen and Commons both stress the importance of maintaining goodwill as the primary concern of the owner (Veblen 1904; Commons 1924). While this is done in several ways – customer service, maintaining good reputation, etc. – the most important is advertising. Advertising allows the enterprise to both obtain a consumer base and increase the cost of entry; once one enterprise advertises its product, all are required to do so or face the loss of market share (Veblen 1904; Galbraith 1958; Eichner 1976).

Intangible assets in the second degree of separation grant a differential advantage through control over these rationing transactions²². Whereas intangible assets granted pecuniary returns to owners in the first degree of separation by allowing them to facilitate and control bargaining transactions, in the second degree the advantage is extended from the ability to limit the number of producers of a good. Not only are the owners able to increase expected returns, but they also have the option of garnering additional income through licenses of intellectual property. In addition, these barriers to entry have the ability to shield dominant enterprises from the possibility of creative destruction as described by Schumpeter (1942). With high barriers to entry, rather than fear that new entrants will erode their market share, core enterprises are able to control the conditions under which new enterprises enter the market, protecting their position²³.

Synthesis

From the discussion above, we may conclude that while Veblen and Commons have differences in terms of the origin and purpose of intangible assets, they are in agreement in terms of the effect on the business enterprise. For Veblen, intangible assets represent the ability for owners to “lock out” the general community from the

²² While Commons does not use rationing transactions in this way, the function of intangible assets in the second degree of separation is to limit the number of sellers of a product. In this manner, I am here extending the way in which rationing transactions are used in industrial production to capture the evolving nature of intangible assets from “locking out” to “limiting factor.”

²³ This is seen primarily in studies that put innovation into a network framework, as seen in Acs and Audretsch (1987); Carlsson (1989); Carlsson and Stankiewicz (1991); Orsenigo, Pammolli, and Riccabonie (2001); Acemoglu and Linn (2004); Acs and Sanders (2008), and Bergek et al. (2008).

joint stock of knowledge. The owner is granted a set of differential advantages resulting in income streams due to the creation and control over bargaining transactions in the first degree of separation and monopoly rights that allow the enterprise to erect barriers to entry to protect market shares in the second degree. In general, intangible assets are seen as emerging with the appropriation of the joint stock of knowledge and reflect control over social relations. In the case of legal monopoly rights, intangible assets reflect control over the relationship between the community and its joint stock of knowledge; in the case of customary relationships such as goodwill, they represent control over the relationship between buyer and seller.

For Commons, intangible assets emerge as a means to create a degree of stability within the transaction process. He views goodwill as the decision of the customer to give up their ability to go elsewhere when engaging in bargaining transactions. The differential advantage, then, arises as enterprises create customary relationships and the ability to induce the sale of liberty becomes recognized in higher prices for the product. Further, because the enterprise is able to charge a higher price, it reduces the uncertainty with regards to the ability of the enterprise to reproduce itself. Monopoly rights serve to create rationing in the second degree of separation by limiting the number of sellers of a particular product.

While Veblen and Commons differ in their views on the origins of intangible assets and whether they represent exploitative or harmonious processes, they are in agreement with regard to the effect on the business enterprise. In both theories, the primary function of an intangible asset is to grant the owner a differential advantage. In

the first degree of separation, this advantage emerges from the ability for the enterprise to control bargaining transactions by dictating access to the joint stock of knowledge and forming customary relations with consumers. In the second degree, these advantages are used to control the number of suppliers of a particular good, granting the enterprise control over the process of distribution. Intangible assets come to take the form of market equities in this stage, as they effectively grant the right to access a particular market. In general, both Veblen and Commons see intangible assets as necessary tools for ensuring the price at which output is sold is sufficient to reproduce the enterprise; in cases when it may not be, they then grant the enterprise the ability to fix the price by withholding output (Veblen 1904, 1921; Commons 1924, 1934).

It may be noted that within the first and second degree of separation, the ability for the enterprise to earn a profit revolves around its ability to sell output; intangible assets are useful to the enterprise insofar as they help facilitate this activity. The job of the owner/agent/manager, then, is to manage the differential advantage conferred so they do not lose it. However, as industrial production grows and the pecuniary mindset becomes dominant, the business enterprise becomes less concerned with the sale of output and more concerned with the value of the enterprise. In the next section, the way in which intangible assets affect the basis for capitalization of the going concern is examined.

Intangible Assets as the Basis for Capitalization

In the first degree of separation, intangible assets increase the pecuniary earning capacity for the business enterprise by assigning property rights over the joint stock of

knowledge. This enclosure of the knowledge base locks the greater part of the community out of the social provisioning process. To gain access, then, members of the community must engage in bargaining transactions with the owners. This is the Veblenian form of exploitation; the joint stock of knowledge is created by the community as a whole, but is owned or controlled by a few who use this position to extract payments, akin to rent payments as described by Ricardo (1817). In the second degree of separation, with the internal separation of the going business and the going plant within the going concern, intangible assets create a rationing transaction in terms of the number of sellers of a particular good. While the first degree was marked by small, petty traders and handicraft production in which firms relied upon gains from bargaining transactions to be viable, the second degree is marked by large scale production in which the focus for the enterprise is not simply the ability to sell output, but the ability to do so at a price that will ensure its viability. "Under the old regime of handicraft and petty trade, dearth (high prices) meant privation and might mean famine; under the new regime low prices commonly mean privation and may on occasion mean famine." (Veblen 1904, p. 177) The primary concern for the enterprise becomes obtaining a differential advantage that allows it to sell output at a going concern price (Langlois 1989; Lee 1998; Gu 2012). Intangible assets serve this role by granting monopoly rights to a particular seller. This may take the form of goodwill in the form of control over a particular location; or it may take the form of legal monopoly rights, such as a patent, over a portion of the production process or product itself. In

both cases, intangible assets limit the number of sellers, thereby abetting the survival of the concern.

As the business enterprise grows, it may begin to fund investment in industrial processes through the sale of stock or ownership claims on income. This creates a third degree of separation in which the owners of the concern – stockholders – are separated from the controllers – the managers (Veblen 1904, 1923; Berle & Means 1997; Lazonick & O’Sullivan 2000; Lazonick 2003; Dean 2013, 2015). These new types of stock issuances create a new category of property, referred to by Commons as “incorporeal property.” (1924, 1934) This type of property consists of “debts, credits, bonds, mortgages, in short of promises to pay.” (1924, p. 19) It represents the “expected fulfillment of promises which [others] have made to us.” (p. 28) Stock ownership grants with it a promise of payment, e.g., the distribution of profits *qua* earning capacity appropriated by the company. Insofar as this imposes a rationing transaction on the enterprise, the company must engage in transactions – primarily bargaining and managerial, but also rationing in some cases – in such a manner that meets the standards set by the shareholders as owners of the going concern.

It should be noted that this type of property has its root in tangible property, through the values of the two have become separate. As Commons explains

The investor, when selling that part of his liberty which consists in control over the purchasing power which had been his, accepts, in return a promise of future purchasing power, an encumbrance on the debtor or the going concern, and it is this investment encumbrance, or incorporeal property, that has emerged out of the primitive notion of holding physical things for one’s use (1924, p. 238).

The stockholder acquires the right to a share of the going concern's profits, meaning their primary concern is on the earning capacity of the enterprise. This depends on a number of variables beyond the going plant's productive capacity, including the power of the enterprise, the ability of the enterprise to maintain a going concern price, the rate of interest, and expectations towards the future valuation of the enterprise (Veblen 1904, 1921, 1923; Keynes 1926, 1936; Commons 1899-1900, 1934; Wray 1994; Atkinson & Oleson Jr. 1998).

The value of tangible property depends primarily on the internal activity of the going concern *via* the relationship between the going plant and the going business, as well as its ability to control the industry within which it produces and sells output. The value of incorporeal property, however, depends on both the value of the productive capital *and* the overall valuation of the enterprise, or its perceived earning capacity. The 1901 Report of the Industrial Commission found this to be the case, in that

Two general opinions regarding the basis of capitalization of companies and combinations are represented by witnesses: First, that the amount of capitalization should be limited by the actual value of the properties owned, or should at any rate bear some strict relation thereto; second, that the capitalization should be dependent on the earning capacity of the company. (United States Industrial Commission 1901, p. IX)

The first case describes the situation as outlined in the first and second degrees of separation when the value of the enterprise depends upon the ability to sell output. The second case describes the situation when the primary concern of the enterprise is its ability to generate a return to its absentee owners. Indeed, the report found that even those witnesses who preferred the first method of capitalization accepted the idea that

the value of common stock would be based on intangible assets – patents, trademarks, brands, and goodwill – which represent pure earning capacity. As the value of common stock represents the wealth of the absentee owners, it is in the interest of those owners to implement business strategies that swell the valuation of the company, regardless of the productive capacity. This strategy requires the use of intangible assets.

Lazonick (2005, p. 5) states that “A business model can be characterized by its *strategy*... its *finance*... and its *organization*.” Within the third degree of separation, there are two types of business models. In the first, consistent with Minsky’s (1996) “managerial capitalism” and Lazonick’s (2003, 2005) “Old Economy Business Model” (OEBM), management takes a leading role in directing the activities of the enterprise, giving rise to the Chandlerian-form of organization. “The power of the OEBM...[is] in the ability of already successful firms to routinize innovation and thereby to build on their superior capabilities in existing product markets to move into new product markets.” (Lazonick 2005, p. 5; see also Schumpeter 1942; Penrose 1959; Chandler 1962, 2005; and Galbraith 1967). In this form, management dictates long-term strategy goals, including which products to produce and which industries to branch into, and the structure of the industry emerged out of these goal (Chandler 1962). Activity is financed primarily through retained earnings from selling output (Lee 1998; Hall, Walsh, & Yates 2000).

With the highly specified nature of technology and the necessary interlinkages involved in industrial production, industry becomes more concentrated in the OEBM, with the decisions of managers *de facto* deciding the course of industrial activity.

Munkirs' theory of centralized private sector planning illustrates this concept in which economic activity is dictated by a small group of firms whose stock ownership, bond ownership, inter- and intra-locked boards of directors, and intraindustry interlocks gives them control over the larger portion of the provisioning process (Veblen 1921; Galbraith 1967; Munkirs 1985; Munkirs & Sturgeon 1985; Munkirs & Knoedler 1987). Due to the monopoly-like nature of these enterprises, intangible assets function in a similar manner as they do in the second degree of separation – maintaining going concern prices and generating earnings. The primary difference is that rather than earnings being kept within the enterprise, they are distributed to shareholders in the form of dividend payments and swell the value of the stockowners' incorporeal property. Prices, then, are no longer going concern prices; they must also ensure a satisfactory return to shareholders (Hilferding 1910). This creates a conflict between managers concerned with the long-term viability of the enterprise and the shareholders concerned with their immediate return (Marglin 1974; Moss 1981; Herman 1981; Jo & Henry 2015).

The second type of business organization under the third degree of separation is referred to by Lazonick (2003, 2005, 2008, 2010a) as the “New Economy Business Model” (NEBM), consistent with Minsky's (1996) “finance capitalism” in the pre-depression era and “money manager capitalism” in the modern era. Under this model, shareholders take a more active role in dictating the activity of the enterprise. While they are not involved in the day-to-day activities and decision-making, they impose their will on the enterprise, setting the parameters within which it may act. So long as

they receive the highest possible return, the enterprise may do as it pleases; in this way the shareholders and business enterprise interact through rationing transactions. This also has the effect of influencing the enterprise's strategy; while in managerial capitalism the focus was on increasing capacity through maintaining high prices based on differential advantages and industrial sabotage, finance capitalism and money manager capitalism in the NEBM are concerned with increasing the overall valuation of the company (Veblen 1921; Lazonick 2008; Jo & Henry 2015; Dean 2015).

The shift from the Old Economy to the New Economy begins in the 1980s with the financialization of the business enterprise in response to Japanese competition (Lazonick 2005, 2008). The shareholder revolution, beginning during the fourth U.S. merger wave, re-organized not only the business enterprise but also the business model (Black 2000; Stockhammer 2004; Serfati 2009). In the Old Economy, return to shareholders was a by-product of ensuring the enterprise maintained itself as a going concern. In the New Economy, the opposite is true; return to shareholders is the primary focus, with the viability of the business enterprise secondary. Before this shift could occur, manager and shareholder interests had to be brought into alignment. This was achieved by offering top executives stock options as compensation – in order for the manager to increase their pay, the stock price had to increase (Lazonick & O'Sullivan 2000; O'Sullivan 2003; Lazonick 2010b). As shown by Hall and Leibman (1998) and Lazonick (2005), stock options increased from 19% of executive compensation in 1980 to 48% in 1994, while the mean value of stock options increased 684% - from \$153,037 to \$1,213,180 – and salary and bonus compensation increased 95% - \$654,935 to

\$1,292,290²⁴. Further, dividend payouts “increased by an annual average of 10.8% while after-tax corporate profits increased by an annual average of 8.7%. In the 1990s these figures were 8.0% for dividends and 8.1% for profits.” (Lazonick 2008, p. 483-484) Recent data supports this trend as well. From 2003 to 2008 the annual real dividend per share for S&P 500 companies increased by an annual average of 8.15% and since the Great Recession – from 2011 to 2014 – dividend payouts have increased 11.71% per year (Standard & Poor’s 2015). This data may be found in Table 2.2 and Figure 2.1. After-tax corporate profits – shown in Table 2.3 and Figure 2.2 – from 2003 through 2014, even when taking the Great Recession into consideration, increased on average 9.04% (St. Louis Federal Reserve Economic Database 2015).

By offering stock-based compensation, managers implemented strategies designed to increase the value of the company’s stock. While greenfield investment²⁵ continued to be largely financed with internal funds (Harcourt & Kenyon 1976; Nitzan & Bichler 2009; Dzarasov 2011), mergers, acquisitions, and stock-buy backs – none of which increase the productive capacity of the economy, but influence the valuation of the corporation – were undertaken using either external funds or stock as currency (Minsky 1986; Nitzan & Bichler 2009; Lazonick 2008, 2010). The role of stock in the New Economy Business Model has changed from being a way to finance *industrial*

²⁴ Another such factor that may have caused executive compensation to increase was making such information public. Executives began competing for higher compensation than their competitors, a form of pecuniary emulation that put upward pressure on executive salaries (Johnson & Kwak 2010).

²⁵ Greenfield investment is defined as investments in the productive capacity of an enterprise, such as building *new* plants as opposed to purchasing already existing plants (Nitzan & Bichler 2009; Scheibl & Wood 2005).

Table 2.2: Real Dividend Per Share for Standard and Poor 500 Firms, 2003-2008

Year	Real Dividend Per Share
2003	\$21.23
2004	\$23.37
2005	\$25.44
2006	\$27.71
2007	\$30.11
2008	\$31.37
2009	\$27.94
2010	\$24.15
2011	\$25.84
2012	\$29.64
2013	\$33.95
2014	\$37.54

Source: Standard and Poor's 500 (2015)

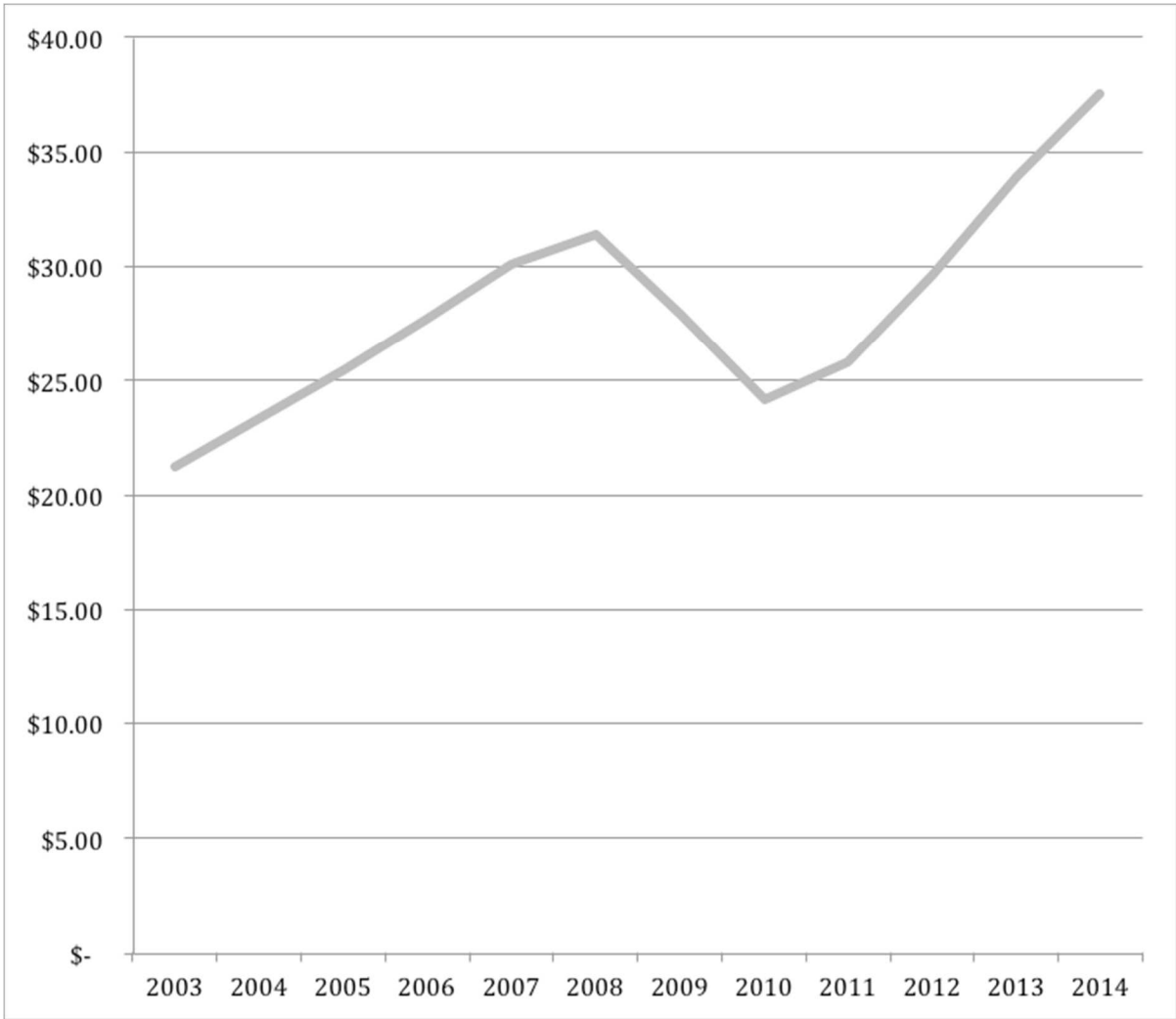


Figure 2.1: Real Dividend Per Share for Standard & Poor's 500 Firms, 2003-2008 (Standard & Poor's 2015)

Table 2.3: After Tax Corporate Profits, 2003-2014, Billions of Dollars

Year	After Tax Profit
2003	725.7
2004	948.5
2005	1,240.9
2006	1,378.1
2007	1,302.9
2008	1,073.3
2009	1,203.1
2010	1,470.2
2011	1,427.7
2012	1,683.2
2013	1,692.8
2014	1,693.9

Source: St. Louis Federal Reserve Economic Database (2015)

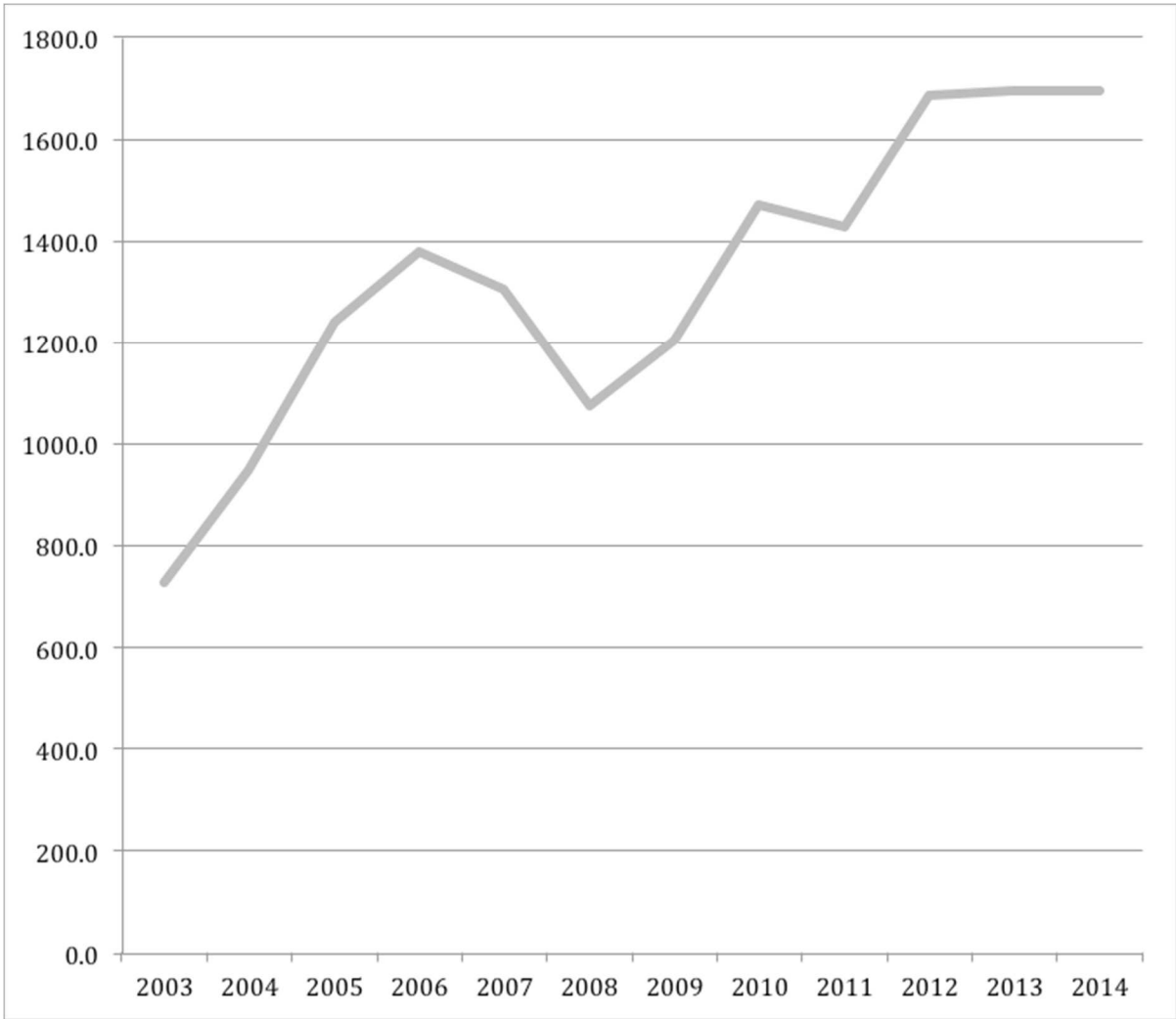


Figure 2.2: After Tax Corporate Profits, 2003-2014, Billions of Dollars (St. Louis Federal Reserve Economic Database 2015)

activity to being a way to finance *business* activity. Lazonick and O'Sullivan (2004) and Lazonick (2008) describe five key functions of corporate stock in this new organization:

1. *Creation*, whereby stocks act as tradable securities to allow financiers to withdraw their ownership of new enterprises they have helped create (see also Hilferding 1910).
2. *Control*, whereby stockholders can influence the concentration of ownership, which may influence the relationship between owners and controllers.
3. *Combination*, whereby stocks can act as an exchange currency in the process of acquiring or merging with other enterprises, as seen in stock-swap mergers.
4. *Compensation*, whereby the motives of controllers may be brought in line with the owners by offering stock options as compensation.
5. *Cash*, whereby stock can be used to raise liquidity to finance various types of business activity.

Thus, while the value of the incorporeal property issued by the enterprise is separate from the value of the productive capacity, it acts as an important asset for businesses in their endeavor to increase the valuation of the enterprise as a whole.

Intangible assets increase the value of this incorporeal property through several means, but most important is their classification as an asset. First, all benefits from the first and second degrees of separation remain in that the intangible asset allows the enterprise to privatize the communal knowledge stock, thus creating monopoly power and allowing the enterprise to collect rent payments. Second, with the financialization of economic activity, intangible assets form the basis for the valuation of the enterprise.

Financialization refers to “a pattern of accumulation in which profits accrue primarily through financial channels rather than through trade and commodity production.” (Krippner 2005, p. 174)²⁶ In this era, the business enterprise organizes itself in the form of a Transnational Corporation, which is

an *institutional* sector, made up of firms whose business is based on financial activity... However it is also a *functional* process through which money becomes capital for its owner thanks to its advance as property claims and loans. In contemporary capitalism, this functional opportunity... is offered to industrial groups through the holding of financial assets or other rent-generating assets, which with regards to this opportunity can be considered as components of finance capital. (Serfati 2008, p. 40, emphasis in original)

For the transnational corporation, intangible assets capture value through control of social relations, and because of their importance in increasing earning capacity, “intangible assets are now said to have supplanted tangible assets as the key value drivers in the economy.” (Serfati 2008, p. 45) Intangible assets have transformed from increasing earnings through control over the buyer-seller relationship to increasing earnings by increasing the asset base of the enterprise out of which incorporeal property may be issued. The greater the value of the asset-base, the better the ability of the enterprise to expand and increase the value of its incorporeal property.

²⁶ Jo and Henry (2015) identify seven primary features to financialization. These are, in brief: the corporatization of the enterprise in a joint-stock company; absentee ownership, primarily by banks and insurance companies; the use of rationing transactions to dictate economic activity; maximization of the value of incorporeal property as the primary goal of enterprise activity; mergers and acquisitions as the common method of increasing the value of the enterprise, driven by speculation; stock-based compensation for executives; and the sacrifice of productive capacity in favor of pecuniary returns. For more, see also Whalen (2002), Medlen (2003), Wray (2007), and McCarthy (2013).

Further, the transnational corporation is composed of subsidiaries that carry out the activities of the business enterprise. These subsidiaries, termed Special Purpose Entities (SPE) by Serfati (2008), have several obligations. With specific regards to intangible assets, they

have been given ownership of intellectual property rights by their parent companies and collect income in the form of royalties or as fees on (sub)licenses. Clearly, the creation of such financial entities makes transactions in intellectual property (e.g. R&D) and related incomes widely unknown from statisticians in charge of presenting national accounts (Serfati 2008, p. 43)

The SPE, in this structure, is responsible for the appropriation of social knowledge in the form of patent rights; however, rather than use this knowledge for the creation of output, they license it to the transnational corporation, who pays a licensing fee and royalty for access to the knowledge. These payments to the SPE, however, are insignificant in comparison to the potential returns from monopoly sales and the increase in capitalization. From the perspective of the transnational corporation, the threat of creative destruction is not problematic as innovation is conducted through licenses in a manner that reinforces the dominance of the enterprise²⁷.

Intangible assets allow the enterprise to increase the valuation of the company in two ways. First, the differential advantage conferred by such assets during the first degree of separation increases the asset base, which may then be capitalized upon in

²⁷ This discussion of the Transnational Corporation will be revisited in the next two chapters with application to the pharmaceutical industry and the Pfizer Corporation. Specifically, the focus will be on the core pharmaceutical companies who direct the activities of the industry and the relationship of the periphery – composed of the SPEs – that carry out commands.

the form of stock issuances or other forms of incorporeal property. This process of valuation and re-valuation becomes the main goal of the enterprise management seeking to increase shareholder value, as the intangible assets must be re-valued at increasingly higher rates for the enterprise to maintain itself as a going concern (Jo & Henry 2015). Indeed, as pointed out by Veblen (1904), Keynes (1936), and Minsky (1975, 1986), when the company re-values its assets²⁸ at a lower level – or even at a less than expected increase – it may cause shareholders to panic and lead to a sell-off, potentially ending in a deep and prolonged recession. Mergers and acquisition are important in this stage as they allow the enterprise to swell the value of its goodwill through acquisition (Zeff 1999, 2005).

A second function of intangible assets in the third degree of separation affects the enterprises' access to external finance. When acquiring loans, the enterprise may use such assets as collateral, allowing them to increase the amount of external finance available for financial maneuverings such as stock buy-backs and acquisitions. Between 2009 and 2014, for example, 14.63% of JP Morgan's loans were made using patents and applications as collateral. This was also true of Bank of America (14.06% of loans), Citigroup (10.39%), and Wells Fargo (9.81%), as well as others (Ellis 2015). Increasing the availability of external financing, while not directly increasing earning capacity, makes such manipulations easier, and is therefore a form of differential advantage. Intangible assets also have the effect of reducing borrowing costs, making it cheaper to

²⁸ Goodwill, for example, must be tested at the end of each year to check for impairment. If goodwill is impaired, this represents a decrease in value since the time of purchase, and if this impairment is large enough, it may have significant impact on the value of the company's asset base (KPMG 2014)

issue incorporeal property. Levitas and McFayden (2009) found that “enterprises mitigate the costs associated with raising cash through external capital markets by reducing knowledge asymmetries through highly valued patenting activities.” (p. 675) Intangible assets – particularly intellectual property rights – are useful tools in raising external funds by signaling to lenders that the enterprise is a successful innovator and worthy of financing at a lower cost; this is a form of business goodwill, as described above by Commons.

When management and control of the enterprise have been separated from ownership, intangible assets take on the additional role of providing the basis for capitalization and expansion of incorporeal property²⁹. In money manager capitalism and the NEBM, managerial and absentee owner goals are brought in-line by providing stock-based compensation to executives, resolving the conflict between the two groups that existed during managerial capitalism and the OEBM. Strategy, then, emphasizes increasing stock prices and the value of such property, with intangible assets serving two important functions. First, the greater the value of intangible assets, the better able the enterprise is to expand the volume and value of incorporeal property. Second, through their use as collateral and signaling mechanisms, intangible assets make external financing more available and cheaper. This cheaper and easier financing is used to acquire and merge with other companies and repurchase stocks, which have the

²⁹ While it is true that intangible assets increase the basis for valuation in earlier degrees of separation that may be used to expand debt financing, it is under finance and money manager capitalism with absentee ownership that they become the primary focus of management to increase the value of shares for absentee owners.

effect of increasing the valuation of the enterprise. While such actions benefit the owner through increased returns, they do not affect the technological capability for the community to provision itself and as such have little benefit to the greater society; they influence the distribution of output and claims to the social surplus, rather than produce it³⁰.

Conclusion

This chapter has examined the changing ways in which intangible assets have been used by the going concern within the context of the degrees of separation described by Dean (2013). In the first degree, intangible assets give the enterprise property rights over the community's knowledge stock allowing them to dictate access. This type of control takes the form of monetary bargaining transactions, thus generating pecuniary earnings. In the second degree, intangible assets allow the enterprise to engage in rationing transactions with one another, limiting the number of sellers of a particular good. This generation of monopoly and oligopoly power allows the enterprise to increase earning capacity through reductions in competition. Finally, in the third degree, intangible assets form the basis for capitalization and allow the

³⁰ From an economy-wide standpoint, mergers and acquisitions influence the distribution of output, not the capacity to produce; they influence differential *depth* not *breadth* (Nitzan 1998, 2001; Nitzan & Bichler 2009). From an industry wide perspective, while mergers and acquisitions may allow for more efficient production through scale and scope effect, empirical evidence from the pharmaceutical industry – discussed in a later chapter – shows that such activities are primarily focused on the accumulation of intangible assets, while tangible assets are divested when the enterprise encounters difficulty. This result reflects that transition from the OEBM to the NEBM and, more generally, the financialization of the economy (Papadimitriou & Wray 1997; Lazonick & O'Sullivan 2000; Lazonick 2010a; Lazonick & Tulum 2011).

enterprise to increase the issuance of incorporeal property. In doing so, higher returns to the absentee owners are achieved.

The value of intangible assets from a bookkeeping perspective is derived in two ways. First, goodwill reflects customary relationships, or the ability for the enterprise to engage in ongoing bargaining transactions with consumers. Goodwill management under managerial capitalism becomes the primary focus for the enterprise, as it allows it to obtain a differential advantage. Under money manager capitalism, goodwill is accounted for as the difference between acquisition value and book value when one company acquires another. The emphasis is now on mergers and acquisitions as a part of business strategy to increase the volume of intangible assets. Second, patents and other forms of intellectual property rights reflect the ability for the enterprise to appropriate communally created knowledge, and earn an income stream based on this appropriation. Under the first and second degree of separation, this income stream results from the enterprises' ability to swell the volume of sales. Under the third degree of separation, this income stream comes from the ability to increase the value of incorporeal property held by absentee owners and the easier access to external funds from financial markets.

With the emphasis on increasing earnings *qua* increasing capitalization in the NEBM, the function of intangible assets has changed. Where once the focus was on acquiring monopoly power for the purpose of selling output at a going concern price, the new focus is on increasing earning capacity for the purpose of increasing the valuation of the company. The following chapters present a modified version of the

structure-conduct-performance model of the pharmaceutical industry designed to capture this change in business models.

CHAPTER 3

STRUCTURE AND PERFORMANCE OF THE PHARMACEUTICAL INDUSTRY: AN ORIGINAL INSTITUTIONAL ECONOMICS PERSPECTIVE

Introduction

This and the following chapter present a modified version of the structure-conduct-performance model for the pharmaceutical industry designed to capture the change in business models discussed in the previous chapter. In this model¹, the market structure emerges out of basic market conditions. This structure then defines the conduct and performance of the industry. Firm conduct influences the structure, as in the case of mergers and acquisitions. Performance can affect both the conduct and structure; for example, firms that are more profitable or have higher earning capacity may be able to engage in different activities than those with lower earning capacity, while lower performing firms may exit the market influencing the overall structure (Church & Ware 2000). Government policies, further, may affect the structure, conduct, and performance of the industry, and must be taken into consideration when examining any industry (Waldman & Jensen 2013).

The main modifications to the SCP model reflect the structure of the transnational corporation at the core of the industry, the importance of mergers and acquisitions as strategic tools to increase earning capacity, and the return to shareholders as the main measurement for performance. From a structural standpoint, the neoclassical view of market structure from the framework of monopoly and

¹ See Figure 3.1

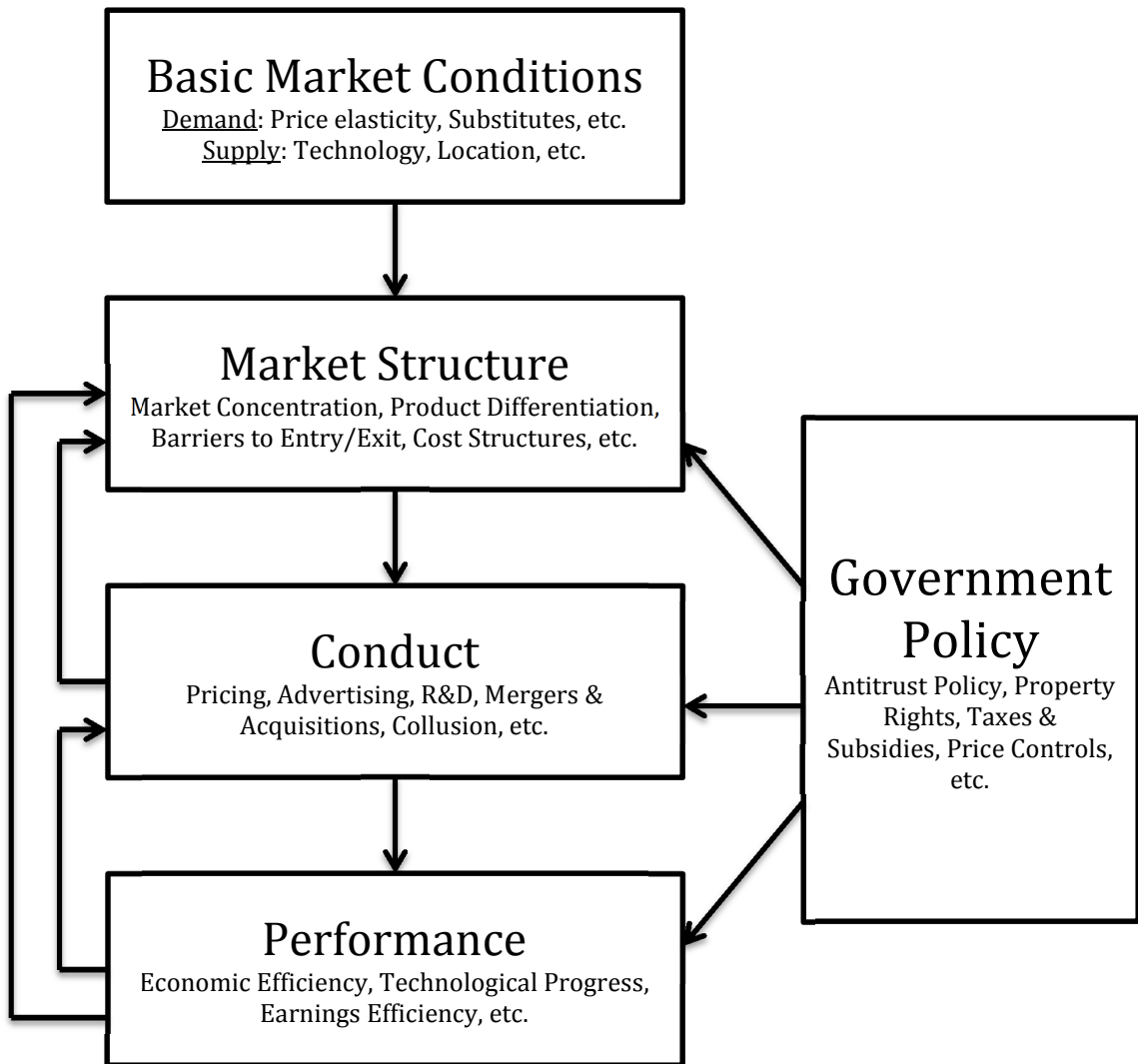


Figure 3.1: Standard Structure-Conduct-Performance Model of Industrial Organization (Modified from Waldman & Jensen 2013)

imperfect competition, measured in terms of the Lerner Index² (Lerner 1934), are no longer accurate. Rather, due to the power of the transnational corporation and the emphasis on special purpose entities to carry out strategic decisions, industry may be seen as structured around a core that dictates the course of action for the industry as a whole, and a supporting nexus that carries out commands (Galbraith 1967; Munkirs 1985; Munkirs & Knoedler 1986; Fligstein 2001; Chandler 2005; Gagnon 2009).

When discussing industry conduct, pricing decisions are less important in the NEBM than mergers and acquisitions. If the return to shareholders depends upon a company's earning capacity *qua* capitalization of the company, then the ability to sell output at a particular going concern price is less important than the ability to increase the company's valuation through merger policies. In the following chapter, I discuss mergers and acquisitions as the main conduct focus and how such activity increases the valuation of the enterprise through increasing the value of intangible assets.

In understanding performance, there are several key measures I use, each reflecting the strategy of the business enterprise in the different degrees of separation. To measure performance in the third degree, I focus on measurements concerning return to shareholders. This is similar to the approach taken by agency theories of

² The Lerner Index is a way to measure the degree of monopoly power for an industry by relating the price to the marginal cost. It is calculated as:

$$Lerner\ Index = \frac{P - MC}{P} = \frac{1}{|\mathcal{E}_D|}$$

where \mathcal{E}_D is the elasticity of demand, P is the firm's price, and MC is the firm's marginal cost. The more inelastic demand faced by the firm, the greater the difference between price and marginal cost and the greater the Lerner Index, reflecting a higher degree of monopoly power.

industrial organization, which posit “that in the governance of corporations, shareholders [are] the principals and managers [are] their agents.” (Lazonick & O’Sullivan 2000, p. 16) In this view, the maximization of shareholder value is a proxy for economic performance:

Since in the modern corporation, with its publicly listed stock, these shareholders have a market relation with the corporation, the economic argument for making distributions to shareholders is an argument concerning the efficiency of the replacement of corporate control over the allocation of resources and returns with market control. (Lazonick & O’Sullivan 2000, p. 28)

A firm that does not efficiently allocate its resources – real, financial, human, managerial, etc. – will not be maximizing returns to shareholders. Shareholders, as the residual claimants to a firm’s earnings, bear the most risk in terms of innovative activities and investment. Therefore, if the firm is not maximizing their return, they will choose to shift their control to firms that aim to maximize shareholder value through the efficient allocation of resources (Ross 1973; Jensen & Meckling 1976; Fama & Jensen 1983; Jensen 1986).

I make no claim here that financial performance and economic performance are equivalent. First, agency theories ignore the ways in which workers are residual claimants due to their investments in enterprise-specific “human capital”³. Second, stocks in the NEBM are rarely used to finance enterprise activity, but more often as currency for mergers and acquisitions to redistribute corporate revenues from Labor to capital (Lazonick 2008, 2010; Serfati 2009; Reuss 2012). Just as Adelman (1951) and

³ The notion of human capital is admittedly problematic, but will not be discussed here. For more, see Shaikh (1987) and Fine (2010).

Sylos-Labini (1969) demonstrate the difference between economic concentration and financial concentration, there is a difference between economic performance and financial performance. From an OIE perspective, economic performance emphasizes the ability for the community to reproduce itself through the instrumental use of its technological know-how in a non-invidious manner⁴ (Veblen 1914, 1921; Foster 1981e). Financial performance, captured in the return to shareholders, emphasizes the ability for an enterprise to reproduce itself through its capture of the joint stock of knowledge *qua* intangible assets; it is a fundamentally ceremonial measurement (Veblen 1899b, 1904, 1908b; Foster 1981e; Bush 1987; Tool 2000). The focus on increasing shareholder value is not due to desires for economic efficiency, but the rationing transactions imposed on the enterprise within the third degree of separation. My focus here is on this ceremonial measurement of performance, as it is in this measurement that intangible assets come to take a prominent role in maintaining the enterprise as a going concern.

Basic market conditions in the SCP model reflect the demand and supply side situations that influence the delivery of the product to consumers. In the pharmaceutical industry, the demand side issues include many complications beyond the health or income of the consumers. For example, generic pharmaceuticals provide a market for substitutes in which consumers may engage instead of brand-name medications (Steele 1962; Gagnon 2009, 2015). Public policy regarding the patent protection of pharmaceuticals and the availability of generics is an important factor in

⁴ This may be measured, e.g., through the availability of output to the greater portion of the population.

influencing the activity and financial performance of pharmaceutical companies. Another important demand side characteristic of pharmaceutical markets is the separation between the agent *choosing* the drug, the agent *consuming* the drug, and the agent *paying* for the drug. The demand side includes not only the consumer, but also the doctors, insurance companies, and HMOs. As Gagnon (2013) explains:

Pharmaceutical markets can be compared to a dinner for three: the first person orders the meal, the second person eats it, and the third one pays for it. While the third person might want to have a say about which meal is being ordered, the waiter is pretty aggressive in promoting the newest meals – which also happen to be the most expensive. (p. 573)

The demand conditions, then, include the connections between the patients, doctors, insurance companies, and pharmaceutical companies. The patient is not as knowledgeable as the doctor, and therefore is not the one deciding which drug to consume. The doctors, because they are not the one consuming or paying for the medication, do not have an incentive to prescribe the cheapest option (Steele 1964). Finally, the insurance company does not wish to pay for the higher-priced drugs. In many cases, managed healthcare organizations will attempt to negotiate discounts with drug companies or place limits on which drugs they will pay for to treat certain conditions (Scherer 1997; Levy 1999).

Supply side conditions of the pharmaceutical industry depend primarily on the ability for pharmaceutical companies to develop new medications. While the process of innovation in the pharmaceutical industry is largely beyond the scope of this dissertation, I will make it a point to examine the way in which these supply side

conditions influence firm behavior through mergers and acquisitions. A primary issue that will be discussed is the cost associated with FDA approval, and how government regulations with regards to drug approval have abetted in generating a core-nexus type of structure⁵ (Chandler 2001, 2005).

Outline

The rest of this chapter proceeds as follows. First, a discussion of several government policies that have had considerable consequences for the pharmaceutical industry is presented. The emphasis here is that government policy has real, lasting consequences on the pharmaceutical industry and influences primarily the conduct of the industry; these laws typically regulate the behavior of firms in terms of R&D and marketing. Second, a broad structural analysis of the industry is given, including the value of shipments, number of firms, concentration ratios, and Herfindahl-Hirschman Indices, before developing further the idea of the pharmaceutical core based on the work of Alfred Chandler (2005) and Marc-Andre Gagnon (2009). Finally, the chapter concludes with a discussion of the industry core's performance, measured in terms consistent with the degrees of separation. This will provide a good base for the next chapter's discussion of the Pfizer Corporation's history of mergers and acquisitions.

Government Regulation in the Pharmaceutical Industry

Regulation in the pharmaceutical industry has evolved over time in response to several events that necessitated changes in the legal structure. In some cases, regulations were implemented in response to tragedies; in others, they were the results

⁵ For a brief description of the FDA approval process, please see Appendix A

of technological developments; and in others still they were the results of philosophical changes regarding intellectual property rights and how they should be treated. In this section, I examine several major changes to the legal structure, beginning with the 1906 Pure Food and Drug Act and ending with the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

Though there had been other regulations regarding drugs, such as the short-lived 1813 Vaccine Act and the 1848 Drug Import Act, it was not until the turn of the century that drug regulation became a primary policy focus (Swann 1988, 2005). In 1906, Congress passed the Wiley Act, also known as the Pure Food and Drug Act. Prior to then, the pharmaceutical market was dominated by mislabeled medications, quacks, and in many cases, drugs that were well below standards or potentially dangerous (Parascandola 1990; Swann 2005). In response, Congress separated the Division of Chemistry from the Department of Agriculture into its own bureau – the Bureau of Chemistry – run by Harvey Wiley. The purpose of this bureau was to “devote attention to the assay and composition of drugs.” (Swann 2005, p. 2; see also Kebler 1940). The Drug Laboratory, a department within the Bureau of Chemistry, was created to fulfill this purpose. In charge of the Drug Laboratory was the chief chemist and SmithKline and French, Lyman Kebler (Miles 1976). While Kebler found many labeling problems, with reagents being labeled as chemically pure when they were nothing of the sort, the Bureau did not have the power to prosecute mislabeled medications until 1906 when the Pure Food and Drug Act was passed. This act gave the Bureau of Chemistry regulatory power regarding standards of identity, allowing them to “bring actions

against products whose strength, quality, or purity varied from the official standards for that drug.” (Swann 2005, p. 5) In 1927, the Bureau of Chemistry was split. The regulatory functions were spun off into the newly formed Food, Drug, and Insecticide Administration, while the non-regulatory functions joined the Bureau of Soils to create the Bureau of Chemistry and Soils (Temin 1979a; Swann 1988). In 1931, the administration was renamed the Food and Drug Administration.

In 1938, in the wake of the Elixir Sulfanilimide tragedy, Congress passed the Food, Drug, and Cosmetic Bill, expanding the regulatory powers of the FDA. In 1937, the S.E. Massengill Company sold a mixture of sulfanilamide dissolved in diethylene glycol to treat streptococcal infections. Previously sulfanilamide had been used in tablet and powder form, but a liquid preparation was requested for children. However,

The new formation had not been tested for toxicity. At the time the food and drug laws did not require that safety studies be done on new drugs. Selling toxic drugs was, undoubtedly, bad for business, but it was not illegal. Because no pharmacology studies had been done on the new sulfanilamide preparation [Chief Chemist and Pharmacist Harold Cole] Watkins failed to note... diethylene glycol, a chemical normally used as antifreeze, is a deadly poison. (Ballentine 1981, p. 18-19)

One hundred people died as a result. More so, the 1906 law did not give the power to prosecute Massengill for these deaths. Rather, the only punishment they could impose was for mislabeling the product; “Elixer’ was a term used to describe an alcohol solution, and it was misapplied to diethylene glycol.” (Temin 1979a, p. 69)

The 1938 Food, Drug, and Cosmetic bill rectified this problem in two fundamental ways. First, it required that manufacturers submit an application to the

FDA showing that the medication was safe for use prior to release. If the FDA did not act on the application within 60 days, the drug was automatically approved (Meadows 2006). Second, the act increased the amount of information required on the label. Drug labels now had to contain all ingredients and the quantity of each ingredient used, directions for use, and warnings about the danger of use.

There was one major exception to the labeling rule: any drug prescribed by a licensed physician, dentist, or veterinarian did not have to have the same labels. In doing so, the 1938 bill created a distinction between over-the-counter drugs and prescription drugs (Temin 1979a). Prior to then, the only drugs that required a prescription were narcotics, under the 1914 Harrison Narcotics Tax Act (Temin 1979b). To circumvent the labeling requirements, drug companies created a class of drugs that could only be sold using a prescription. As a result, the primary target for pharmaceutical marketers were no longer the consumers of the drugs, but the doctors who would prescribe them – and who did not have the same budget constraints as the consumers.

With doctors now the main intermediary between consumers and pharmaceutical companies – and the strong patent protection offered as part of the U.S. Constitution – drug prices began to rise. In 1961, the Subcommittee on Antitrust and Monopoly of the Senate Judiciary Committee released a report detailing studies of the ethical drug industries in which they found “unreasonably high” prices, monopolistic restriction of the market, abuses of the patent privilege, and excessive waste of resources in selling activity (Steele 1964). As part of measures to control costs under

state Medicaid plans and in response to growing consumer movements, states began repealing what were known as “anti-substitution laws.” In the 1950s, anti-substitution laws were enacted to prevent counterfeiting, where pharmacists would distribute drugs of the same size, color, and packaging to the brand name drugs, but unknown quality. These laws prevented any type of substitution for the brand given by the physician’s prescription (Grabowski & Vernon 1979).

Between 1961 and 1978, 40 states and the District of Columbia repealed the anti-substitution laws and introduced substitution laws (Grabowski 1978; Grabowski & Vernon 1979). While these laws varied, each of them had the same general guidelines: pharmacists were permitted to substitute generics or other less-costly medications for the brand-name medication, unless the physician specified “dispense as written” on the prescription (Grabowski & Vernon 1979; Suh 1999; Gagnon 2009). Subsequently, “generics, as a share of all prescriptions in the US, from 5% in 1965 to 9% in 1974 and 15% in 1983” (Gagnon 2009, p. 179-180; see also Redwood 1987) while prices fell (Giaccotto, Santerre, & Vernon 2005).

The next major regulatory change in the pharmaceutical industry came in response to the Thalidomide tragedy⁶, which struck several European countries, Canada, and Australia⁷ (Bren 2001). The 1962 amendments to the 1938 act – known

⁶ Thalidomide was used as a sleep aid, but was also prescribed off-label to help alleviate morning sickness. Children whose mothers took thalidomide were often born with serious and significant birth defects, most common of which was malformation of limbs (Bren 2001; Fintel, Samaras, & Carias 2009).

⁷ In the United States, FDA reviewer Frances Oldham Kelsey refused approval of the drug, stating more tests were necessary. While over 2.5 million tablets had been

asthe Kefauver-Harris Amendments – gave the FDA four new powers. First, and most importantly, they required firms to submit documented scientific evidence regarding not only the drug’s safety, but also the drug’s efficacy as shown by clinical trials (Meadows 2006; FDA 2012). Efficacy, as defined by the FDA, initially meant better than placebo, but over time came to mean better than existing alternatives (FDA 1998; Montalban & Sakinç 2013; Gagnon 2015). This ensured not only that the drugs being released were useful, but also reduced the number of “me-too” drugs, which represent a poor use of R&D resources and do not actually generate any price reductions⁸ (Hollis 2004; Gagnon 2009). Second, the amendments gave the FDA discretionary power over the clinical research process. “Prior to any testing in humans, firms must now submit a new drug investigational plan (IND) that provides the results of animal testing and plans for human testing.” (Grabowski, Vernon, & Thomas 1978, p. 137) Third, the FDA was given power over advertising claims as a means to prevent off-label use of medication. This inclusion was directly the result of thalidomide being used off-label by pregnant women to alleviate morning sickness (Fintel, Samara, & Carias 2009). Finally, the condition that allowed for automatic approval of a new drug application after 60 days without FDA action was removed (Grabowski, Vernon, & Thomas 1978).

distributed to 1,000 doctors as part of clinical testing, the United States more or less avoided widespread problems (Bren 2001). Only 17 children were born in the United States with complications from Thalidomide, compared to 10,000 in West Germany (Dove 2011; CBC News 2015).

⁸A “me-too” drug is a drug that offers no significant therapeutic advantage to an already existing drug and is often a follow-on. Any advantage is typically minimal and takes the form of a slight alteration to the drug to reduce certain side-effects or change the release time (Hollis 2004).

The impact of these two legal changes, the Kefauver-Harris Amendments and the introduction of substitution laws in various states, affected the pharmaceutical industry primarily in terms of the effective patent life of a medication. Though patents in the United States grant protection for 17 to 20 years, the drug is not marketed throughout this entire period, as drugs are patented prior to being approved by the FDA – typically once the compound is discovered. The effective patent life of a drug – the patent time remaining after being approved by the FDA – is much less than the actual patent. Grabowski and Vernon (1979) found that between 1966 and 1977, the effective life of the patent dropped slightly from 10 to 13 years to eight to nine years. Research by Grabowski, Vernon, and Thomas (1978), Peltzman (1973), and Baily (1972) also found that the Kefauver-Harris Amendments greatly influenced R&D activity in the industry, as they increased the cost of approval.

In response to these amendments, pharmaceutical enterprises adopted the “blockbuster” model of drug development, where firms developed drugs that could treat a large number of patients by treating broad illness categories, such as Lipitor for high cholesterol (Gagnon 2015). The blockbuster model resulted in a high level of concentration and the use of patents – despite reduced effective patent life – to increase prices. Steele (1962, 1964) found that the combination of patent protection and marketing to doctors more or less eliminated price competition. He also criticized the idea that patents were required to incentivize drug innovation, showing that

Between 1886 and 1962, 82 drug discoveries have been made in countries without product patents, compared with 79 in the United States, only 60 of which were found in the laboratories of drug firms. Fifteen were found in foreign

countries with drug patents. Hence, 75 drugs were found by American commercial firms in foreign countries with product patents, while 101 drugs have been found in countries without product patents, and by noncommercial American investigators. (Steele 1962, p. 50)

Patents, though they did not generate new drug discoveries, were very useful in organizing markets and protecting core producers. During this time, the 36 largest companies represented 95% of research activity and selling, but only 5% of the total number of firms in the industry (Schifrin 1967). Meanwhile, prices only fell when licensing agreements were violated, as shown in the cortisone agreements between Schering, Merck, Parke Davis, UpJohn, and Pfizer⁹ (Steele 1964).

In the 1980s, three new laws – the 1980 Bayh-Dole Act, the 1983 Orphan Drug Act, and the 1984 Hatch-Waxman Act – were passed that greatly influenced monopoly protection for pharmaceuticals. The Bayh-Dole Act of 1980 greatly expanded the limits of what could be protected by a patent. Prior to this act, research conducted with public funds could not be patented; the patent was seen as an incentive to devote private funds to knowledge creation, and with no private funds at risk, there was no reason for patents to be awarded. This act reflected a philosophical change in the role of the patent – rather than protect the *creation* of new knowledge, the patent was seen as incentivizing the *commercialization* of that knowledge, or the transformation of knowledge into a commodity (Mazzoleni & Nelson 1998; Acs & Sanders 2008). The

⁹ Merck, UpJohn, Parke Davis, and Pfizer each agreed on a cross-licensing arrangement, with Schering to pay 3% of sales for three years to produce prednisone and prednisolone and to market it in its finished dosage form. Merck and Pfizer violated this agreement and began making bulk sales, leading to a drop in prices. Schering took no action, as the sales part of the agreement was not legally enforceable (Steele 1964).

Bayh-Dole act allowed for research conducted with funds received from a federal contract, grant, or cooperative agreement with a non-profit organization to be patented, regardless of whether the work was fully or partially funded. The result of this law was the creation of the biotechnology industry out of the university laboratories and other public institutions conducting research with public funds. This new industry became the primary component of the supporting nexus for the pharmaceutical industry due to its new paths of learning in biology, genomics, and biochemistry (Chisum et al. 2004; Chandler 2005; Gagnon 2009).

In 1983, the intellectual property of pharmaceutical companies was further strengthened. To counter the perceived problem with the “blockbuster” model of pharmaceutical research – the lack of treatments and cures for diseases that did not affect large portions of the population – Congress passed the Orphan Drug Act. To qualify for Orphan Drug Status, a drug must be produced for the treatment of any rare disease, or a condition that affects fewer than 200,000 people in the United States. Firms producing drugs that qualify for this special status receive seven years of marketing exclusivity, an expedited approval process, various tax cuts, and research assistance so as to alleviate the high costs of drug research and development that resulted from the Kefauver-Harris Amendments (Simoens 2011; Côte & Keating 2012; Gagnon 2015). Between 1983 and 2010, 353 drugs received Orphan Status from the FDA in the United States, 75% of which were treatments for cancer, metabolic disorders, blood disorders, infectious diseases, and neurological disorders (Haffner, Whitley, & Moss 2002; Cheung, Cohen, & Illingworth 2004; Côte & Keating 2012).

The main effect of this act, however, has been to increase the returns to pharmaceutical companies. One issue has been “salami slicing”, where firms resubmit the same drug for FDA approval, but to treat a different rare disease. Based on work by Côte and Keating (2012), I compiled a list of drugs that obtained more than one orphan designation while having sales of over \$100 million in 2008, found in Table 3.1¹⁰. This ability to extend control over a particular drug has led to the development of what Montalban and Sakinç (2013) and Gagnon (2015) call the “nichebuster” model: drugs are developed for the purpose of treating orphan diseases, and then resubmitted for approval to maintain their orphan status. Further, these drugs have not shown to provide significant benefits, most commonly with regards to cancer treatment. “Most new niche drugs often provide only marginal therapeutic benefits. In oncology for example, they sometimes prolong survival by only a few weeks, but provoke serious adverse effects and can cost more than \$100,000 per patient per year.” (Gagnon 2015, p. 457; see also Fojo & Grady 2009)

In 1984, to increase the entry of generic drugs in pharmaceutical markets, Congress passed the Hatch-Waxman Act. This law came out of a patent infringement case between Roche and Bolar. Bolar wanted permission to develop a generic version of Roche’s drug Dalmane, but would not have been able to begin the approval process until expiration; because the approval process could take years to complete, they argued that the existing law unjustly extended the life of Roche’s patent. While the

¹⁰ For instances in which the current marketer is a subsidiary, the parent company is given. If the drug is being co-marketed, both companies are given.

Table 3.1: Drugs Having At Least Two Orphan Designations With Over \$100 Million Sales (2008)

Trade Name	Generic Name	Current Marketer	Number of Designations
Humira	Adalimumab	AbbVie	2
Fosamax	Alendronate	Merck	2
Ceredase	Alglucerase	Sanofi*	2
Avastin	Bevacizumab	Genentech	4
Velcade	Bortezomib	Takeda Pharmaceuticals*	2
Tracleer	Bosentan	Actelion Pharmaceuticals	2
Botox	Botulinum Toxin	Allergan	4
Novoseven	Coagulation Factor	Novo Nordisk	10
Epogen	Epoetin Alfa	Amgen	2
Procrit	Epoetin Alfa	Amgen	3
Enbrel	Etanercept	Amgen	2
Neupogen	Filgrastim	Amgen	6
Copaxone	Glatiramer Acetate	Teva Pharmaceuticals	2
Gleevec	Imatinib	Novartis	7
Remicade	Infliximab	Johnson & Johnson*	6
Betaseron	Interferon	Bayer Healthcare	2
Avonex	Interferon	Biogen	2
Rebif	Interferon	Merck*	2
Revlimid	Lenalidomide	Celgene	4
Sandostatin	Octreotide	Novartis	3
Kogenate	Octocog	Bayer	2
Pegasys	Peginterferon	Roche AG	2
Rituxan	Rituximab	Biogen & Genentech**	4
Prograf	Tacrolimus	Astellas Pharmaceuticals	2
Temodar	Temozolomide	Merck	2
AmBisome	Amphotericin B	Astellas Pharmaceuticals	3
Vidaza	Azacitidine	Celgene	2
Dysport	Botulinum Toxin A	Amgen	3

Table 3.1, Continued

Trade Name	Generic Name	Current Marketer	Number of Designations
Erbitux	Cetuximab	Bristol-Myers Squibb	2
Sprycel	Desatinib	Bristol-Myers Squib	2
Fludara	Fludarabine Phosphate	Sanofi*	2
Intron A	Interferon Alfa-2b	Merck	10
Humatrope	Somatropin	Eli Lilly	3
Genotropin	Somatropin	Pfizer	3
Nutropinaq	Somatropin	Novo Nordisk	5
Nexavar	Sorafenib	Bayer & Onyx Pharmaceuticals**	3
Thalomid	Thalidomide	Celgene	4
Tobi	Tobramycin	Novartis	2

*Parent Company

** Co-Marketed

Source: Modified from Côte and Keating (2012)

courts ultimately ruled in favor of Roche¹¹, Bolar lobbied Congress to change the law (Chisum et al. 2004). Companies that submitted generic medications to the FDA for approval were no longer required to go through the same clinical testing procedures as brand name drugs; rather, they only had to show bioequivalence. A streamlined application process for generics was also created, called the “abbreviated new drug application.” This not only reduced the costs of producing generics, it also made it possible for generics to be introduced much sooner than they otherwise would have been.

At the same time, the act allowed firms holding the expiring patent to file for an extension if they could show that the FDA delayed in the approval of the drug. In so doing,

The Hatch-Waxman Act struck a balance between the interests of patentees of brand-name pharmaceuticals and the generic pharmaceutical industry, as well as the interests of the general public in competitively priced pharmaceuticals. In short, the act was designed to promote technological innovation while, at the same time, enhance the public welfare. (Chisum et al. 2004, p. 1264-1265)

This law had the effect of simultaneously increasing both generic entry and patent protection. In 1983, the generic share of the prescription pharmaceutical market was 15%; this increased to 29% in 1988 and 50% in 2005. In terms of market value, this constituted an increase from 5% of the value of all prescriptions in 1983 up to 11% in 2004 (Suh 1999; Pharmaceutical Industry Competitiveness Task Force 2006; Gagnon

¹¹ The courts found that the FDA does not have the power to rewrite patent law, which is what they would have been doing in giving Bolar permission to begin the approval process prior to patent expiration.

2009). Concurrently, the effective patent life of a new drug increased; Grabowski and Vernon (2000) found that between 1984 and 1995, the effective patent life increased from 10.17 years to 11.38 years.

The last major legal change discussed in this dissertation occurred in 1995. While this change was neither the result of happenings in the pharmaceutical industry, nor did it target the industry directly, it has had extremely important effects and was primarily the result of industry lobbying. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was developed in 1995 at the World Trade Organization (WTO) and required all members to provide strong intellectual property protection, with that protection being standardized among WTO nations. In the case of the domestic pharmaceutical industry, the goal was for firms to be able to protect their patents abroad. The TRIPS agreement included patent rights for WTO member countries “without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.” (WTO 1995, p. 331) The agreement also included ways for nations to punish other members that violated the terms, ranging from “soft tools”, such as dialogue and persuasion, to more forceful coercion, such as suspension of trade or loss of membership (Drahos 2004).

The agreement can be traced back to executives from the Pfizer Corporation (Braithwaite & Drahos 2000) and emerged primarily out of the industry’s desire to protect the value of their intangible property¹². According to Helpman (1993),

¹² The TRIPS agreement was not the first time an international standard for intellectual property rights protection had been proposed. The United States, under pressure from the pharmaceutical industry, had pushed for stronger intellectual property protection

American firms lost \$2.3 billion in profits due to global intellectual property right infringements, but that the results of these infringements was a gain of \$3.6 billion in consumer surplus to both domestic and foreign consumers and firms. This is the primary reason why TRIPS has been criticized heavily: stronger intellectual property right protection on international levels has harmed lesser-developed countries in terms of R&D and product availability while increasing the benefits to the monopoly producers and their home nations (Helpman 1993; Adkisson 2002; Drahos 2004; Collins-Chase 2008; Sell 2009; Dean 2015). Further, the TRIPS agreement was passed in the middle of a global HIV/AIDS epidemic, and there was fear that the agreement would make it nearly impossible to get the necessary medication to the areas most harmed (Collins-Chase 2008; Emilio 2011). In response, the WTO declared in 2001 that member nations were encouraged to take necessary steps to provide for public health (World Trade Organization 2001). These necessary steps have included actions such as compulsory licensing and even the potential for claims of eminent domain (Adkisson 2002). Still, the overall effect of the TRIPS agreement has been to improve the strength of American intellectual property rights abroad, which has strongly benefitted the core of the pharmaceutical industry (Scherer 2013).

in several free trade agreements (Drahos 2004). In the mid-1980s, the United States shifted from the World Intellectual Property Organization to the General Agreement on Trade and Tariffs, finding that it could increase their odds of success in GATT by linking market access to intellectual property standards. At the same time, the United States pushed for stronger bilateral and regional trade agreements with high intellectual property standards, with policies to permit the imposition of sanctions on trade partners that violated American intellectual property rights (Sell 1998, 2009).

This section has examined the various legal changes to the pharmaceutical industry. The creation of the FDA and the granting of regulatory powers through the 1938 Food, Drug, and Cosmetics Act and the 1962 Kefauver-Harris Amendments meant that pharmaceutical companies were forced to alter their research, development, and marketing strategies to a “blockbuster” model. This change in firm conduct is also seen in the 1983 Orphan Drug Act, which has led to the development of the “nichebuster” model, as firms focus more resources on the development of drugs for the treatment of rare diseases. The removal of anti-substitution laws and the 1984 Hatch-Waxman Act all influenced the structure of the industry by making generic entry easier, providing competition in the market for prescription drugs. The 1980 Bayh-Dole Act also influenced the market structure and conduct by providing patent protection on publicly funded research; this led to the development of the biotechnology sector and strategic alliances between pharmaceutical and biotech companies for the purpose of researching, developing, and selling drugs. Finally, the three acts in the early 1980s along with the TRIPS agreement influenced the financial performance of pharmaceutical companies by strengthening patent protection.

The next section takes a more in-depth analysis of the pharmaceutical industry structure and, based on the concepts of the technostructure, organizational capabilities, and centralized private sector planning, focuses primarily on the pharmaceutical core and its role in the prescription drugs market (Galbraith 1967; Munkirs 1985; Munkirs & Knoedler 1987; Chandler 2005; Gagnon 2009).

Industry Structure

The pharmaceutical industry is composed of network relationships between enterprises within different industries. This network includes pharmaceutical manufacturing companies, biotechnology companies, university and private research laboratories, and chemical companies (Chandler 2005). Governments, further, give federal grants to many of these actors and impose regulations to restrict certain behaviors and set standards, which have effects on the industry structure.

This section examines the structure of the pharmaceutical industry from the perspective of the pharmaceutical core, which has the ability to direct the course of action for the industry as a whole. I begin with an overview of the basic measurements of industry structure – including the value of shipments; value of inventories; number of firms; concentration ratios at the 4, 8, 20, and 50 level (CR_N); and the Herfindahl-Hirschman Index (HHI)¹³ – and what they imply about the pharmaceutical industry as a whole. From here, I will examine the structure of the industry based on two paradigms that focus on the relationship between agents in the industry – Averitt’s dual economy in conjunction with Galbraith’s concept of the technostructure, and Munkirs’ theory of centralized private sector planning (Galbraith 1967; Averitt 1968; Munkirs 1985). In each of these theories, there is a separation between what might be labeled as the “core” of the industry, which directs the course of action, and the periphery or

¹³ Data on these basic measurements comes from the St. Louis Federal Reserve Economic Database (FRED) and the U.S. Economic Census. Data on the number of firms, concentration ratios, and Herfindahl-Hirschman Indices were taken at the four-digit SIC code prior to 1992 and the four digit NAICS code from 1992 forward. Herfindahl-Hirschman Indices were calculated using the 50 largest firms in the industry.

supporting nexus, which carries out actions as dictated by the core and provides support for core activities. This will give a much more detailed understanding as to industry structure and the power relations within the industry.

Concentration in the Pharmaceutical Industry

Traditional understandings of market structure begin with a discussion of industrial concentration. These views focus on attempting to place industries on the perfect competition/monopoly power spectrum. In industries with differentiated products, like the pharmaceutical industry, neoclassical economists have traditionally used market concentration as a proxy for market power (Waldman & Jensen 2013). The rationale behind this is that market concentration is directly related to the ability for an individual firm to influence market price and market output. However, there are other issues that may influence and generate market power. In the pharmaceutical industry, structure is better understood in terms of relationships between members of the industry core and a larger group of firms that make up the periphery. In this type of structure, economic activity, and more importantly the course of evolution of the industry, is largely dictated by the core with the periphery providing supporting functions.

Since the early 1990s, the pharmaceutical industry has experienced strong growth, as seen in Table 3.2 and Figure 3.2. Beginning in 1992 through 2014, the value of pharmaceutical manufacturing companies' inventories has more than tripled, from \$9.2 billion to \$31.2 billion. In terms of the value of manufacturers' shipments – the value of products sold – the industry has also experienced growth, increasing from \$6

**Table 3.2: Pharmaceutical Industry Value of Shipments and Value of Inventories
(Millions of Dollars, Seasonally Adjusted), 1992-2014**

Year	Value of Shipments	Value of Inventories
1992	\$6,009	\$9,153
1993	\$6,367	\$9,872
1994	\$6,700	\$10,274
1995	\$7,588	\$11,320
1996	\$7,987	\$11,797
1997	\$8,386	\$12,548
1998	\$9,704	\$14,127
1999	\$9,278	\$15,696
2000	\$11,378	\$17,818
2001	\$12,066	\$17,093
2002	\$13,050	\$17,928
2003	\$12,232	\$18,899
2004	\$13,436	\$20,786
2005	\$14,027	\$21,579
2006	\$14,741	\$24,794
2007	\$16,154	\$26,403
2008	\$16,894	\$26,659
2009	\$16,027	\$26,464
2010	\$15,821	\$30,193
2011	\$16,795	\$29,823
2012	\$15,485	\$31,314
2013	\$15,534	\$31,327
2014	\$15,012	\$31,192

Source: St. Louis Federal Reserve Economic Database (2015)

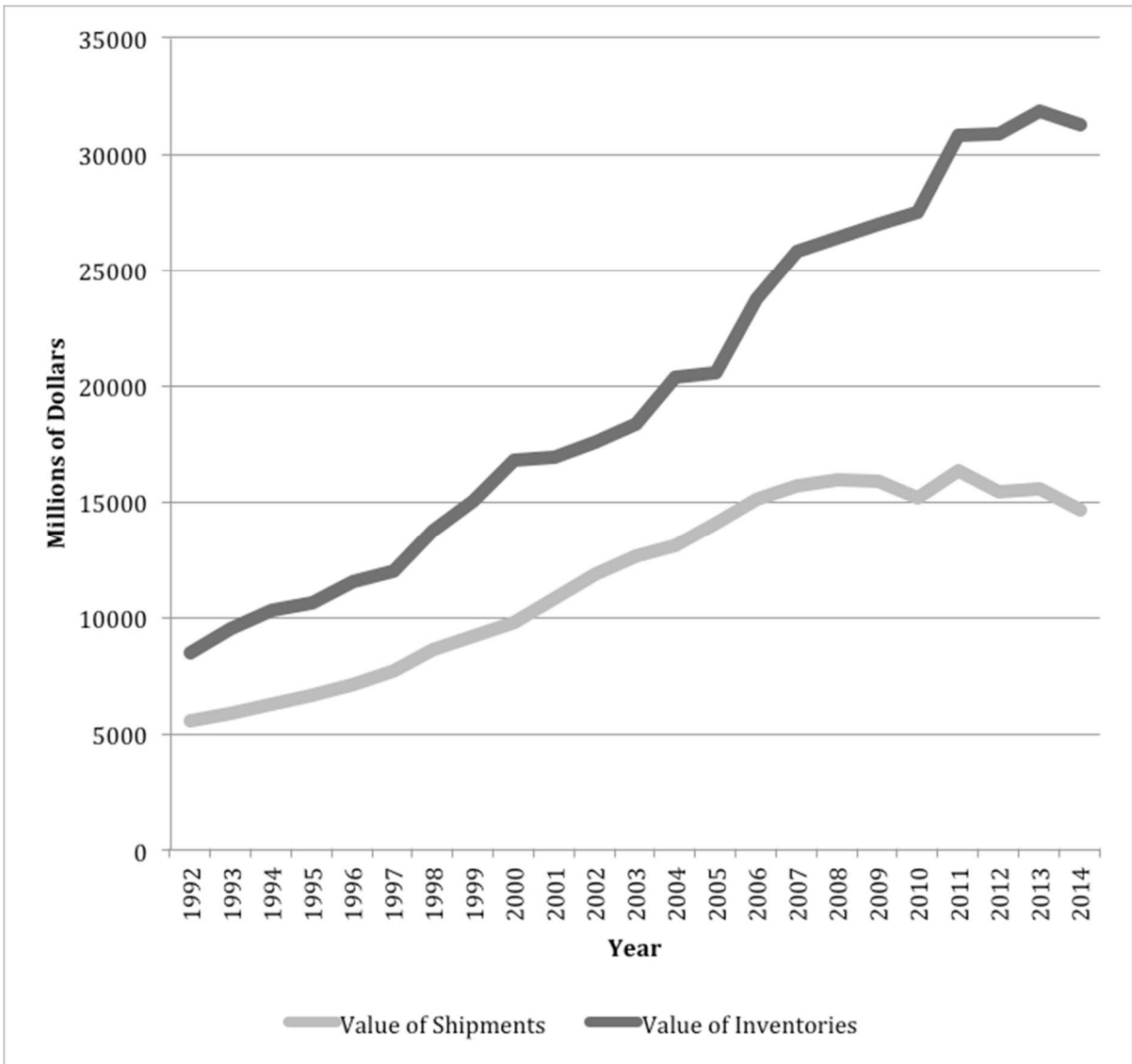


Figure 3.2: Pharmaceutical Industry Value of Shipments and Value of Inventories (Millions of Dollars, Seasonally Adjusted), 1992-2014. (St. Louis Federal Reserve Economic Database 2015)

billion in 1992 to \$15 billion in 2014, with a highest value of \$16.9 billion in 2008. With this high growth, an examination of industry concentration over time should give a better understanding of how that growth has been created and distributed.

There are several ways in which to measure the concentration of an industry¹⁴. Here, I focus on the number of firms; the concentration ratio at the 4, 8, 20, and 50 firm levels; and the Herfindahl-Hirschman Index, shown in Table 3.3. The first is simply counting the number of firms in a given industry. Theoretically, the fewer the number of firms in an industry, the more concentrated the industry and vice-versa. Figure 3.3 shows the number for firms in the Pharmaceutical industry from 1947 to 2012¹⁵. Between 1963 and 1982, the number of companies decreased steadily, before increasing rapidly in 1992. The decrease during the 1960s and 1970s reflects the effect of the changes in the regulatory structure brought about by the Kefauver-Harris amendments. The combination of increased research costs and the conglomerate merger wave led to a reduced number of larger, more dominant firms (Greer 1992; Chandler 2005). The increase seen in the early 1990s reflects the biotech revolution and the wave of entry from small firms that spun off from university departments and the privatization of previously public research laboratories (Chandler 2005).

¹⁴ Adelman (1951) and Sylos-Labini (1969) discuss different ways to measure concentration based on different variables: employees, sales/income, and assets. Based on the measurement use, both recognize that there are three general types of concentration: technical, which deals with concentration in industrial plants measured by the distribution of employees; economic, which deals with the concentration in firms measured by the distribution of output; and financial, which deals with concentration based on interlocking finances and directories based on the distribution of assets.

¹⁵ Data for 1966 and 1970 are unavailable.

Table 3.3: Industrial Concentration based on the Number of Companies; Concentration Ratio 4, 8, 20, and 50; and Herfindahl-Hirschman Index

Year	Number of Companies	CR-4	CR-8	CR-20	CR-50	HHI
1947	1123	28	44	64	-----	-----
1954	1128	25	44	68	-----	-----
1958	1064	27	45	73	87	-----
1963	944	22	38	72	89	-----
1966	-----	24	41	-----	-----	-----
1967	791	24	40	73	90	-----
1970	-----	26	43	-----	-----	-----
1972	680	26	44	75	91	-----
1977	655	24	43	73	91	-----
1982	584	26	42	69	90	318
1987	640	22	36	65	88	273
1992	583	26	42	72	90	341
1997	1428	32.3	47.9	66.6	82.5	446.3
2002	1444	34	49.1	70.5	83.7	506
2007	1538	29.5	47.1	68.7	83.8	359.1
2012	1,680	31.2	44.2	62	80	474

Source: United States Economic Census (Various years, 1947-2012)

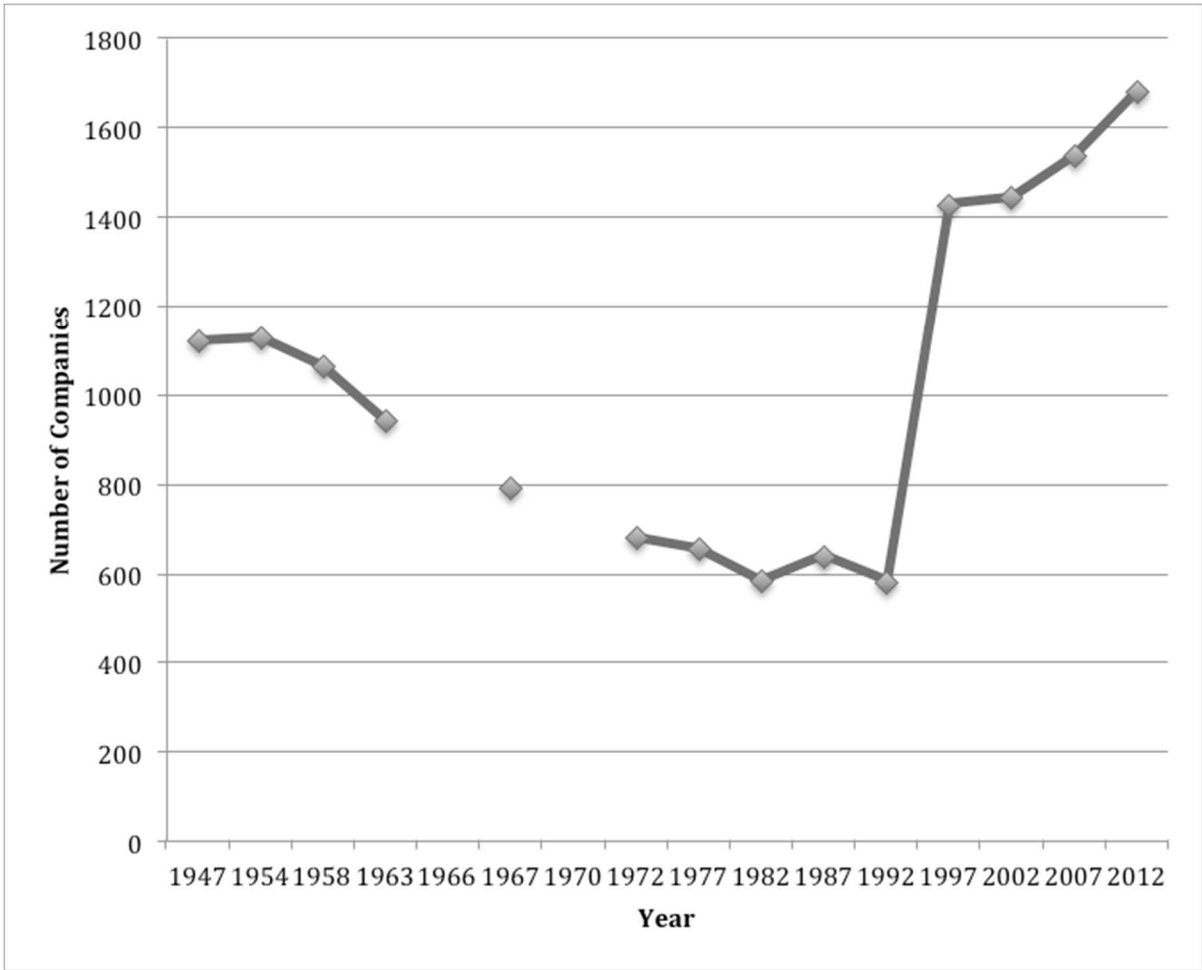


Figure 3.3: Number of Companies in the Pharmaceutical Industry, 1947-2012 (United States Economic Census, Various Years 1947-2012)

Only looking at the number of firms does not give a completely accurate description of industrial concentration. One can picture an industry with many firms, but one large, dominant firm that has captured a majority of the market share; in this case, the industry may be more concentrated than an industry with fewer firms, but a more equally distributed market share. A second, more accurate measure of industrial concentration is the concentration ratio¹⁶. Figure 3.4 shows the sales concentration ratios for the four, eight, 20, and 50 largest firms in the pharmaceutical industry from 1947 through 2012¹⁷. Between 1947 and 1987, CR₄ and CR₈ are fairly stable. However, between 1987 and 2012, the industry becomes more concentrated at the top, with the CR₄ increasing from 22% in 1987 to 31.2% in 2012 and a peak of 34% in 2002. Similar results are seen when examining the CR₈, which increases from 36% in 1987 to 44.2% in 2012, peaking at 49.1% in 2002. CR₂₀ and CR₅₀ both increased from 1987 (65% and 88%) to 1992 (72% and 90%), but subsequently declined through the 1990s and 2000s to below their pre-1987 levels (62% and 80% in 2012). This demonstrates that during the time period when the pharmaceutical industry was experiencing the largest number of entrants, the overall industry was becoming *more* concentrated at the top. This

¹⁶ Concentration ratios are calculated by taking the market share of the n-largest firms in the industry and adding them together:

$$CR_N = \sum_{i=1}^n s_i$$

Where s_i is the market share of the i^{th} firm. CR-N is calculated by adding together the market shares of the n largest firms.

¹⁷ Data for the CR₂₀ is unavailable for 1966 and 1970, while data for the CR₅₀ is unavailable for 1947, 1954, 1966, and 1970

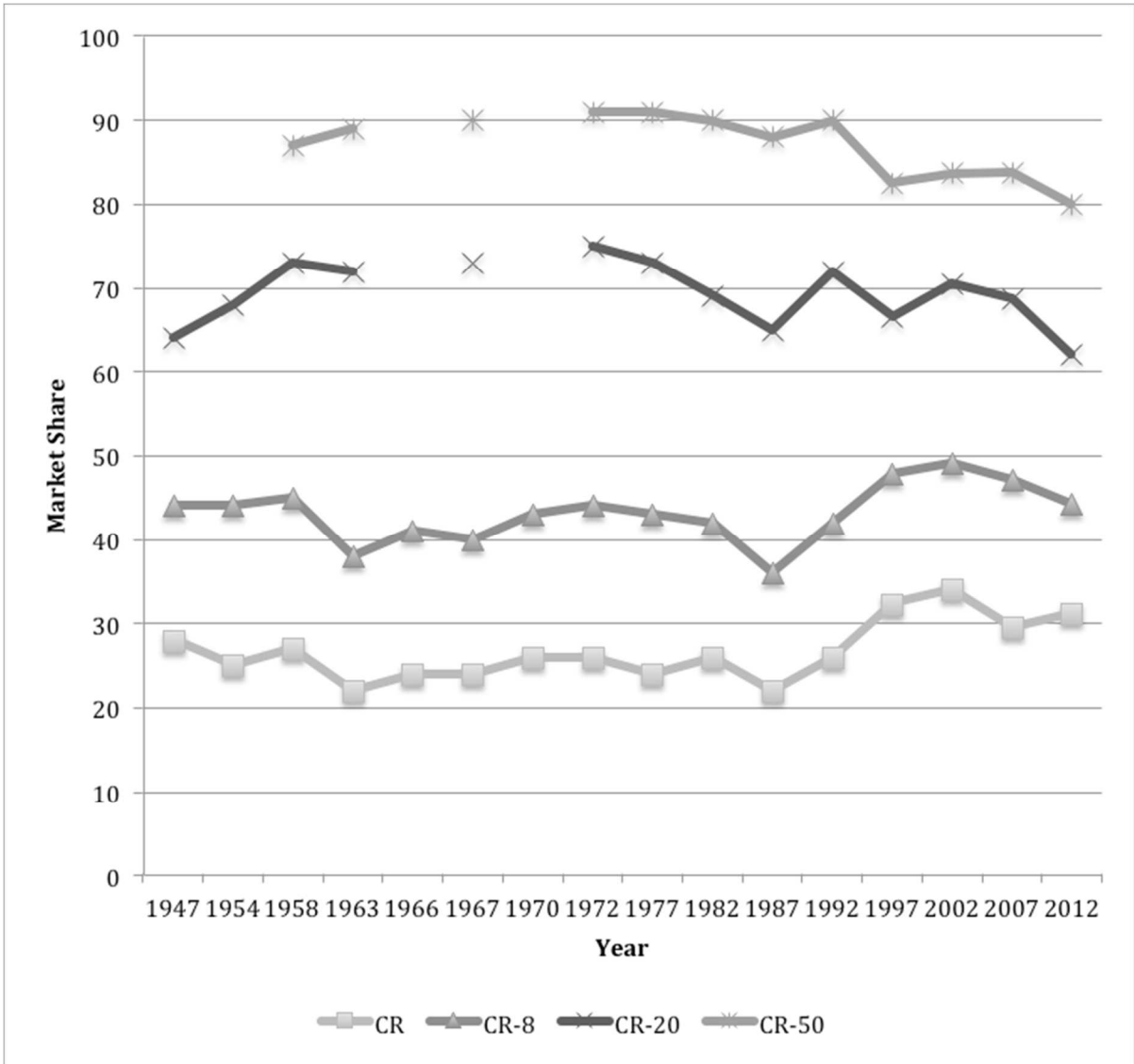


Figure 3.4: Pharmaceutical Manufacturing Concentration Ratios at the 4, 8, 20, and 50 firm level, 1947-2012 (United States Census, Various Years 1947-2012).

reinforces the conclusions found by Orsenigo, Pammolli, and Riccaboni (2003) that new entrants reinforce the dominant position of entrenched firms.

A similar result is seen when considering the HHI¹⁸. Industries with an HHI of less than 1,500 are considered competitive, 1,500 to 2,500 are moderately concentrated, and over 2,500 are considered highly concentrated. The Justice Department and Federal Trade Commission, further, consider any merger that increases the HHI by 200 points to significantly affect market power (Federal Trade Commission 2010). Figure 3.5 shows the HHI for the pharmaceutical industry. Like the CR₄ and CR₈, this chart shows that between 1987 and 2002, when the industry experienced the largest number of entrants, the industry became more concentrated – increasing from 273 to 506. There was a slight decline from 2002 to 2007, but concentration increased from 2007 through 2012. Still, at no point does the HHI surpass 506, so theoretically the industry should be competitive.

¹⁸ The HHI corrects a major weakness in the concentration ratio, in that it accounts for unequal distribution of market shares. For example, two industries may both have a CR₄ of 80%, but market share in one may be allocated equally – 20% per firm – while the other may have one firm with 79% of market share. To correct for this problem, the HHI weights each firm's share, so companies with larger shares will be weighted more heavily than those with smaller shares this is done using the formula:

$$HHI = \sum_{i=1}^n s_i^2$$

Where s_i^2 is the market share of the i^{th} firm squared. Based on this formula, the largest HHI possible is 10,000 in the case of a pure monopoly and zero in the case of perfect competition.

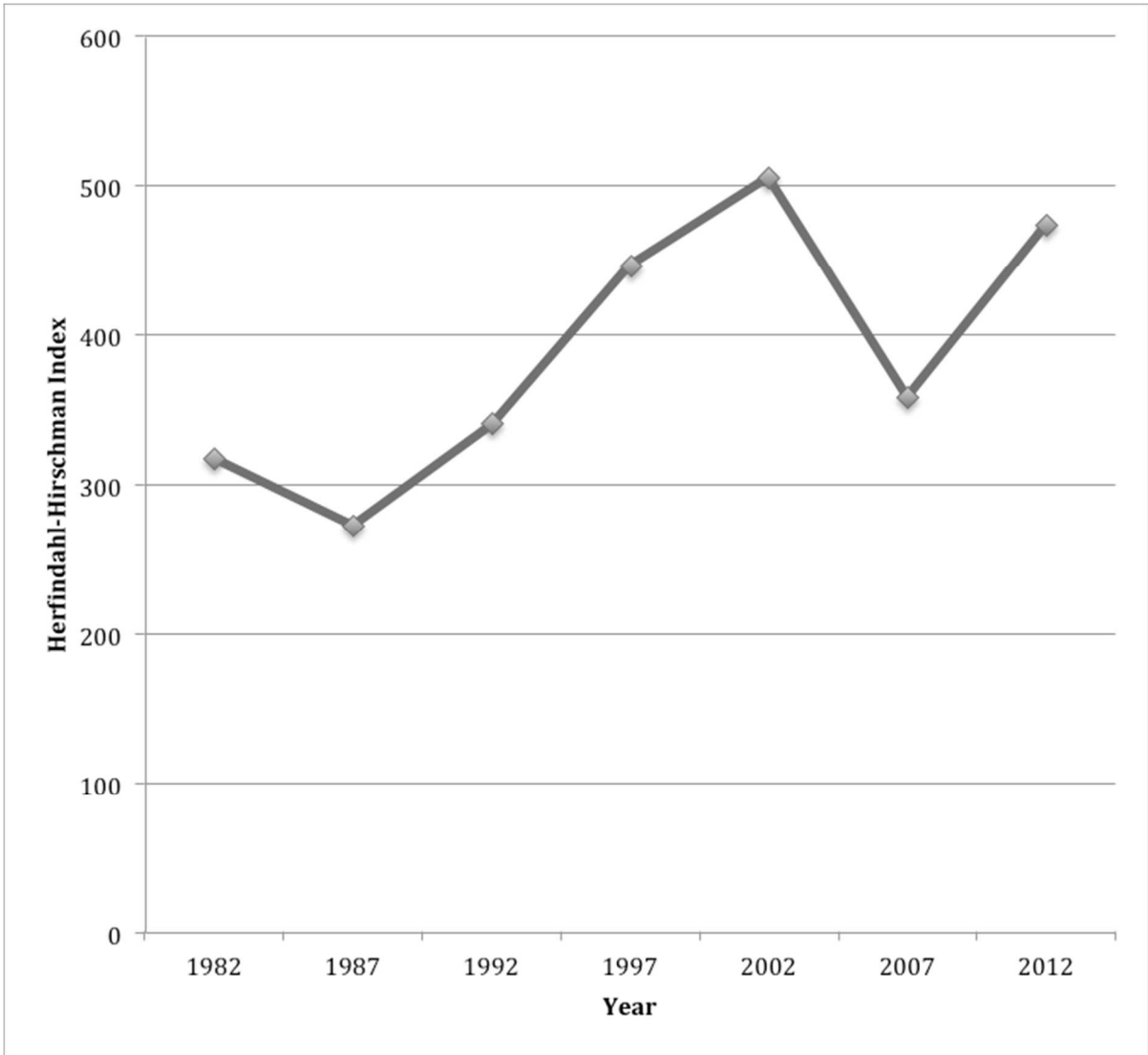


Figure 3.5: Pharmaceutical Industry Herfindahl-Hirschman Index for the 50 largest firms, 1982-2012 (United States Economic Census, Various Years 1982-2012).

One issue with focusing on the HHI and the concentration ratios as *absolute* measures of concentration is the fact that many goods included in these calculations are not substitutable. As Waldman and Jensen point out

Included in this industry are a wide range of therapeutic groups such as anesthetics, anticancer agents, antibiotics, and cardiovascular hypotensives. Clearly these products are not substitutes from the consumer's point of view... [the concentration ratios and HHI] therefore understate actual market concentration; the manufacturers of products in different therapeutic groups are not truly competitors. (2013, p. 94)

Because of the wide range of non-substitutable products, simply looking at baseline measures of concentration does not give a good indication of the competitiveness of the industry or the industry structure. A better strategy would be to examine structure in terms of the nature of relationships between the enterprises to determine which companies, if any, have the power to direct the course of action and which companies follow these directions and provide support.

Market Power and Industry Structure

When discussing industry structure, understanding the relationship between firms is more important than measures of concentration, as it is through these relationships that issues of economic power arise. *Economic power* is defined as “the ability of some persons or firms to produce intended effects on others.” (Greer 1992, p. 94; see also Wong 1979) In other words, it is “a constrained set of conduct option.” (Greer 1992, p. 94; see also Smith 1981), or the ability of a firm to impose rationing transactions on other firms in the industry.

The relationship between market power and industry structure may be seen in the relationship between different sectors of the industry. In one conceptualization, described here as the Common-conception and seen in Figure 3.6, the focus is on the relationship between the government, planning, and entrepreneurial sectors (Commons 1950). The planning sector is in charge of large-scale production and composes most of the economic activity of a modern economy; this is essentially what Galbraith calls the “technostructure”. (1967, p. 60) Much of this sector is, and must be, centrally planned due to the degree of technological specialization, interconnectedness within the industrial systems, and the need for returns to cover investment outflows (Veblen 1904; Galbraith 1967; Munkirs 1985). This does not mean, however, that the planning sector is devoid of change; new ideas are delivered to this sector from the entrepreneurial sector. In this sector, new products are created and brought to market, but whether these products become successful long-term depends upon decisions by managers and directors in the planning sector (Galbraith 1967).

New ideas are developed in one sector, but their development and distribution depend upon the decisions of another sector. The planning sector, further, has no incentive to introduce new products that may destroy the profitability of the ones the currently produce via the process of creative destruction¹⁹ (Schumpeter 1942; Munkirs & Sturgeon 1985). Therefore, it will attempt to manage the entrepreneurial sector in a

¹⁹ This does not include product line extensions, which serve to extend the life of a commodity. There is a difference, then, between *true* invention, which leads to creative destruction, and *routinized* innovation, which reinforces the position of dominant capital. The entrepreneurial sector is in charge of the former; the planning sector is in charge of the latter (Baumol 2002).

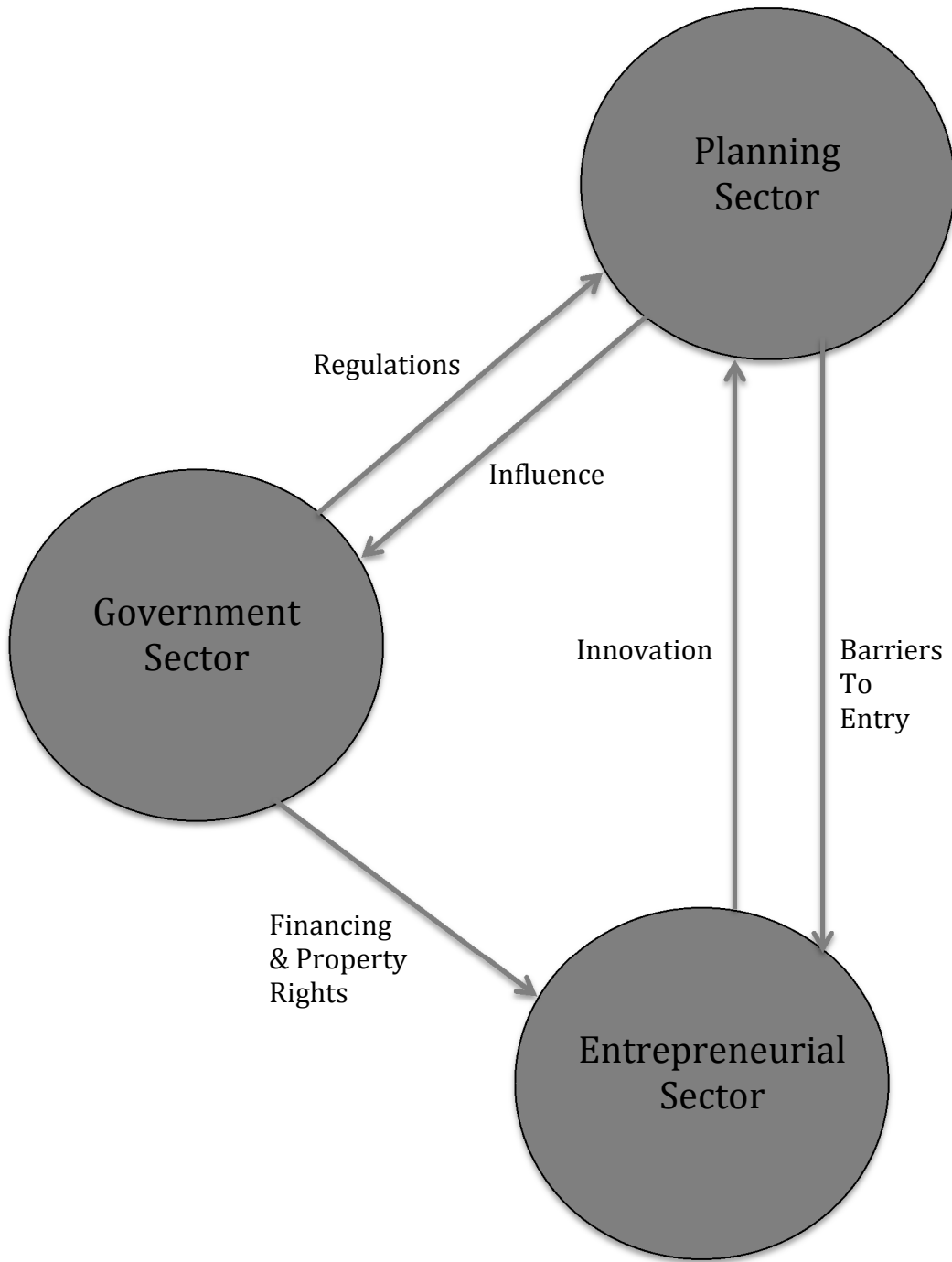


Figure 3. 6: Three-Sector Diagram of Industrial Relations

way that ensures the entry of new products does not erode their market power. This is done through excess capacity, high capital requirements for production, and patent licensing agreements to control access to production and distribution networks (Hall & Hitch 1939; Acs & Audretsch 1987; Choi 2003; Chein 2008). It is the job of the third sector, the government sector, to ensure that the entrepreneurial sector is not dominated by the planning sector. This is done in two ways: first, with rules and regulations regarding the size and scope of industry, such as anti-trust laws; second by providing the entrepreneurial sector with funds and financing to ensure that it can go about its business unmolested. The industrial sector, in turn, does not simply accept the rules and regulations delivered to them from regulators; they work to change those rules to suit their own needs via lobbying, campaign finance, and other similar methods. The government sector, then, is just as likely as the entrepreneurial sector to be captured by the planning sector.

When the planning sector is large, centrally planned production takes over the entrepreneurial sector and innovation also becomes centrally planned. This is seen in the R&D budgets of firms, which are designed to extend the life of products (Baumol 2002). As Pearce (2006) explains, with the existence of patent monopolies, firms' R&D budgets are structured in a way to ensure the firm will maintain their dominance after patent expiration. This is done by focusing energies into pre-emptively launching generic products to gain a first-mover advantage in the generic market; layering innovations by tweaking the product and re-patenting; and creating product line

extensions so that consumers are switched to the new – patented – version of the product prior to the creation of generics for the old.

This type of shift has been shown in research on centralized private sector planning (Munkirs 1983, 1985; Sturgeon 1983; Munkirs & Sturgeon 1985; Munkirs & Knoedler 1987). With the existence of private sector planning, the economic activity of a given country takes the form of a core-periphery relationship. Decisions regarding investment, pricing, product development, and other long-term activities that influence the course, direction, and evolution of economic activity are made by a core group of firms while these actions are carried out by a group of enterprises that compose the supporting nexus (Lee 2009). Put another way, this represents the creation of the transnational corporation with its special purpose entities, as discussed in the previous chapter.

The core-nexus resulting from centralized private sector planning may be thought of as the diagram shown in Figure 3.7. Government rules and regulations form an action space within which industrial activity may occur. However, these rules and regulations are in part determined by the industry as a whole via feedbacks. At the center is a central planning core group of firms that direct the activities of the entire industry. This is done directly through interlocking boards of directors, stock ownership, and debt ownership as shown by Munkirs (1985) in the most direct form of centralized private sector planning, or indirectly through control of networks or production and distribution. The ability for periphery firms to gain access to markets, then, is regulated by the demands and requirements of the core (Fligstein 1996, 2001;

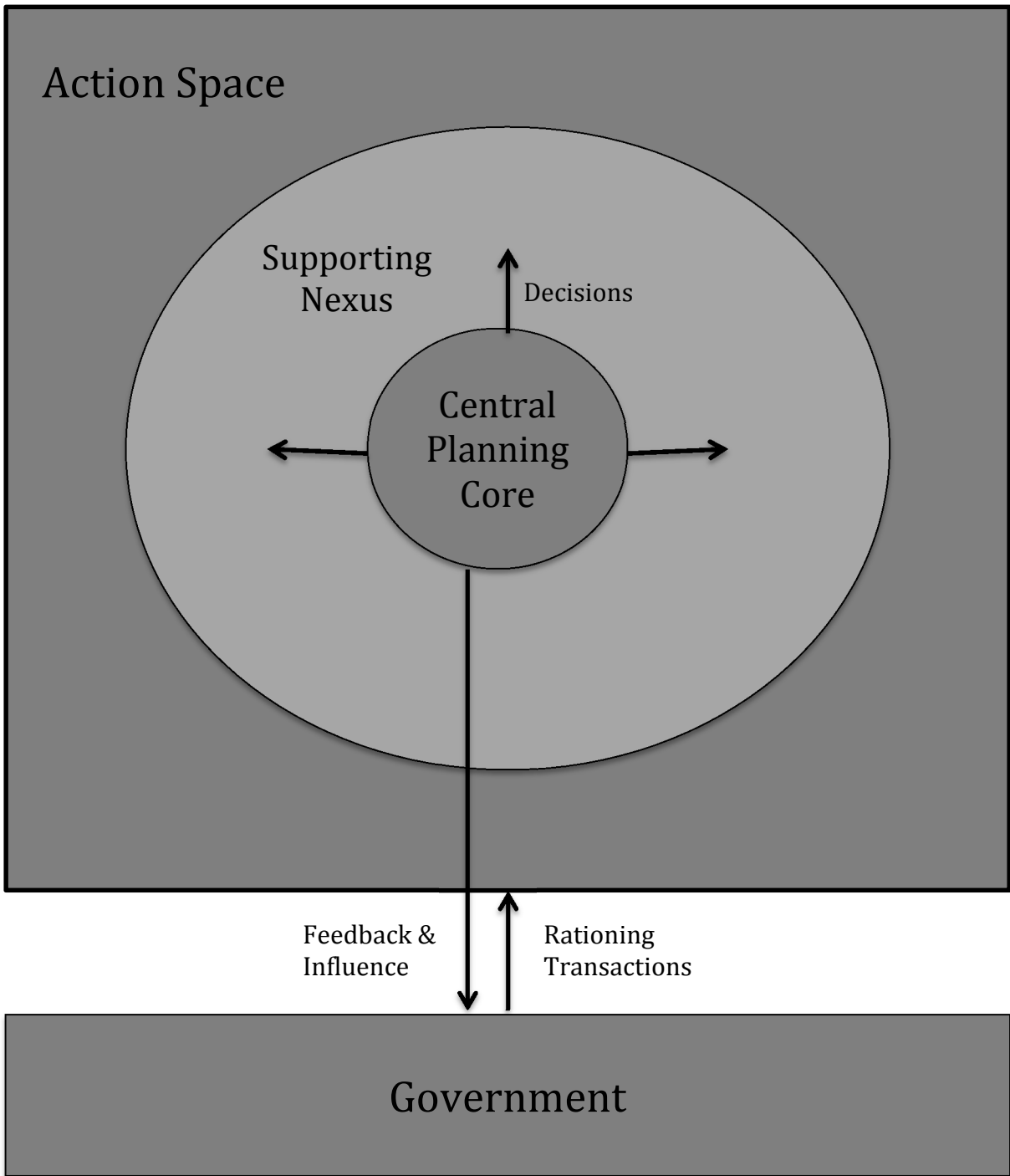


Figure 3.7: A Core-Nexus Diagram of Industrial Relations

Chandler 2005; Gagnon 2009). Orsenigo, Pammolli, and Riccaboni's (2001) study of technological change in the pharmaceutical industry found that the development of new drugs, rather than lead to changing power dynamics in the core, reinforced the dominant position of core firms, as the smaller, entrepreneurial firms depended upon the financing, production, and distribution capabilities of these central firms. This fits with the results found by Acs and Audretsch (1987), which showed that innovation in industries with high barriers to entry due to capital intensity did not lead to the erosion of dominant market shares *qua* creative destruction, but rather reinforce the position of dominant firm.

So, to understand the pharmaceutical industry in terms of structure, the first step is to identify the core of the industry. These are the firms whose actions and decisions are responsible for maintaining the industry as a going concern. The ability for the industry to reproduce itself as a going concern, then, depends upon the ability for the core to reproduce itself (Jo & Henry 2015).

The Pharmaceutical Core

To determine which firms compose the core of the pharmaceutical industry, I begin with the largest firms. As Greer points out, "firm size is, in general, a major power source." (1992, p. 94) So, firms with market power are likely going to be large themselves.

Table 3.4 lists the pharmaceutical companies listed in the FT Global 500 and the Fortune 500. However, there are several issues with simply using size as determination of the core. Recall that to have market power, a firm must be able to influence the

Table 3.4: Largest Pharmaceutical Companies, Globally

Company	Country	FT Global Rank	Market Cap. (Million \$)	Fortune Ranking	Revenues (Million \$)
Johnson & Johnson	US	6	277,828.20	39	71,312
Roche	Switzerland	9	258,542.10	-----	-----
Novartis	Switzerland	14	229,770.40	-----	-----
Pfizer	US	19	205,359.90	48	53,785
Merck	US	33	166,938.90	65	44,033
Sanofi	France	40	138,132.80	-----	-----
GlaxoSmithKline	UK	45	128,915.80	-----	-----
Gilead Sciences	US	60	108,972.20	250	11,202
Novo Nordisk	Denmark	68	100,804.40	-----	-----
Amgen	US	80	93,122.50	154	18,676
Bristol Myers Squibb	US	93	86,079.70	176	16,385
AbbVie	US	97	82,036.90	152	18,790
AstraZeneca	UK	98	81,492.60	-----	-----
Biogen Idec	US	115	72,305.70	375	6,932
Eli Lilly	US	132	65,908.80	129	23,113
Abbott Laboratories	US	157	59,423.60	-----	-----
Celgene	US	166	56,680.40	401	6,494
Teva Pharmaceuticals	Israel	202	48,971.50	-----	-----
Valeant Pharmaceuticals	Canada	226	44,125.80	-----	-----
Takeda Pharmaceuticals	Japan	271	37,511.40	-----	-----
Allergan	US	277	37,119.40	408	6,415
Actavis	US	285	35,919.70	-----	-----
CSL	Australia	341	31,178.80	-----	-----
Alexion Pharmaceuticals	US	354	30,095.90	-----	-----
Regeneron Pharmaceuticals	US	364	29,399.80	-----	-----
Shire	UK	375	28,866.90	-----	-----
Astellas Pharmaceuticals	Japan	408	27,155.60	-----	-----
Forest Laboratories	US	443	25,001.60	-----	-----
Mylan Inc.	US	-----	-----	377	6,909

Source: Fortune; Financial Times (2014)

conduct of other firms. Therefore, this list must be altered to identify which firms are large *and* have market power, and which firms are simply large. This is done using Chandler's concept of "learned organizational capabilities":

In market economies, the competitive strengths of industrial firms rest on learned organizational capabilities... The capabilities are product related in terms of technologies used and markets served. These product-related capabilities, moreover, are learned and embodied in an organizational setting: individuals come and go, but the organization remains. Thus, in modern industrial economies, the large enterprise performs its critical role in the evolution of industries not merely as a unit carrying out transactions on the basis of flows of information, but more important as a creator and repository of product-related embedded organizational knowledge. (Chandler 2005, p. 6)

There are three main types of learned organizational capabilities: technological, or can the firm conduct its own research and product discover; functional, or can the firm develop, commercialize, manufacture, and market the product to a global consumer base; and managerial, or can the firm manage a multiproduct company. Companies that do not have all three of these are not included in the core²⁰. Gagnon (2009, 2014) uses this concept to identify a core of 15 pharmaceutical firms. In Table 3.5, I update Gagnon's core to include updated information. The main change is the removal of Abbott Laboratories and the inclusion of Novo Nordisk.

²⁰ For example, Takeda and Shire require aid from larger firms to sell their drugs overseas, and biotechnology companies like CSL, Biogen, and Celgene require aid to get their products through FDA approval and marketing; these companies lack the functional capabilities to be a part of the core. Other companies, like Teva and Mylan, focus primarily on generics, while still others – like Alexion – focus on niche products. These companies lack the technological capabilities to be a part of the core.

The Pharmaceutical Industry's Performance

Within the third degree of separation, an efficient enterprise is not one that can produce the most output, but the one that can generate the largest earning capacity. Enterprises seek to gain differential advantages that allow them to swell their earning capacity relative to other firms in the same industry *and* relative to other industries in general (Veblen 1904). Companies may obtain differential advantages through increasing differential breadth or differential depth (Nitzan & Bichler 2009). Differential breadth refers to increasing the *scale* of business faster than industry average through greenfield investment that adds productive capacity – called external breadth – or through mergers and acquisitions²¹ – called internal breadth. Differential depth, alternatively, refers to increasing *earnings* faster than average without increasing capacity. This, too, may be done externally, through stagflation in which enterprises increase prices without a change in productive capacity, or internally – through increases in the profit markup without an underlying change in costs. Goodwill and patents allow a firm to achieve differential depth by allowing the enterprise to sell output at higher prices than normal, allowing inputs to be obtained cheaper than average and protecting the technology used to produce output. This grants a differential advantages by allowing the enterprise to produce cheaper than competitors or reduce competition (Commons 1924; Levitas & McFayden 2009).

²¹ Nitzan and Bichler argue that mergers and acquisitions are more common for three reasons: “it directly increases differential breadth; it indirectly helps to protect and possibly boost differential depth...; and it reduces differential risk.” (2009, p. 330)

Table 3.5: Core of the Pharmaceutical Industry, 2014

Company	Country	Global Rank in Terms of Capitalized Value	Capitalized Value (Million \$)
Johnson & Johnson	United States	6	277,828.20
Roche	Switzerland	9	258,542.10
Novartis	Switzerland	14	229,770.40
Pfizer	United States	19	205,359.90
Merck	United States	33	166,938.90
Sanofi	France	40	138,132.80
GlaxoSmithKline	United Kingdom	45	128,915.80
Bayer	Germany	57	112,126.20
Gilead Sciences	United States	60	108,972.20
Novo Nordisk	Denmark	68	100,804.40
Amgen	United States	80	93,122.50
Bristol Myers Squibb	United States	93	86,079.70
AbbVie	United States	97	82,036.90
AstraZeneca	United Kingdom	98	81,492.60
Eli Lilly	United States	132	65,908.80

Source: Modified from Fortune (2014); Financial Times (2014); Gagnon (2014)

Measuring Differential Depth

In order to gauge the performance of the pharmaceutical industry in terms of pecuniary return, I calculated the rate of profit for the core discussed above between 1993 and 2014²². The core has been somewhat fluid, but for the most part remains stable. Table 3.6 shows the firms that were included in this calculation, along with the years they were members of the core. For certain firms, notes as to why they entered or exited were included. In almost all cases, it should be recognized that firms exited the core by merging with or being acquired by other core firms.

Of the 23 companies examined, eight were core companies throughout the entire time period. These are Johnson & Johnson, Pfizer, Roche, Novartis, Sanofi, Merck, Bayer, Novo Nordisk, Bristol Myers Squibb, and Eli Lilly. Two, GlaxoSmithKline and AstraZeneca, formed as a result of mergers between other core companies²³. The most recent exit, Abbott Laboratories, does not constitute a major change in the core as it spun off its research pharmaceutical business into its own entity, which explains the entrance of AbbVie in 2013. In a similar fashion, Aventis SA was formed when Rhône Poulenc and Hoechst AG merged in 1999, but left the core after merging with Sanofi in 2004. Of the core, only two companies entered during the time period that were not the result of mergers; these were first movers in the biotech industry. Amgen entered in 2000 after 20 years of building its own learning base and following what Chandler

²² Data on profit rates come from Compustat accessed via Wharton Research Data Services and the SEC Annual Filings. Data is gathered from 1993-2014.

²³ GlaxoSmithKline formed as a result of the merger between Glaxo Wellcome and SmithKline Beecham. AstraZeneca formed as a result of the merger between Astra AB and Zeneca Group PLC.

refers to as the virtuous path of reinvesting profits into the production of new pharmaceuticals (Chandler 2005). Gilead²⁴ followed a similar strategy, taking advantage of the royalty payments it received from licensing Tamiflu to Roche to engage in profitable acquisitions that allowed it to build its learning base and become part of the core in 2008²⁵ (Agrawal, Rewwatkar, Kokil, Verma, & Kalra 2010).

To measure performance, my focus is on the earning efficiency of the core. This is in line with the stated goal of enterprise activity under Money Manager Capitalism being the generation of earning capacity (Veblen 1904; Gagnon 2009; Dean 2013; Jo & Henry 2015). There are five different measures that can be used to analyze the earning capacity of the firm, each consistent with the three degrees of separation.

The first is the return on revenue, also known as return on sales. This is the ratio of net income to revenue, and effectively shows the firm's ability to increase its revenue relative to its expenses, shown by an increased ROR. In the first degree of separation, the firm uses its intangible assets to prevent the community from accessing its own stock of knowledge; they are able to engage in bargaining transactions with the community, and their profits result from the sale of output. In this degree, the firm's activities are focused on increasing the volume of sales while reducing their expenses,

²⁴ Gilead is currently a first mover in the Hepatitis C market with its drugs Solvadi and Harvoni being largely responsible for its \$25 Billion in revenue during 2014 (Palmer 2015).

²⁵ One company of future interest is Valeant Pharmaceuticals. While it is not currently part of the core, it was acquired by Biovail in 2010, which gave it the ability to follow a different strategy. Rather than conduct its own R&D, it has taken on characteristics of an investment bank, engaging in frequent acquisitions and cost cutting to the point where it has been dubbed the pharmaceutical version of Berkshire Hathaway (Helfand 2015; Kishand & Bit 2015).

Table 3.6: Pharmaceutical Industry Core, 1993 through 2014

Firm	Years as Core Member	Notes
Johnson & Johnson	1993-2014	
Pfizer	1993-2014	
Roche	1993-2014	
Novartis	1996-2014	Formed as a result of a merger between two chemical companies, Ciba Geigy and Sandoz in 1996
Sanofi	2000-2014	Entered core as a result of merger with Synthélabo; Merged with Aventis in 2004
Aventis SA	1999-2003	Formed as result of merger between Rhône Poulenc and Hoechst; Merged with Sanofi in 2004
Merck	1993-2014	
GlaxoSmithKline	2000-2014	Result of Merger between Glaxo Wellcome and SmithKline Beecham
Glaxo/Glaxo Wellcome	1993-1999	Glaxo and Wellcome merged in 1995; it merged with SmithKline Beecham to form GSK in 2000
SmithKline Beecham	1993-1999	Merged with Glaxo Wellcome to form GSK
Bayer	1993-2014	
Amgen	2000-2014	
Novo Nordisk	1993-2014	
Bristol Myers Squibb	1993-2014	
AbbVie	2013-2014	Spun off by Abbott Laboratories
Eli Lilly	1993-2014	
AstraZeneca	1999-2014	Formed via merger of Astra AB and Zeneca Group PLC
Astra AB ²⁶	1993-1998	Merged with Zeneca Group PLC to form AstraZeneca
Zeneca Group PLC	1993-1998	Merged with Astra AB to form AstraZeneca
Abbott Laboratories	1993-2013	Spun off its pharmaceutical business into AbbVie
Wyeth	1993-2008	Acquired by Pfizer in 2009
Schering-Plough	1993-2008	Merged with Merck in 2009
Gilead Sciences	2008-2014	

Source: Modified from Chandler (2005); Gagnon (2009, 2014)

²⁶ Earnings per share were unavailable for Astra AB.

so return on revenue offers a good measurement of the firm's profits resulting from the first degree of separation.

The second measure is return on assets, also typically referred to as return on investment, and measures the ability of the firm to derive profits from its asset base. There are three reasons why this is a good measurement for firm's performance. First, in the pharmaceutical industry, R&D expenses may become realized as assets in the form of patents and trademarks (Gagnon 2009). Return on assets is a way to measure the ability for a firm to use those intangible assets to generate profits. Second, ROA over time gives an understanding of the firm's business strategy with regards to mergers and acquisitions, especially if such strategies include the sale and closure of manufacturing plants and facilities. These are tangible assets sold to other companies that improve ROA by reducing operating expenses and the tangible asset base (Denning 2011; Christensen 2011). Finally, and most important, in the second degree of separation, business activities emphasize increasing the pecuniary earning capacity by erecting barriers to entry. Such barriers can take two forms: productive capacity through greenfield investment (Hall & Hitch 1939; Waldman & Jensen 2013) and legal barriers to entry through the acquisition of market equities (Hamilton 1943; Dean 2013). Both are recognized by the firm as assets – tangible or intangible – so ROA can be thought of as the return due to these barriers to entry.

The final measurements used here are the stock price, return on equity, and earnings per share. First, the stock price represents the value of the incorporeal property held by the absentee owner. The New Economy Business Model emphasizes

the maximization of shareholder value, and one way to gauge the company's success in this goal is to measure the value of the company's stock. Second, we can examine the return on shareholder's equity, or the ratio of net income to the company's shareholder equity. This measures the profits generated out of shareholders' investments. A high ROE implies that a firm is able to take the financial investments from shareholders and use it to swell their profits. ROE, then, is an essential measure to the owners of the firm who wish to see a high return on their equity investments (Lazonick & O'Sullivan 2000; Church & Ware 2000; Sheela & Karthikeyan 2012; Waldman & Jensen 2013). Finally, I examine earnings per share, which represent the net income of the company "generated" by one share of the company. A high EPS represents that each share owned by the absentee owner generates more profit for the company; therefore, shareholders will, *ceteris paribus*, prefer a higher EPS. Each of these measurements reflects the separation of ownership and control present in the third degree of separation. Owners are not concerned with the everyday activity captured by ROR and ROA, but rather their return on financial investments (Herman 1981; Moss 1981). The rate of profit that is most important to the enterprise in the New Economy Business Model is the return to shareholders, measured by stock price, ROE, and EPS.

By examining these five measurements it is possible to get an accurate depiction of the profits to the industry resulting from each degree of separation. As most of these measurements – in particular, EPS – are used to examine industry performance over time, I focus on the pattern of performance from 1993 through 2014. The next section examines this data, beginning with the first degree of separation and the return on

revenue. Summary statistics for all measures may be found in Table 3.7, while Table 3.8 shows the average profit rates for each company over the time period, weighted by firm size, and Table 3.9 shows the yearly average for each measurement.

Returns in the First Degree: Return on Revenue

Figure 3.8 shows the pattern of the return on revenue for the pharmaceutical core from 1993 through 2014. Over the time period, the total industry average ROR was 15.61% with a standard deviation of 6.47%. Recall that ROR represents how well the firm is able to generate profit from its sales. A rising ROR represents one of two things: either an increase in net income holding expenses constant or a constant net income with falling expenses. ROR over the time period has fluctuated, but increased. In 1993, ROR was 12.92%, but increased to 18.27% in 2014. The lowest ROR was in 2004 at 10.85%. The increases seen after were the result of cost-cutting measures by selling of portions of business that were not seen as a key area of focus and extensive M&A activity that aided in cutting costs. In 2009, there was a consolidation of the core as Schering-Plough was acquired by Merck and Wyeth was acquired by Pfizer. This activity has continued, with \$59.3 billion worth of deals being conducted in 2014 (Fisher & Liebman 2015) and M&As becoming the core part of business (Helfand 2015).

Returns in the Second Degree: Return on Assets

Figure 3.9 shows the pattern for return on assets for the pharmaceutical core from 1993 through 2014. Overall, the industry average ROA was 9.84%. Recall that ROA represents the ability for a firm to generate profits from its asset base, obtained through investment. This investment may be greenfield – increasing productive capacity by

Table 3.7: Summary Statistics for Pharmaceutical Core, 1993-2014

Measurement	Mean	Standard Deviation
Return on Revenue	15.61%	6.47%
Return on Assets	9.84%	6.99%
Stock Price	\$53.01	\$25.81
Return on Equity	24.29%	24.83%
Earnings per Share	\$2.27	\$1.69

Source: Wharton Research Data Services (2015)

Table 3.8: Average Core Company Profit Rates, 1993-2014

Company	ROR	ROA	Stock Price	ROE	EPS
Abbott Laboratories	15.33%	12.34%	\$47.74	27.12%	\$2.19
AbbVie	15.43%	10.29%	\$59.13	96.87%	\$1.84
Amgen	23.14%	13.63%	\$72.08	21.98%	\$2.93
Astra AB	23.51%	18.54%	\$31.59	26.94%	
AstraZeneca	17.49%	12.89%	\$47.63	28.19%	\$3.14
Zeneca Group PLC	10.76%	10.93%	\$62.27	27.60%	\$1.24
Aventis	3.29%	2.37%	\$66.52	6.66%	\$0.91
Bayer AG	5.27%	4.08%	\$59.85	10.97%	\$2.74
Bristol-Myers-Squibb	18.30%	14.35%	\$51.67	32.80%	\$2.40
Gilead Sciences	35.43%	22.55%	\$59.20	44.86%	\$3.46
Glaxo	21.96%	18.07%	\$37.55	97.32%	\$1.64
GlaxoSmithKline	18.33%	14.41%	\$46.33	58.44%	\$2.68
Johnson & Johnson	17.00%	13.73%	\$69.16	25.18%	\$3.37
Eli Lilly	17.58%	11.23%	\$60.25	26.46%	\$2.56
Merck	19.93%	12.21%	\$56.72	28.65%	\$2.73
Novartis	19.16%	9.79%	\$60.23	16.61%	\$3.15
Novo Nordisk	17.93%	16.32%	\$72.63	25.87%	\$3.51
Pfizer	19.74%	10.61%	\$42.58	22.54%	\$1.74
Roche	16.08%	9.24%	\$77.94	31.00%	\$3.42
Sanofi	13.83%	7.74%	\$40.82	12.71%	\$1.65
Schering-Plough	12.82%	12.70%	\$41.43	28.34%	\$1.46
SmithKline Beecham	10.73%	10.25%	\$52.88	52.65%	\$1.22
Wyeth	13.33%	8.01%	\$55.08	20.68%	\$1.92

Source: Wharton Research Data Services (2015)

Table 3.9: Yearly Profit Averages for the Pharmaceutical Core, 1993-2014

Year	ROR	ROA	Stock Price	ROE	EPS
1993	12.92%	10.16%	\$28.73	22.50%	\$1.23
1994	13.81%	9.32%	\$31.57	23.04%	\$1.53
1995	14.60%	10.41%	\$54.63	39.27%	\$1.50
1996	13.96%	10.71%	\$57.70	30.00%	\$1.27
1997	9.99%	9.53%	\$67.53	22.85%	\$1.41
1998	15.82%	11.93%	\$81.98	28.31%	\$2.63
1999	12.91%	10.30%	\$65.34	22.99%	\$1.83
2000	15.38%	12.07%	\$70.42	22.94%	\$2.23
2001	16.30%	11.95%	\$52.49	28.95%	\$1.86
2002	12.79%	10.41%	\$42.63	24.66%	\$1.42
2003	14.04%	8.62%	\$48.43	19.20%	\$1.57
2004	10.85%	7.83%	\$46.17	17.45%	\$1.55
2005	15.88%	9.46%	\$45.10	20.52%	\$2.06
2006	19.76%	11.09%	\$51.24	22.22%	\$2.71
2007	17.65%	10.05%	\$52.52	21.92%	\$3.36
2008	17.25%	9.86%	\$42.96	22.35%	\$2.90
2009	22.13%	9.87%	\$43.14	27.76%	\$3.33
2010	14.96%	7.76%	\$42.40	20.35%	\$2.70
2011	16.51%	8.66%	\$45.60	23.40%	\$3.07
2012	17.55%	8.47%	\$54.15	23.52%	\$3.18
2013	20.11%	9.28%	\$68.05	25.00%	\$3.39
2014	18.27%	8.75%	\$73.48	25.16%	\$3.27

Source: Wharton Research Data Services (2015)

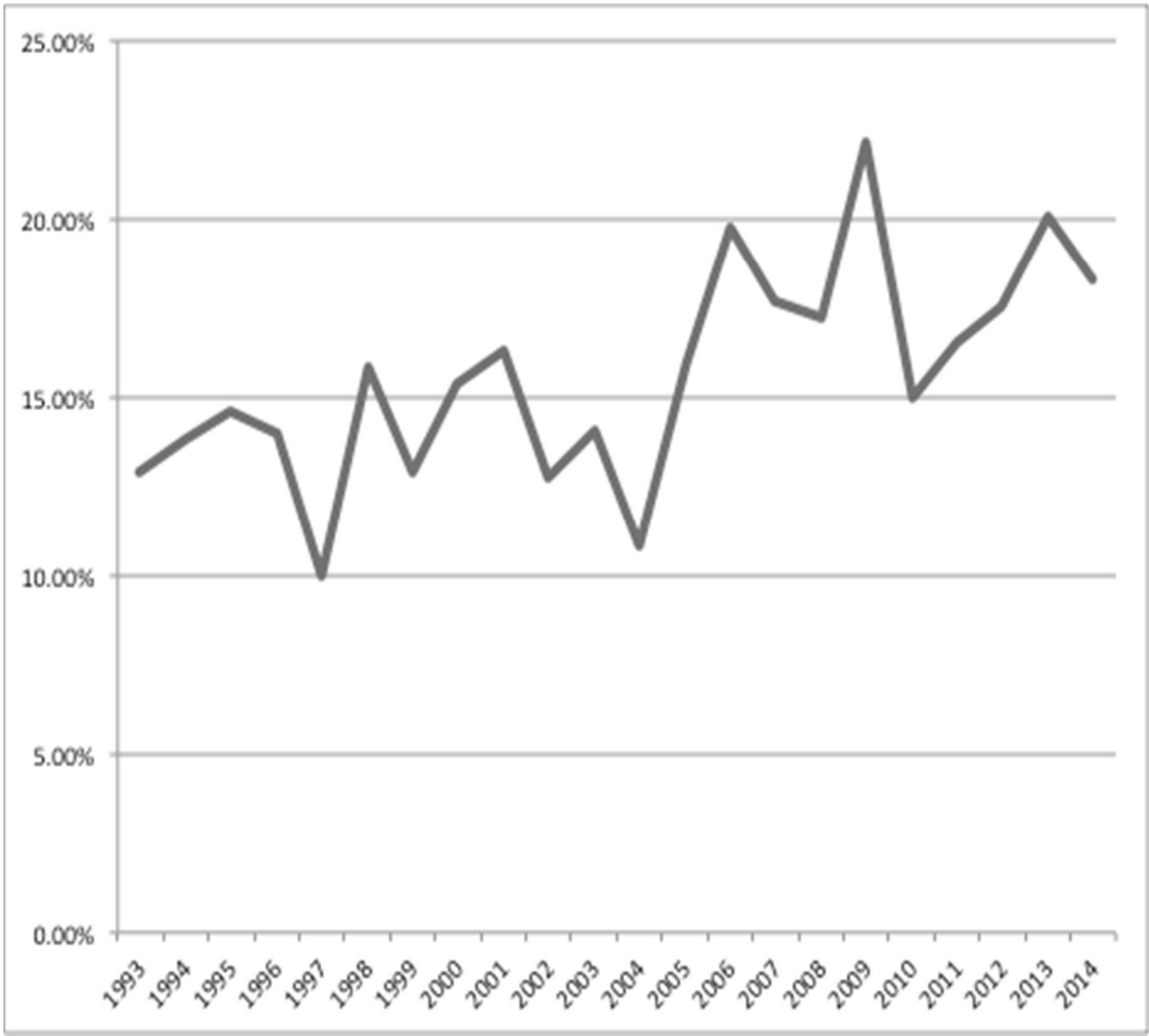


Figure 3.8: Pharmaceutical Core Return on Revenue, 1993-2014 (Wharton Research Data Services 2015)

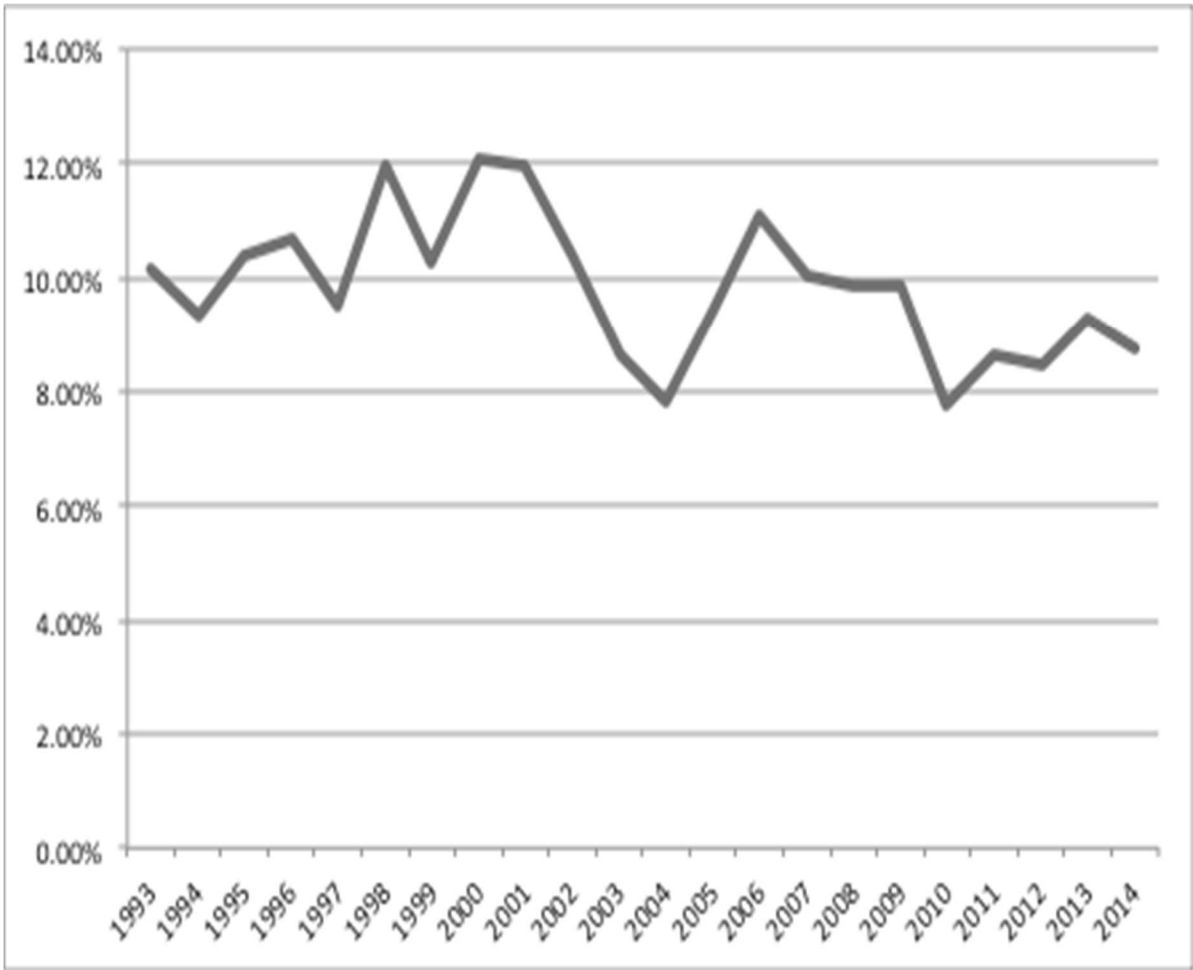


Figure 3.9: Pharmaceutical Core Return on Assets, 1993-2014 (Wharton Research Data Service 2015)

building new plants and machines – or investments in intangible property – increasing control over the joint stock of knowledge. The core’s average ROA has actually slightly decreased during the time period, from 10.16% in 1993 to 8.75% in 2014. Similar to ROR, ROA was low in 2004 (7.83%), but hit its lowest point in 2010 (7.76%). There are several reasons for this decrease. First, the expiration of patents during the 2000s has led to increased generic entry, reducing the profitability of existing drugs (Montalban & Sakinç 2013). Second, R&D expenses are not considered part of the asset base until the patent is generated, and they do not generate income until the patented drug is approved by the FDA; if such expenses are not realized in patents that generate net income, they reduce ROA (Gagnon 2009). During the mid-2000s, the rate at which new drugs were being produced declined (FDA 2016). For example, from 2000 to 2008, Pfizer spent \$60 billion on R&D but only released nine new drugs, and only four truly new drugs, as opposed to product extensions (Elkind & Reingold 2011). Finally, the increases from 2004 through 2014 – and the spike in 2009 – reflects the cost-cutting and consolidation procedures through M&A. This involves the outsourcing of tangible assets to third party producers, a strategy used by high-tech firms as shown by Sturgeon (2002). By reducing the quantity of assets, ROA increases and the enterprise appears to be more profitable, even if this profitability is not based on the true ability for the firm to generate revenue through investments (Christensen 2011; Denning 2011; Fisher & Liebman 2015).

While ROA may have decreased over the time period for several reasons – e.g., high R&D costs that do not recognize themselves as valuable assets if the drug does not

gain approval and the heavy focus on intangible assets (Gagnon 2009) – the main threshold for ROA is approximately 5% (Herciu, Ogrean, & Belascu 2011). So, despite performing worse over time in terms of ROA, the core still performs reasonably well based on second-degree measures, though the pattern suggests that performance is slipping.

Returns in the Third Degree: Stock Price, Return on Equity, and Earnings Per Share

In the third degree of separation, the enterprise is governed in such a way that prioritizes generating returns to shareholders. There are three ways in which this can be measured. First, the stock price represents the market value of one share of the company – a higher stock price, the more value the owner of the share may claim to have. Second is return on equity, or the ability to generate profits from shareholders' equity – this shows how well managers use the financial investments of the absentee owners to create returns²⁷. The third measurement is earnings per share, which measures the profit allocated to each of the company's shareholders. When discussing performance from the perspective of absentee ownership, these measurements essential.

Figure 3.10 shows the pattern of stock price for the pharmaceutical core from 1993 through 2014. The industry average stock price over the time period was \$53.01 with a standard deviation of \$25.81, however the fluctuations were not as drastic as the

²⁷ This is the performance measurement commonly used by agency theories of industrial organization, as “practically, ROE reflects the profitability of the firm by measuring the investors' return.” (Herciu, Ogrean, & Belascu 2011, p. 45; see also Lazonick & O'Sullivan 2000; Church & Ware 2000; Sheela & Karthikeyan 2012; Waldman & Jensen 2013)

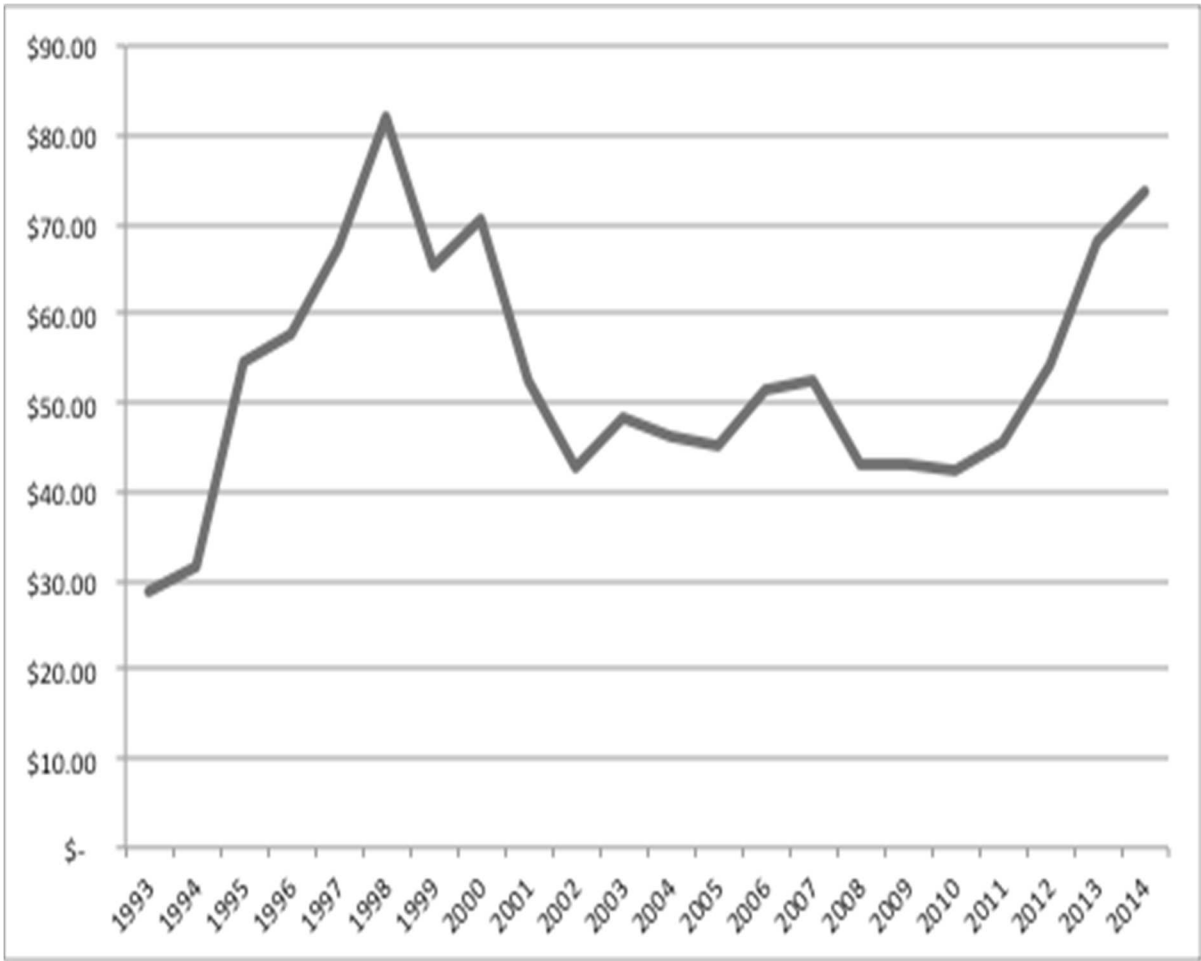


Figure 3.10: Pharmaceutical Core Stock Price, 1993-2014 (Wharton Research Data Service 2015)

summary statistics appear. The chart can be split into four regions: an initial spike from 1993 through 1998, a sharp decline from 1999 through 2002, a prolonged trough from 2002 through 2010, and from 2010 onward. From 1994 to 1998, the average core company stock price increased from \$28.73 to \$81.98. This increase was driven by two factors. First, expansions in the paths of learning from the biotechnology sector increased the perceived value of companies in the high-tech pharmaceutical industry²⁸ (Chandler 2005). Second, the availability of finance during the fifth merger wave allowed core companies to absorb those biotech companies and their intangible assets for the purpose of providing access to their networks of production and distribution (Black 2000; Sturgeon 2002; Lazonick 2010). Both factors can be seen as related to the tech bubble that occurred during this time (Cassidy 2002). After the drop to \$42.63 in 2002 due to the bursting of the tech bubble, stock prices did not begin to recover until 2010; prior to then, the highest was \$52.52 in 2007. However, starting in 2010, the average core stock price rose from \$42.40 to \$73.48 in 2014. Again, there are several reasons behind this boom. Cost-cutting measures in the mid-2000s manifested themselves in larger net incomes, increasing the market value of the firms (Gagnon 2014). Further, in response to the “patent cliff” in 2011 and 2012 – when many drugs lost patent exclusivity (Nature 2011) – the industry transformed in two ways. First, firms altered their strategies from following a blockbuster model to a nichebuster model, combining the Orphan Drug Act protections with advancements in the field of pharmacogenics. Such drugs, though they treat a smaller portion of the population, have

²⁸ The importance of the tech bubble in driving increases in stock prices in most high-tech sectors should not go unnoticed (Cassidy 2002).

higher expected earnings due to stronger protection and lower R&D costs (Coté & Keating 2012; Gagnon 2015). Second, firms engaged in upstream and horizontal M&A activity. During this time, Pfizer acquired Wyeth and King Pharmaceuticals, Merck acquired Schering-Plough, and there were several deals between the core and supporting nexus – Bristol Myers Squibb purchased Inhibitex, a hepatitis C specialist, while Merck, Eli Lilly, and AstraZeneca all acquired or licensed compounds from biotechnology companies (Mullin 2012).

Figure 3.11 shows the return on equity for the core of the industry over the time period. The industry average is 24.29% with a standard deviation of 24.83%. Over the time period, ROE stays fairly stable, with a spike in 1995 and 1996, driven by Glaxo. There is also a dip in 2004 (17.45%), but this recovers to a spike in 2009 (27.76%), as seen in other measures. For the most part, however, ROE stays close to its average over the time period. Given that the basic guideline for a “good” ROE is 15% (Herciu, Ogrea, & Belascu 2011), the core at all points in the time period analyzed was generally “efficient” at transforming shareholder’s investment into profits.

The final measurement used is earnings per share, which measures the earnings a single share of the company returns to its owner; therefore an investor will want as high an EPS as possible. To keep shareholders happy in the New Economy Business Model, company management will guide the firm with an eye towards increasing EPS (Herman 1981; Moss 1981). Figure 3.12 shows the industry EPS, the mean of which was \$2.27 with a standard deviation of \$1.69. Earnings per share increased throughout the time period, with spikes in 1998 (\$2.63) and 2007 (\$3.36). The spike in the early period

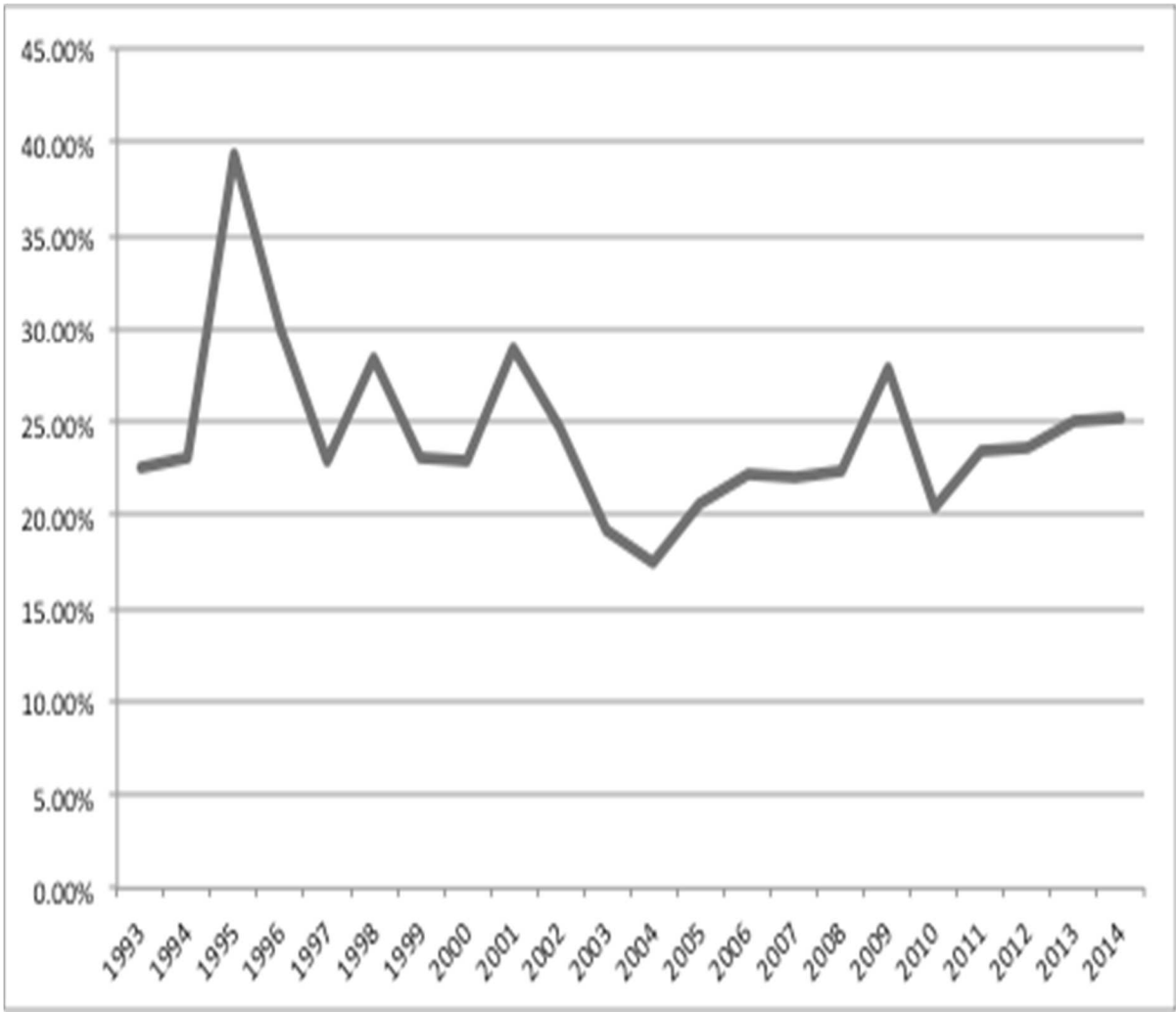


Figure 3.11: Pharmaceutical Core Return on Equity, 1993-2014 (Wharton Research Data Services 2015)

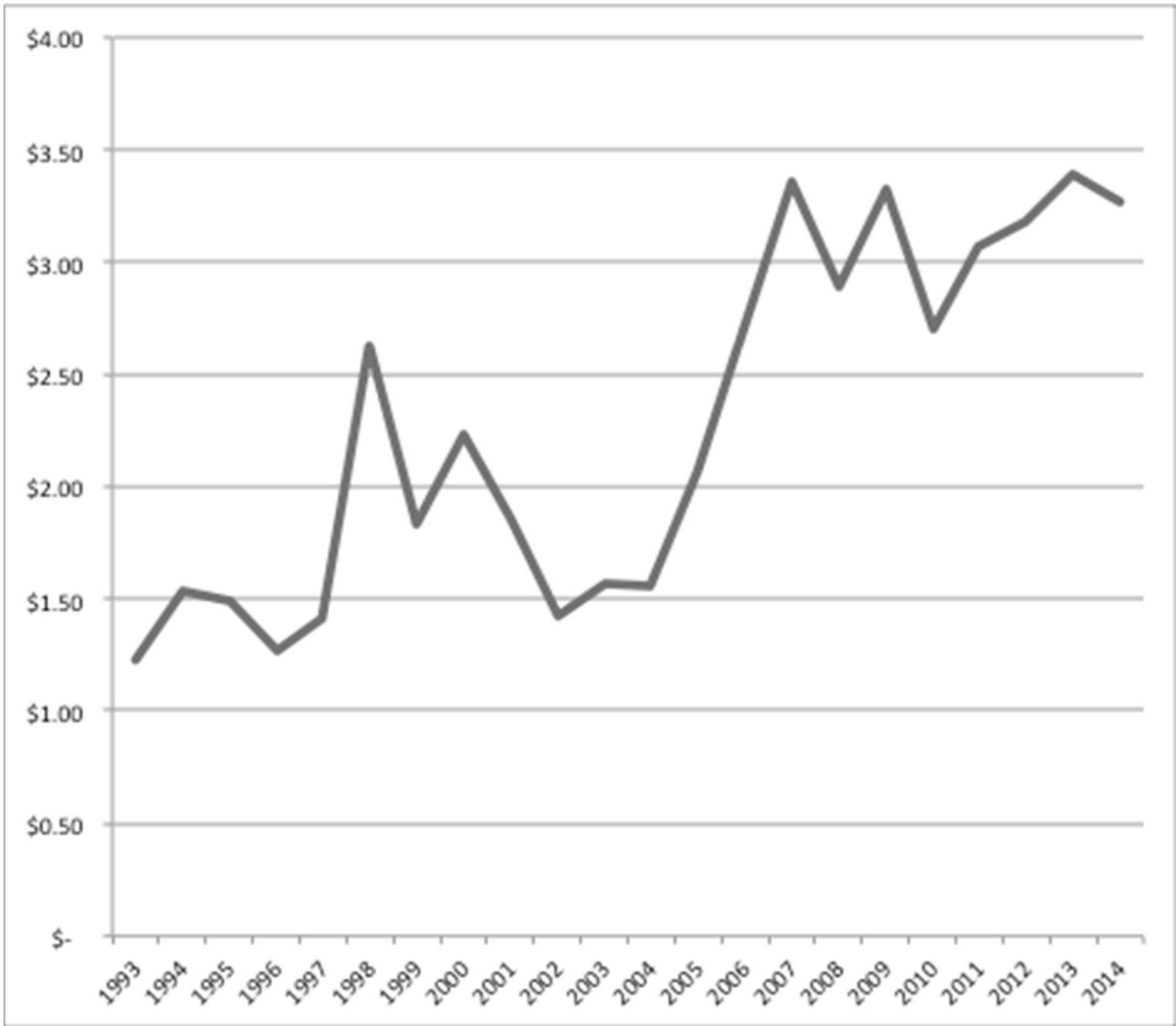


Figure 3.12: Pharmaceutical Core Earnings Per Share, 1993-2014 (Wharton Research Data Service 2015)

coincides with the increasing stock prices seen above, while the increase over this latter period coincides with first the moves to cut costs by reducing the amount of tangible assets held by the enterprise and, second, the increase in M&A activity in the industry. This, combined with the similar patterns of results found when looking only at stock price, corroborates the results found by Ravenscraft & Long (2000); Danzon, Epstein, and Nicholson (2004); and Montalban and Sakinç (2013), which found that merger activity was a quick, if temporary, way to increase returns to shareholders.

Discussion and Conclusion

This chapter has given several key insights into the pharmaceutical industry as a whole. First, by examining the evolving legal structure, it has shown how the industry came to take the core-periphery structure. Government regulations requiring increased labeling and FDA approval over drugs led to marketing being focused on doctors rather than consumers. The Kefauver-Harris amendments greatly increased the costs of drug research and development, while substitution laws and the Hatch-Waxman Act led to an increase in the share of generics. Counteracting these restrictions were the Bayh-Dole Act, the Orphan Drug Act, and the international TRIPS agreement, which increased monopoly protection on drugs and the market power of firms. The industry core, then, is composed of that group of firms that has been able to maneuver itself into a position where they have the organizational capabilities in the discovery, development, production, and distribution of new drugs, allowing them to direct the path of evolution for the industry.

This is seen in the performance of the industry. As shown by Scherer and Ross (1990), Gagnon (2009), and Spitz and Wickham (2012), the pharmaceutical industry has enjoyed differential advantages over other industries in terms of profit rates. For example, Scherer and Ross found that pharmaceutical enterprises earned 2-3% more profits per year than other enterprises between 1976 and 1987, while Spitz and Wickham found that pharmaceutical firms earned 3.2 times higher net profit margins than non-pharmaceutical firms. Further, when accounting for the high-R&D nature of the industry, Spitz and Wickham showed that pharmaceutical enterprises had profits that ranged from 2.5 to 3.7 times higher than the average high-R&D enterprise. Another striking result in terms of performance is the pattern of profits. Regardless of measurement, a clear pattern was found in that return was high in the 1990s before falling in the early and mid-2000s, with a valley around 2004. Then, profits began to rise again through the late 2000s and early 2010s, with a peak in 2009.

As mentioned in this and the previous chapter, mergers and acquisitions are important tools for increasing the pecuniary earning capacity in Money Manager Capitalism. The next chapter provides a case study of the Pfizer Corporation in terms of its M&A conduct. The emphasis will be on the effect that Pfizer's M&A history has had on the structure of its balance sheet and its reliance on intangible assets to remain a going concern.

CHAPTER 4

INTANGIBLE ASSETS AND THE PFIZER CORPORATION: THE IMPORTANCE OF MERGERS, ACQUISITIONS, AND STRATEGIC DEALINGS

Introduction

In the previous chapter, I discussed the structure of the pharmaceutical industry in terms of the core-periphery. The core of the industry is composed of a group of firms who, due to their learned organizational capabilities, are able to direct both present and future activities within the industry. I then examined the performance of these core firms by calculating the rate of return. Each rate showed a pattern, with fairly high returns in the 1990s before dropping in the early 2000s, but rising again after 2004.

The questions that must now be answered reflect the reasons for the emergence of this pattern of profits and this industry structure. This requires an understanding of conduct, or how enterprises within the industry behave. “Conduct” is a broad term, and can be used to represent activities including, but not limited to, pricing behavior, R&D decisions, and merger activity. In this dissertation, the focus is on intangible assets and how they have influenced the evolution of the pharmaceutical industry. Intangible assets are primarily created in two ways: internally through R&D expenditures, or externally by acquisition – e.g., Pfizer’s acquisition of Wyeth gave it both goodwill and ownership rights over Wyeth’s patents, brands, and trademarks.

The core-periphery structure of the industry has led to a system of drug development based on strategic agreements between the core and periphery. Firms in the periphery handle much of the discovery and pre-trial research, while the core enters when a drug has been approved for testing, usually in stage II or stage III trials.

These agreements take the form of cross-licenses, by which the core firm will handle the financing for the development and marketing of the drug due to their strong functional capabilities. This implies a network effect, in which the industry has become broader due to the new entrant, but more centralized, as these new firms reinforce the dominance of the core firms (Acs & Audretsch 1987; Orsenigo, Pammolli, & Riccaboni 2001; Danzon, Nicholson, & Pereira 2003; Danzon, Epstein, & Nicholson 2004). Here, I focus on the Pfizer Corporation with regards to its merger and acquisition history and the effect that this has had on the structure of their assets. As the data show here, Pfizer becomes increasingly reliant on intangible assets over time; not only do intangible assets as a percentage of total assets come to make up a larger portion of their total assets, but their net tangible assets in the more recent years have gone negative. Further, Pfizer's revenue structure becomes dominated by drugs obtained through acquisition, rather than development. This implies that Pfizer's ability to remain a going concern relies upon its ability to acquire intangible assets through merger, acquisition, and strategic alliance, rather than internal development.

The first part of this chapter reviews the general theoretical issues surrounding mergers and acquisitions. A brief summary of the justification for M&As is given to set the context for the analysis of the Pfizer Corporation. As will be shown later in the chapter, the most common reasoning for Pfizer's M&As were core-periphery speculative agreements – which may be thought of as “new entry deals” – and additions to their product pipeline.

I then specifically examine Pfizer's M&A history. This is done in two subsections: the first investigates Pfizer's history in terms of strategic dealings from its early days as a supplier of iodine preparations and citric acid for pharmacists to its rise as a dominant firm during World War II and the conglomerate merger wave. The second subsection explores Pfizer's recent M&As as it attempts to re-focus on pharmaceuticals. This will give an understanding as to Pfizer's corporate strategy over time.

In general, this history of Pfizer's conduct is one in which its knowledge in the production of chemicals spilled over into pharmaceuticals, allowing it to enter this industry through the production of penicillin. However, it diversified beyond its knowledge base; rather than using its profits to create new drugs within its organizational capabilities, it expanded through acquisition. In doing so, Pfizer was unable to take advantage of the technological advancements generated by the biotechnology revolution in the 1970s and 1980s. In the late 1980s and early 1990s, it divested itself of many unrelated business lines and re-focused on prescription-based pharmaceuticals.

Theoretical Issues of Mergers and Acquisitions

The United States has experienced six major merger waves since the passing of the Sherman Antitrust Act in 1890. The first took place from 1897 through 1903 and was composed primarily of horizontal mergers. This wave resulted from a loophole in the Sherman Act, which banned collective stock ownership in the form of trusts, but not holding companies. The second merger wave took place from 1925 through 1930 and was characterized primarily by vertical mergers. Because of increased government

regulation with the passage of the Clayton Act in 1914, increasing profits by reducing competition through monopoly-creating mergers was no longer a viable option¹. Firms responded by internalizing costs, leading to the creation of oligopolies during the second merger wave. The third merger wave occurred from 1965 through 1969, with the Federal Trade Commission recording 2,407 mergers in 1968. These types of mergers were primarily conglomerate, as the economic prosperity during this time gave firms the resources needed to expand into non-core business areas (Greer 1992). The Pfizer Corporation, during this time, branched out of pharmaceuticals into chemicals, into specialty minerals and materials and eventually medical equipment.

The fourth merger wave occurred during the 1980s as a result of lenient merger policy by the Reagan administration. There were two stark differences between this merger wave and the ones preceding it. First, while most mergers were friendly, there were more hostile takeovers than previously, with the term “corporate raider” becoming part of the popular vernacular. Second, debt was more widely used to finance these mergers; firms began to take more speculative and Ponzi positions (Minsky 1986; Lazonick 2010b). The fifth merger wave began in 1992 and lasted through 2000, with the primary focus being cross-border expansion. The sixth, and final thus far, merger wave in the United States occurred after the early 2000s recession, spanning from 2003 to 2008. The wave was driven by the abundance of liquidity during the housing bubble,

¹ The purpose of the Clayton Act – among other things – was to close the Sherman loophole by banning the acquisition of stock if it would result in monopoly.

with a focus on increasing shareholder value (Greer 1992; Minsky & Whalen 1997; Black 2000; Sherman et al. 2008; Alexandridis, Mavrovitis, & Travlos 2011).

Corporate conduct regarding mergers, acquisitions, and other types of strategic alliances, such as cross-licensing agreements, has an important effect on industry structure. In the pharmaceutical industry, mergers and acquisitions have been fundamental in the creation of the core. For example, GlaxoSmithKline formed as a result of a merger between SmithKline Beecham and Glaxo Wellcome – which itself was the result of a merger between Glaxo Laboratories and Burroughs Wellcome and Company. Aventis SA became part of the core in 1999 when it formed as a result of a merger between the pharmaceutical divisions of Rhône Poulenc and Hoechst, and eventually merged with Sanofi in 2004 to become Sanofi Aventis². Sanofi itself, meanwhile, became part of the core after merging with Synthélabo in 2000. AstraZeneca, meanwhile, formed as a result of the merger between Astra AB and Zeneca Group PLC. Wyeth and Schering-Plough were core members that were acquired by other core members – Pfizer and Merck respectively. This goes to show that the structure of the pharmaceutical industry was created and is maintained through mergers, acquisitions, and strategic dealings. Understanding conduct in the pharmaceutical industry requires an understanding of mergers and acquisitions.

There are six main reasons for mergers and acquisitions discussed here, both generally and within the context of the pharmaceutical industry (Greer 1992). The first, and most common reason, is economic efficiency. Larger firms are seen as being better

² The Aventis suffix was dropped in 2011.

able to recognize economies of scale and scope, reducing long run average costs. This may occur because it becomes cheaper to purchase inputs as a single bulk buyer, because larger firms are better able to utilize technologies on a larger scale, or because they are able to oust bad managers while giving more power to good managers. While this is a nice theoretical reason that fits the neoclassical theory (Stigler 1950), the evidence is lacking. Caves (1989) found no evidence that mergers either created value or were economically efficient, results that have also been found in similar studies (Pearce 1987; Shiller 1987). Further, there was no evidence that companies post-merger were more efficient due to changes in management (Manne 1965; Fisher 1983), nor evidence to support the idea that mergers created efficiency by eliminating poorly performing companies (Ravenscraft & Scherer 1987). Research specifically within the pharmaceutical industry is of two minds. Within the context of bringing drugs to market, Nicholson, Danzon, and McCullough (2002) have found, however, that agreements between biotech companies and pharmaceutical companies are more successful at bringing drugs to market than individually. This supports earlier findings from Lerner and Tsai (2000). However, from a shareholder value perspective, Ravenscraft and Long (2000) and Danzon, Epstein, and Nicholson (2004) found that such agreements either only created short-term value or did not create value in the first place³.

³ The combination of these two results is interesting. Under money manager capitalism, where returns to shareholder is of primary interest, it would seem mergers and acquisitions do not do what they are supposed to do. However, if we think of such acquisitions from a pipeline-filling perspective, rather than a cost-reduction perspective, they begin to make sense. Rather than develop the drug, the

The second main justification for mergers and acquisitions is their use as a defensive strategy; firms acquire other firms to prevent their own takeover. This strategy was common during the fourth merger wave as a means to protect from corporate raiders, with Time, Inc. acquiring Warner Communications and Maytag acquiring Chicago Pacific Corp. (Roll 1986; Greer 1992). While this is a possible reason for mergers – for example, Pfizer’s failed takeover bid of AstraZeneca and its inversion with Allergan may have fit this strategy – it is not a common or usual reason (CEPTON 2014).

Other reasons for mergers reflect the need to spread risk and the desire for personal aggrandizement of the manager. While these may have been dominant causes at one point, they no longer hold true. For example, during the third merger wave, Merck and Pfizer both expanded into industries in which they had little to no developed organizational capabilities (Chandler 2005). However, recent activity suggests that this is no longer the case, as few large pharmaceutical mergers occur outside of the pharmaceutical, biotech, and related industries (CEPTON 2014). Personal aggrandizement and empire building, further, would be a short-term explanation that depends upon the manager at the time (Greer 1992).

Based on the discussions in the previous chapter, I find it more likely that mergers and acquisitions are undertaken with an eye towards obtaining monopoly power in both the immediate term and the long-term. In the immediate term, mergers

pharmaceutical company has taken the role of an investment bank, financing the R&D of the biotech company and acquiring the property rights over the drug once it reaches market.

and acquisitions grant a differential advantage through control over production and distribution networks by creating barriers to entry⁴ (Greer 1992). Many deals in the pharmaceutical industry rest upon the acquisition of future monopoly rights – in this way, they are speculative in nature. Deals between the core and the firms that make up the supporting nexus are driven by the desire to bring a potential product to market. Core firms speculate that the compounds discovered in the nexus will be profitable, so they acquire the company or exclusive selling license in exchange for financing the drug through development⁵.

Mergers, acquisitions, and strategic alliances can be seen as granting monopoly rights in the pharmaceutical industry in two ways. First, the speculative dealings between the core and the periphery transfer monopoly rights from the nexus to the core firm in exchange for royalty payments and licensing fees (Orsenigo, Pammolli, & Riccaboni 2001). Second, previous studies have found that the most common reason for horizontal mergers in the pharmaceutical industry is to eliminate gaps in the firm's product pipeline (Ravenscraft & Long 2000; Danzon, Nicholson & Pereira 2003; Danzon, Epstein, & Nicholson 2004). Firms that are unable to generate their own intangible assets internally acquire them from other firms. Pfizer's acquisition of Wyeth in 2009 and King Pharmaceuticals in 2011 represent this motive, as between 2000 and

⁴ The tentative merger between Pfizer and Allergan falls under this differential advantage reasoning. The merger would allow Pfizer to shift its location to Ireland, reducing its corporate income taxes and increasing its profits.

⁵ This is the strategy taken by Valeant Pharmaceuticals, which has averaged nearly \$10 billion in mergers and acquisitions per year since 2008 (Helfand 2015; Kishand & Bit 2015).

2008, Pfizer only succeeded in getting four truly new drugs approved. With Lipitor, their top selling drug, scheduled to go off-patent in 2011, it turned to acquisition, rather than internal development. Indeed, Pfizer's press releases from both acquisitions emphasized the importance of pipeline additions in these mergers (Pfizer 2009, 2010).

In the next section, I examine Pfizer's merger and acquisition history, with an emphasis on the last 30 years of M&As. In doing so, we can identify which of the M&A motives has driven Pfizer.

Strategic Dealings of the Pfizer Corporation

Both the European and American pharmaceutical industries arose simultaneously in the 1880s (Chandler 2005). Several factors contributed to this. Politically, in Europe, "the unification of imperial Germany and the growth of its economy on heavy industry in the Rhine Valley gave chemical and pharmaceutical manufacturers scale of operations from which they could dominate European markets." (p. 4) In the United States, it was the development of communications and transportation technologies that made mass production in many industries possible. In both, new developments in the chemical and biological sciences generated the learning bases necessary to produce pharmaceutical drugs. Commercializing the products required a way to protect market share, leading to the erection of strong barriers to entry. With copying being easier due to scientific advancements, companies moved away from trade secrecy and towards patent protection (Kitch 1977; Moser 2013). This protection led to the creation of the pharmaceutical core, discussed in the previous chapter.

A Brief History of the Pfizer Corporation Pre-1985

Pfizer's origins are as a part of the supporting nexus. Established in 1849 by Charles Pfizer and Charles Earhart, it focused on producing input chemicals, such as iodine preparations, boric tartaric acid, and citric acid used by pharmacists. In 1920, Pfizer developed a new way of producing citric acid based on black-bread mold. Because this production process was similar to the way in which penicillin mold was cultured, Pfizer was able to enter into pharmaceutical production, becoming the leader in the United State's World War II penicillin program. After World War II, Pfizer's share of penicillin production dropped as competitors entered the market. In response, the company created the first broad-spectrum antibiotic, Teramycin, which was heavily marketed by then-president John McKeen to doctors, hospitals, and in medical journals. In 1950, the drug accounted for 25% of Pfizer's sales. Using the revenue from Teramycin, Pfizer engaged in what Chandler refers to as the "virtuous strategy": it reinvested these profits to produce new antibiotics, such as Vibramycin, and entered into related fields, like the production of Polio vaccines and treatments for diabetes and mental health. Based on McKeen's agenda, Pfizer also pursued a strategy of growth abroad by acquiring subsidiaries in Canada, Mexico, Cuba, Britain, and Belgium; as well as building plants in Britain, France, and Japan (Pratt 1985; Stopford 1989; Derdak 1994; Chandler 2005).

As a result of the increased regulation stemming from the Kefauver-Harris Amendments, Pfizer began to expand into other areas. Between 1961 and 1964, it acquired companies that produced over the counter medications, including Visine eye

drops and Coty's cosmetic and fragrances line. After McKeen's retirement in 1965, his successor, John Powers Jr., began acquiring companies engaged in the production of speciality minerals and material, turning Pfizer into a conglomerate. Edmund Pratt Jr. continued this trend when he became CEO in 1971, but with an eye towards the healthcare industry. Pfizer acquired two medical equipment production companies in the 1970s – Howmedica in 1972 and Shirley in 1979 (Pratt 1985; Chandler 2005).

There were several downsides to the conglomerate strategy. Because Pfizer was allocating much of its financial and managerial resources on companies and subsidiaries that were unrelated to pharmaceutical preparations, it was unable to take advantage of the new technological advancements in biotech and genetic research that birthed the biotechnology sector. While companies like Eli Lilly and Merck focused on internally developing drugs using the new rDNA technologies, Pfizer had to license its products from elsewhere. Two of its best selling products, Cefoid and Procardia, were licensed from Bayer, while it struggled to produce its own treatments. "Only two new drugs, Minipress, an antihypertensive, and Feldene, and antinflammatory, were developed internally, and Feldene did not enter the market until 1982." (Chandler 2005, p. 190) The lack of new drugs being released and missing out on the biotech revolution meant that Pfizer had to refocus to maintain itself as a going concern.

Strategic Dealings, Refocus, and Expansion Post-1985

Between 1985 and 2014, Pfizer was involved in 110 acquisitions and 81 divestitures⁶. The data were subdivided into four sections: 1985 through 1997; 1998 through 2003; 2004 through 2008; and 2009 through 2014. Table 4.1 and Figure 4.1 show the overall dealings within each section. Table 4.2 and Figures 4.2 and 4.3 track the dealings based on what was acquired and divested. There are three categories of acquisition and divestiture: company, intangible asset, and tangible asset. “Company” refers to the cases in which Pfizer acquired another company or divested an entire company/subsidiary. Pfizer’s acquisition of Warner Lambert in 2000 and their divestment of Zoetis in 2013 would be included in this category. “Intangible asset” includes the acquisition or divestment of a particular product line or joint venture/collaboration with another company. Included in this category are transactions like Pfizer’s acquisition of SmithKline Beecham’s Fefol and Nucof in 1998 and their collaboration with Neurogen Corp. in 1992. “Tangible asset” refers to transactions involving plants, equipment, and buildings; for Pfizer, this was primarily manufacturing plants⁷.

It is important to note that while I have separated the “company” and “intangible asset” categories, most of the company acquisitions were conducted with an eye towards the

⁶ Data for this section comes from the Mergerstat database. This research includes strategic alliances. Data for divestitures is only available from 1988 onwards.

⁷ I am not keeping track of the dollar value of the mergers and acquisitions, as terms for many of these deals – particularly the purchase and sale of assets – are not disclosed. Where the term is important, I will make note of it, but otherwise a binary approach is taken, i.e. did a merger/acquisition occur.

Table 4.1: Pfizer's Acquisitions and Divestitures, 1985-2014

Year Cluster	Acquisitions	Divestitures
1985-1997	38	14
1998-2003	20	21
2004-2008	34	27
2009-2014	18	19
Totals	110	81

Source: Mergerstat (various years)

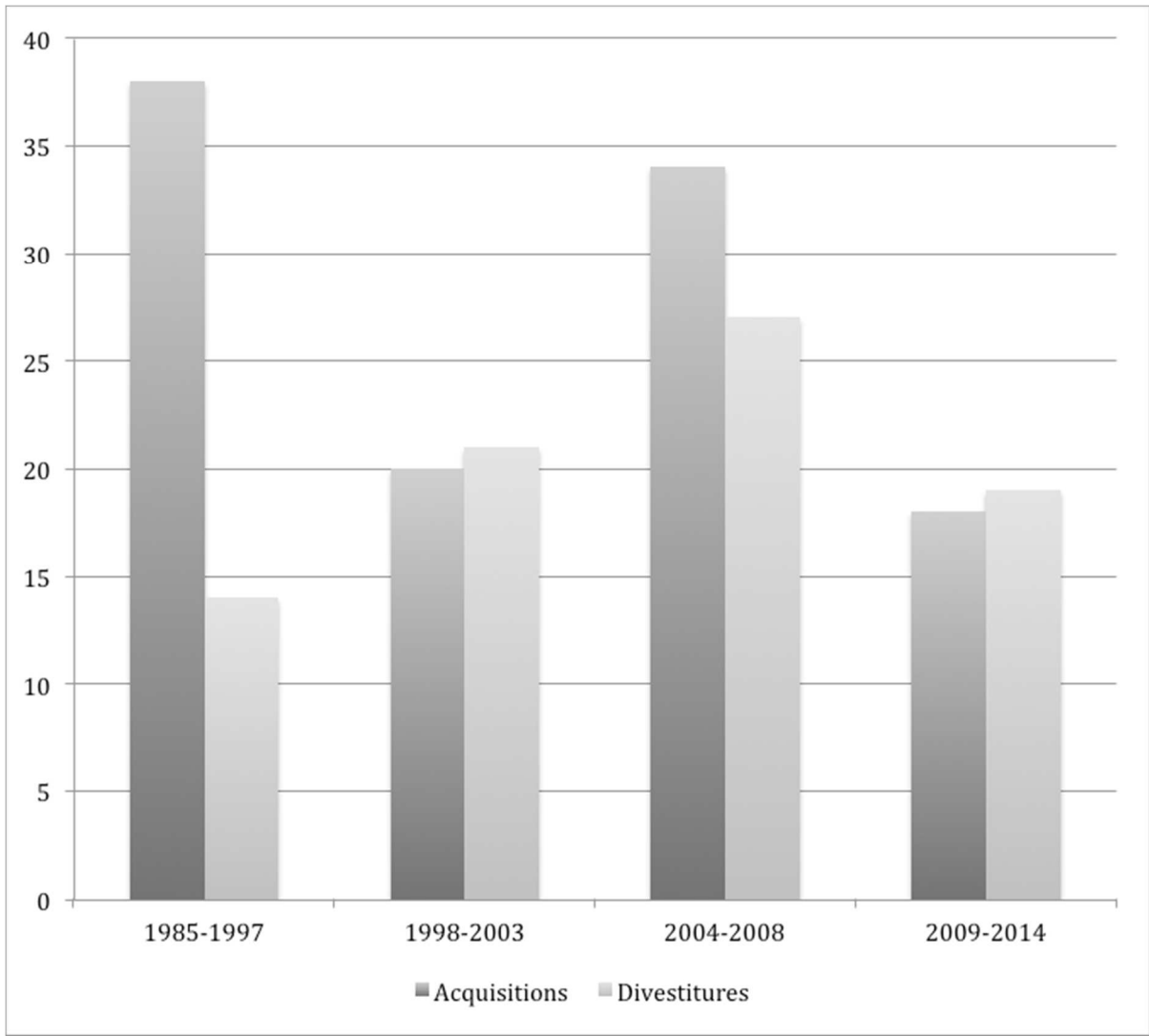


Figure 4.1: Pfizer's Acquisitions and Divestitures, 1985-2014 (Mergerstat, various years)

Table 4.2: Pfizer's Acquisitions and Divestments by Type, 1985-2014

Year Cluster	Intangible Asset		Company		Tangible Asset	
	<i>Acquired</i>	<i>Divested</i>	<i>Acquired</i>	<i>Divested</i>	<i>Acquired</i>	<i>Divested</i>
1985-1997	18	3	19	10	1	1
1998-2003	16	14	4	8	0	0
2004-2008	16	5	17	11	1	11
2009-2014	6	5	12	3	0	10
Totals	56	27	52	32	2	22

Source: Mergerstat (various years)

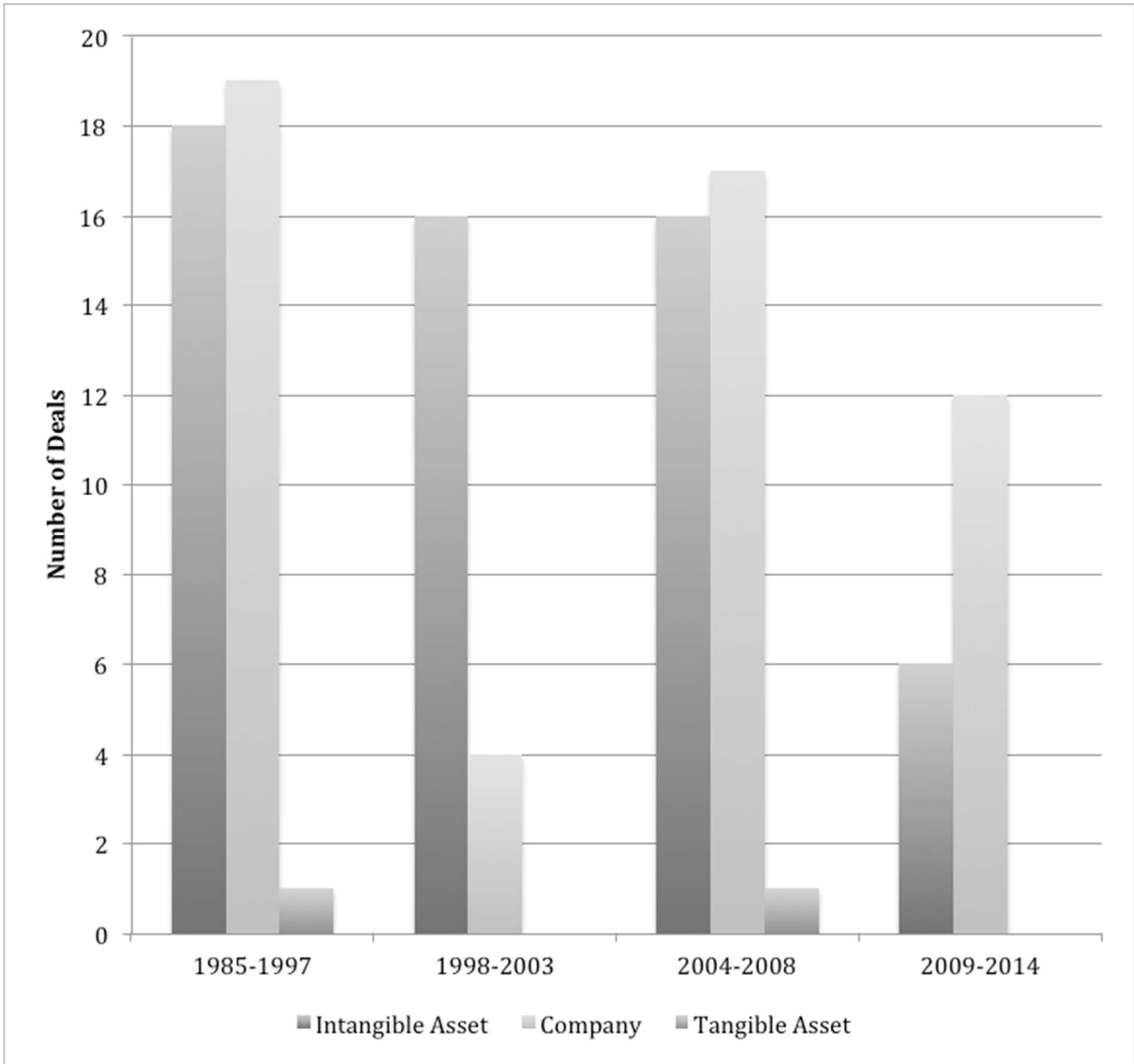


Figure 4.2: Pfizer's Acquisitions by Type, 1985-2014 (Mergerstat, various years)

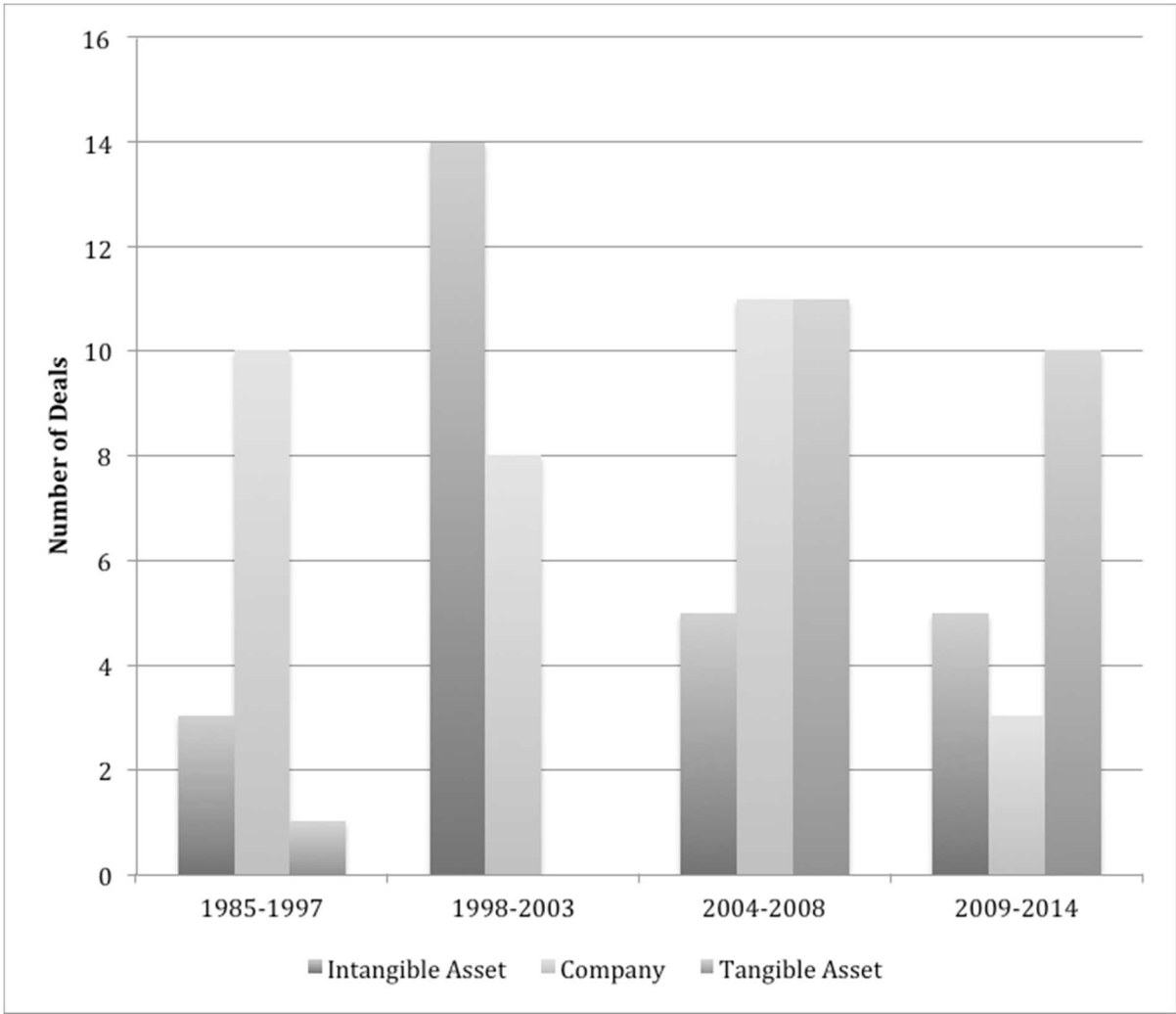


Figure 4.3: Pfizer's Divestments by Type, 1985-2014 (Mergerstat, various years)

intangible property rights held by the acquired company. For example, Pfizer's acquisition of Pharmacia in 2003 was primarily motivated by the acquisition of rights to several patented drugs. While tangible assets are included in these deals, the primary catalyst for them is the intangible assets that grant the new owner a differential advantage. For this reason, though I separate them into unique categories, company acquisitions and intangible asset acquisitions may be considered similar in terms of motivations. Company divestitures may be seen in a similar way, but the motivation here is primarily refocusing. Pfizer's sale of subsidiaries typically results in the relinquishing of control over rights to parts of their business that are not related to pharmaceuticals.

The four time periods are distinguished by business strategy, which emerges out of the data discussed below. Pfizer's merger and acquisition history will show that during the first time period Pfizer ended the conglomeration strategy and began refocusing on pharmaceutical research, building their technological capabilities. During the second time period, Pfizer's strategy involved filling its pipeline through acquisition, with most divestments mandated by the Federal Trade Commission. The third time period may be seen as an extension of the second time period, though includes early stages of cost cutting *via* tangible asset divestment. Data from the final period will show a continuation of this trend of divesting tangible assets, with an acquisition strategy directed at acquiring companies with already established products.

In 1985, Pfizer was still in the conglomerate phase, acquiring American Medical Systems. This trend of acquisition continued during the last half of the 1980s; of the 11

acquisitions made between 1986 and 1990, none were related to pharmaceutical preparations, and only one could be considered part of a related industry: Oral Research Laboratories, a producer of consumer healthcare products, which was acquired in two purchases in 1987 and 1988. The divestments made, however, show Pfizer's desire to begin winding down its conglomerate activities and refocus on research-based pharmaceuticals. Between 1985 and 1992, three of the 10 divestments were remotely related to pharmaceuticals and chemicals, but not to the development of *new* pharmaceutical products. Two were product lines falling under the consumer healthcare business: Plax Mouthwash⁸ was sold to Colgate and the Coty Fragrance and Cosmetics product line was sold to Benckiser Consumer Products. In 1990, Pfizer sold its citric acid business to Archer-Daniels-Midland⁹.

In 1992, Pfizer began to refocus on pharmaceuticals. Between 1992 and 1995, it made 20 acquisitions. Nine were agreements with companies to gain access to technology to be used for genetic screenings or deals giving Pfizer rights to drugs already in development¹⁰. In 1995, Pfizer agreed to collaborate with five companies –

⁸ Pfizer continued to market the product.

⁹ In 1998, Archer-Daniels-Midland was found guilty of fixing prices in the citric acid market (Clarke & Evenett 2003).

¹⁰ The remaining agreements included two associated with medical equipment, the acquisition of consumer healthcare products from four different companies, and two agreements regarding animal health.

Immusol, Myco Pharmaceuticals, AEA Technology, Oxford Asymmetry, and Neurogen¹¹ – to help Pfizer build its learning bases in genetics through the creation of the PfizerGen program, a research program specifically designed to target genetic treatments (Glaser 1995). In exchange for equity purchases, financing, and royalty payments, these companies agreed to give Pfizer access to screening technologies or co-develop drugs. In 1996, Pfizer made three similar deals with Thompson Medical, Microcide Pharmaceuticals, and Catalytica Pharmaceuticals. Each of these agreements were directed at the discovery phase of pharmaceutical research. During this time period, Pfizer made six divestments – none of which involved the core business. Two were medical equipment businesses, while Pfizer also spun off its specialty minerals business into Minerals Technology, Inc.

The period from 1985 through 1997 can be seen as a time of re-focusing, as Pfizer wound down its conglomerate activities and began building its learning base in biotechnology with the PfizerGen program. The time period from 1998 through 2003 continued this trend, though Pfizer made two mega-deals for the purpose of obtaining established pharmaceutical products¹². Each of the 20 acquisitions made during this time period was related to new or established pharmaceuticals, consumer healthcare, and animal health. Thirteen of the deals were collaborations or joint-ventures that granted Pfizer access to the tools developed by the supporting nexus for the purposes of

¹¹ The Neurogen agreement was an expansion of two previous agreements in 1992 and 1994 to give Pfizer access to screening technology for potential central nervous system drugs. The deal would be renewed again in 1999.

¹² An established pharmaceutical product refers to any FDA-approved drug under patent and any generic drug.

drug discovery. In 1998, Pfizer entered into an agreement with Aventis SA to co-develop the drug Exubera, an inhalable form of insulin. In 2001 and 2003, Pfizer made two other deals related to this agreement, partnering with Metabolex Inc. for insulin discovery and licensing Meridica Ltd.'s dry powder inhaler. Pfizer acquired the full rights to the drug in 2006, but dropped the product in 2007 after poor sales (Mack 2007).

In 2000, Pfizer acquired Warner Lambert for \$90 billion (Langreth 2000). The two companies had an existing agreement regarding the blockbuster cholesterol medication Lipitor. Parke Davis – a Warner Lambert subsidiary – had developed the drug while Pfizer owned the exclusive marketing rights. Pfizer took full control over Lipitor, which from the time of acquisition through 2011 when it lost patent protection was the world's top selling drug (Bailey 2015). In 2003, Pfizer acquired the Swedish company Pharmacia for \$60 billion in stock. The deal gave Pfizer rights to five established drugs – Celebrex, Bextra, Xalatan, Camptosar, and Epleronone – and provided Pfizer with the organizational capabilities to enter the cancer market¹³. The deal also increased Pfizer's R&D budget to \$7 billion and its share of the pharmaceutical market to 11% (Frank & Hensley 2002).

During this time, Pfizer made, or was involved in, 22 divestitures. In 1998, it continued its refocusing plan by selling two medical equipment businesses – American Medical Systems and Howmedica, acquired in 1985 and 1972 – along with its aquarium and pond supply business. In 2003, Pfizer also sold its generics business to the South

¹³ Celebrex was the key to the deal, at that time grossing \$3.1 billion in sales.

African Tiger Brands Pharmaceuticals. Of the 22 divestments, 13 were mandated by the Federal Trade Commission as a result of the acquisitions of Warner Lambert and Pharmacia¹⁴ (FTC 2000, 2003). Pfizer was required to sell its RID brand of lice treatment and return its rights to the lung cancer treatment Tarceva to OSI Pharmaceuticals¹⁵, while Warner Lambert sold its drugs Celexa and Cognex. For the Pharmacia acquisition, Pfizer was required to sell three of its established hormone drugs – Estrostep, Leostren, and Femhrt – along with the rights to the overactive bladder medication Enablex. Pharmacia was required to sell the rights to several drugs it had in development, as well as its Cortaid business.

The period from 1998 through 2003 was an extension of the earlier period. Pfizer had, for the most part, ended its conglomeration activities and used mergers and acquisitions to obtain already established intangible assets and gain access to the supporting nexus. This begins to change during the next period. From 2004 through 2008 is another period of re-focusing, though in a different way. On the acquisition side, Pfizer is much more active, making 34 such transactions. Seventeen of the acquisitions were company acquisitions, compared to four during the previous period. Rather than focus on discovery, many of these acquisitions involved acquiring companies that had compounds in the clinical testing phase – Pfizer’s approach during this time was to replenish its product pipeline through acquisition, rather than internal development.

¹⁴ I include divestments made by all parties involved here – Pfizer, Pharmacia and Warner Lambert – as such deals are unlikely to have occurred without the merger.

¹⁵ OSI Pharmaceuticals and Pfizer were co-developing the drug.

In 2004, Pfizer acquired Esperion Pharmaceuticals. Esperion was developing a cholesterol medication – torcetrapib – that Pfizer had hoped would replace Lipitor once it went off patent. However, the drug failed to pass Stage III clinical trials, and Pfizer sold Esperion in 2008 as a result (Harper 2008). Pfizer also acquired two companies in 2005 – Idun Pharmaceuticals and Vicurion Pharmaceuticals – for the sole purpose of filling its pipeline: Vicurion’s drugs Eraxis and Zevan replaced the antifungal Diflucan, which lost patent exclusivity in 2004, while Idun had patents covering 150 different targets, new chemical entities, screening assays, diagnostics, and antibodies ready for development. This trend continued in 2006 when Pfizer acquired Schwarz Pharma AG and PowderMed to obtain the rights to the overactive bladder treatment fesoterodine and to gain access to the vaccine market. In 2008, Pfizer acquired three companies that had compounds in clinical testing: CovX Biotherapeutics had three early stage compounds, one for diabetes and two for oncology; Encysive Pharmaceuticals Inc., which was acquired to obtain the rights to Thelin, a pulmonary arterial hypertension treatment; and Serenex Inc., which had developed the compound SNX-5422, a Stage I clinical trial candidate in oncology.

Pfizer’s divestment strategy, while reinforcing its focus on research based prescription pharmaceuticals, also represents the beginning of their emphasis on intangible assets over tangible. That is to say, Pfizer’s re-focusing represents an effort to accumulate intangible assets and outsource its production activities. Of the 11 company divestments made in 2004 and 2005, three were related to their core prescription

pharmaceutical business, and each was focused on generic products¹⁶. During these two years, Pfizer also sold several manufacturing plants to Warner Chilcott and Fareva SA, as well as a research and development center. The deal with Fareva is notable because later sales of plants would be of a similar characteristic: while Fareva assumed ownership of the plants, they agreed to continue to produce medications for Pfizer in a sub-contracting type of deal¹⁷. Similar agreements were made with Nichol's Primal and Kemwell International in 2006 – Pfizer sold the plant, but the buyers agreed to continue to produce drugs for Pfizer. During 2006, Pfizer also divested itself of its consumer healthcare business, selling to Johnson & Johnson¹⁸. In 2007, Pfizer continued production outsourcing, selling plants to Abraxis BioSciences, Nihon Generic Co. Ltd., and Kaeta Pharmaceuticals, as well as a 3rd party manufacturing business to Fareva SA. In 2008, Pfizer not only sold manufacturing facilities to Actavis and Hovione, it also sold a research laboratory to the University of Michigan, reducing its ability to internally develop pharmaceuticals. Pfizer also spun off two companies focused on developing new pharmaceuticals: Esperion, as mentioned above, after torcetrapib failed to pass Stage III approval; and RaQualia Pharmaceuticals, a Japanese research and development laboratory that formed its own independent enterprise.

¹⁶ The other divestments were in the areas of consumer healthcare, animal health, and medical equipment.

¹⁷ This outsourcing of manufacturing activities to third parties has come to be a common occurrence in high-tech industries. Sturgeon (2002) refers to these as modular production networks.

¹⁸ As part of the deal, Pfizer was required by the Federal Trade Commission to sell its Cortizone, Unisom, and Balmex product lines to Chattem; and Johnson & Johnson was required to sell its Zantax H-2 product line to Boehringer (FTC 2006).

From 2009 through 2014, the strategy of cutting costs by divesting tangible assets became dominant. Further, Pfizer shifted its acquisition strategy from acquiring companies with drugs in development to acquiring companies with already established products. Of the 18 acquisitions made during this time, 15 were company or intangible asset acquisitions, with nine including established pharmaceuticals. The biggest acquisition during this time was the 2009 purchase of Wyeth for \$68 billion, motivated by the threat of the patent cliff (2009). From 2009 through 2014, fourteen of Pfizer's drugs were scheduled to lose patent protection without internally developed replacements¹⁹. The acquisition of Wyeth helped alleviate this threat by adding Prevnar, a treatment for childhood infections, and Enebrele, a rheumatoid arthritis treatment, as well as giving Pfizer a stronger learning base in vaccines. Similarly, Pfizer acquired Axxordia Ltd. for its treatments for heart disease, liver failure, Parkinson's, and multiple sclerosis. In 2010, Pfizer continued to gain intangible assets through acquisition, but also expanded into the rare disease/niche market. The acquisition of FoldRX gave Pfizer an entry into the rare disease/niche industry through the transthyretin amyloid polyneuropathy drug Tafamandis, while it also acquired 16 niche abbreviated new drug applications from Akron Inc.

In 2011, four of Pfizer's five acquisitions were to replenish its pipeline: it acquired Ferrosan SA's consumer healthcare business, Icagen Pharmaceuticals for their pain medications, and Excalliard Pharmaceuticals after successful Stage II clinical tests for their anti-fibrotic antisense drug EXC 001. Pfizer also made a major acquisition in

¹⁹ Between 2000 and 2008, Pfizer released four new molecular entities: Argatroban in 2000, Geodon in 2001, Relpax in 2002, and Toviaz in 2008 (FDA 2015).

purchasing King Pharmaceuticals for \$3.6 billion, enhancing Pfizer's presence in the pain killer market (Pettypiece & Larkin, 2010). The targets of this acquisition were five different drugs: the morphine pill Embeda; the non-narcotic Flector pain patch; Thrombin JMI; Levoxyl; and the in-development Remoxy, being co-developed with Pain Therapeutics. Remoxy had previously failed to obtain approval while owned by King. Pfizer resubmitted the drug to the FDA twice, once in 2011 after acquiring it and once again in 2013, but was rejected both times. After the second rejection, Pfizer returned its rights to the drug to Pain Therapeutics in October of 2014 (Carroll 2014).

In 2012, Pfizer acquired NextWave Pharmaceuticals for the rights to the ADHD treatment Quillivant XR, and in 2014 acquired InnoPharma and Baxter International. From InnoPharma, Pfizer acquired 10 approved generic products, 19 pipeline products, and 30 injectable ophthalmic products in development. The key to the Baxter acquisition was the vaccine unit, which included the meningitis vaccine NeisVac-C and the encephalitis vaccine FSME-IMMUN. This capped off a period of company acquisitions, primarily for the purpose of filling Pfizer's pipeline and expanding its intangible asset base.

On the divestment side, Pfizer's outsourcing strategy continued. Of the 18 divestments made, ten were sales of plants, research sites, and other tangible assets while seven were sales of non-core businesses. In 2009, Pfizer sold plants in Latina, Italy and Frankfurt, Germany to Haupt Pharmaceuticals and MannKing Corp.²⁰

²⁰ The plant sold to MannKing was centered on insulin production, and its sale was related to the failure of Exubera. In 2014, MannKind Corp. received approval for their

respectively, the former agreeing to continue to manufacture antibiotics for Pfizer. As part of the acquisition of Wyeth, the FTC mandated that Pfizer sell half of Wyeth's Fort Dodge animal health business to Boehringer Ingelheim GmbH. These mandates continued in 2010, when Pfizer was required to sell parts of its animal health business to VrBac S.A. by the FTC, Elanco Animal²¹ by European regulators, and Harbin Pharmaceutical group by the Anti-Trust Bureau of China's Ministry of Competition (FTC 2009; Kwok 2010). In 2011, Pfizer continued the outsourcing strategy by selling manufacturing plants to Amgen, KKR&Co., BioMarin, and Fareva SA. Amgen and Fareva agreed to continue to produce output for Pfizer while proceeds from the KKR&Co. deal were used to repurchase outstanding shares. From 2012 through 2014, Pfizer engaged in five divestments – three were sales of plants and production sites, which included subcontracting deals, while Pfizer also sold its nutrition business to Nestle and spun off its animal health business into a separate company, Zoetis.

Finally, it is also worth mentioning Pfizer's stock buybacks. Stock buybacks are a tool used by enterprises to reduce the number of shares outstanding of the company and increase the price of the stock. This is important within the New Economy Business Model, as it increases the earnings per share for owners. Further, when a company chooses to buy back its stock, it is choosing not to use those financial resources in the production of output. A stock buyback is a pure third degree tool used to increase shareholder value without affecting any of the day-to-day operations of the going plant

own inhalable insulin product, Afrezza, which was released in 2015. Like Exubera, it has performed poorly, prompting the CEO to step down (Mittelman 2015).

²¹ Elanco Animal is a subsidiary of Eli Lilly.

or the productive ability of the enterprise as a whole. From 1991 through 2014, Pfizer authorized or completed 16 stock buybacks for a total of over \$103 billion, with \$41 billion being authorized between 2011 and 2014. Several important buybacks include \$169.3 million in 1994, as these shares were used as currency to acquire the medical equipment company Namic USA Corp.; \$17 billion in 2005 which occurred with Johnson & Johnson's acquisition of Pfizer's consumer healthcare business; \$10 billion in 2012, with some of the funds being raised from the sale of manufacturing plants; and an \$11 billion authorization after Pfizer's failed bid to acquire AstraZeneca in the spring of 2014 - rather than repurpose those funds for R&D, Pfizer's strategy was to increase shareholder value through stock buybacks.

Final Thoughts on Pfizer's M&A History

Pfizer's corporate history, as seen here, fits within the framework described in the second chapter. As noted by Serfatti (2008), Lazonick (2008, 2010), and Dean (2013), the business enterprise within the New Economy Business Model takes the form of a transnational corporation. Rationing transactions imposed on the enterprise by absentee owners set the parameters within which the enterprise may act, and these actions are typically carried on by subsidiaries, or the locus of intangible assets. As seen in this history, Pfizer begins as a member of the supporting nexus - in a going-plant type role - but through the development of learning bases in antibiotics and aid from the government crash programs during World War II, becomes an entrenched member of the industry's core. It then uses its earnings from its core pharmaceutical business to branch to fields in which it did not have established organizational capabilities, such as

mining and medical equipment. This stunted Pfizer's development of learning bases in the new fields of biotechnology and enzymology, causing it to fall behind its competitors like Merck and Eli Lilly (Chandler 2005).

The next section examines the effect that the above history has had on Pfizer's revenue and balance sheet structure. This is done in three ways: First, I examine Pfizer's revenue structure by investigating the sales of its highest earners. In doing so, I differentiate between the drugs that Pfizer internally developed and the drugs that it acquired, focusing on the sales generated from each over the different time periods. If Pfizer is emphasizing the acquisition of intangible assets, rather than the internal development of drugs, we should expect to see revenue emanating from drugs acquired in the most recent time period to outweigh revenue from drugs that were internally developed. Next, I examine the composition of total assets. Over time, we should expect intangible assets to take on a more prominent position. Finally, I examine Pfizer's net tangible assets, which should be falling. When taken together, the implication is that Pfizer as a going enterprise is dependent upon its monopoly rights *qua* intangible assets to remain solvent rather than its productive capabilities.

The Accumulation of Intangible Assets

The purpose of this section is to examine the impact of Pfizer's strategic dealings on the structure of its sales and its balance sheet. First, I examine Pfizer's sales in 2014, and the drugs that generated over \$100 million in sales. The focus will be to see whether Pfizer's sales are due to drugs that it has internally developed, or drugs that it has acquired. Next, I examine Pfizer's intangible assets as a percentage of their total

assets. An enterprise with a high intangible asset to total asset ratio is one that is not relying on its productive capacity to earn profits, but rather its control over the social relations those intangible assets embody. Finally, I examine Pfizer's net tangible assets. Net tangible assets refer to the enterprise's book value; low or potentially negative net tangible assets reflect the reliance upon control over social relations to reproduce the enterprise as a going concern. By examining both, then, we can make reasonable claims as to the importance of accumulating intangible assets insofar as it pertains to Pfizer's reproducibility.

Pfizer's Sale and Revenue Structure

Table 4. 3 and Figure 4.4 shows Pfizer's revenues, research and development expenses, overhead expenses²², and net income from 1995 through 2014. Revenues increased fairly continuously from 1995 through the 2003 acquisition of Pharmacia, with only a slight decrease in 2002. From 2004 through 2009, revenues fell from \$43.01 billion to \$36.78 billion. The acquisition of Wyeth in late 2009 temporarily alleviated this problem, as revenues rose to \$49.39 billion in 2010, but since then, revenues have decreased to \$33.62 billion, below the pre-merger levels. R&D expenses increase slowly from 1995 (\$1.44 billion) through 2003 (\$5.95 billion) while Pfizer was in its discovery stage. However, from then on, are fairly stable until the acquisition of Wyeth increases R&D expenses to \$6.86 billion in 2010. Following this acquisition, however, R&D has fallen to \$5.69 below its pre-merger level of \$5.77 billion. This implies that in inflation adjusted terms, though Pfizer currently spends more on R&D than it did prior to 2003,

²² This includes advertising expenses.

Table 4.3: Pfizer's Revenues, R&D Expenses, Overhead, and Net Income, 1995-2014 (Millions of 1995 Dollars)

Year	Revenues	R&D Expenses	Overhead	Net Income
1995	10021.00	1442.00	3855.00	1572.00
1996	11010.10	1639.93	4251.73	1878.51
1997	11892.99	1833.79	4713.83	2104.86
1998	12594.26	2119.19	5177.56	3116.02
1999	14761.91	2528.95	5785.79	2896.08
2000	26300.49	3944.10	10175.50	3313.57
2001	27943.36	4198.56	9787.41	6746.11
2002	27406.44	4381.91	9182.04	7725.92
2003	37704.41	5950.03	12717.77	3262.46
2004	43057.39	6300.04	13858.62	9314.78
2005	41166.89	5973.29	13642.57	6489.39
2006	37872.61	5949.72	12205.58	15140.12
2007	37044.45	6188.87	11955.40	6230.95
2008	36121.46	5942.21	10872.49	6061.13
2009	36776.19	5769.15	10938.95	6350.10
2010	49393.26	6856.59	14287.18	6014.54
2011	48312.47	6529.08	13949.53	7171.81
2012	41392.00	5522.58	11659.88	10224.14
2013	35570.49	4604.91	9898.70	15172.49
2014	33617.91	5688.04	9553.71	6190.90

Source: Pfizer (various years)

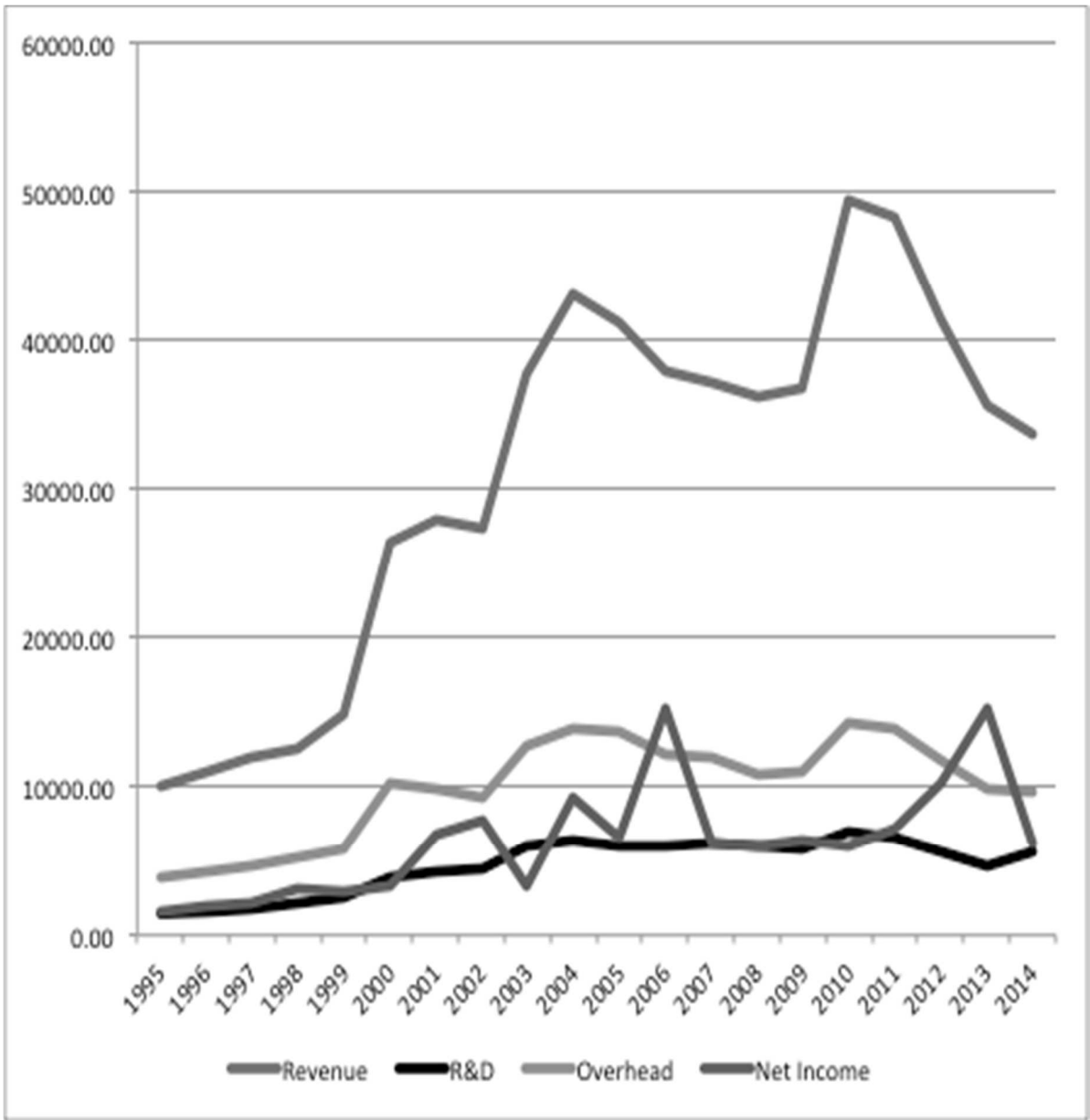


Figure 4.4: Pfizer's Revenues, R&D Expenses, Overhead, and Net Income, 1995-2014 (Pfizer, various years)

it has not experienced rising costs as its CEO Ian Read has claimed in justification for high pharmaceutical prices (Herper, 2015).

Table 4.4 and Chart 4.5 show Pfizer's revenues emanating from drugs grossing over \$100 million in sales in 2014²³. Of the \$37.67 billion in sales in 2014, \$8.01 billion was from drugs Pfizer internally developed, \$26.977 was from drugs Pfizer acquired, and \$2.683 billion was from drugs developed as part of a joint venture²⁴. Of the 45 drugs grossing over \$100 million in sales, only two that were internally developed sold over \$1 billion in 2014 –Viagra and Norvasc, both of which were approved prior to 1998. The emphasis on acquisition of drugs rather than internal development is clear in this data; of Pfizer's 2014 drug sales, \$16.554 billion came from drugs that were acquired between 2009 and 2014, compared to \$410 million from drugs that were internally developed over the same time period. The inability for Pfizer to internally develop and release new drugs is also clearly seen. Internally developed drugs released after 2004 account for only \$1.081 billion of the 2014 total \$37.67 billion in sales. Over this same time period, drugs acquired since 2004 accounted for over \$21 billion of the total sales. These data support the claims from the preceding section that Pfizer is reliant on the external acquisition of drugs to maintain itself as a going concern, rather than internal development.

²³ For a full list of these drugs, their sales, and how they were acquired, please see Appendix B.

²⁴ Of this \$2.683 billion, \$2.061 billion come from sales of Lipitor.

Table 4.4: Pfizer's 2014 Sales From Internally Developed, Acquired, and Joint-Venture Created Drugs Grossing Over \$100 Million Sales in 2014, Based on Year of Drug Approval/Acquisition (Millions of 2014 Dollars)

Year of Approval/Acquisition	Internally Developed	Acquisition	Joint Venture	Total
1950-1997	3,153	0	622	3,775
1998-2003	3,056	5,255	2,061	10,372
2004-2008	1,391	5,168	0	6,559
2009-2014	410	16,554	0	16,964
Total	8,010	26,977	2,683	37,670

Source: Pfizer (2015)

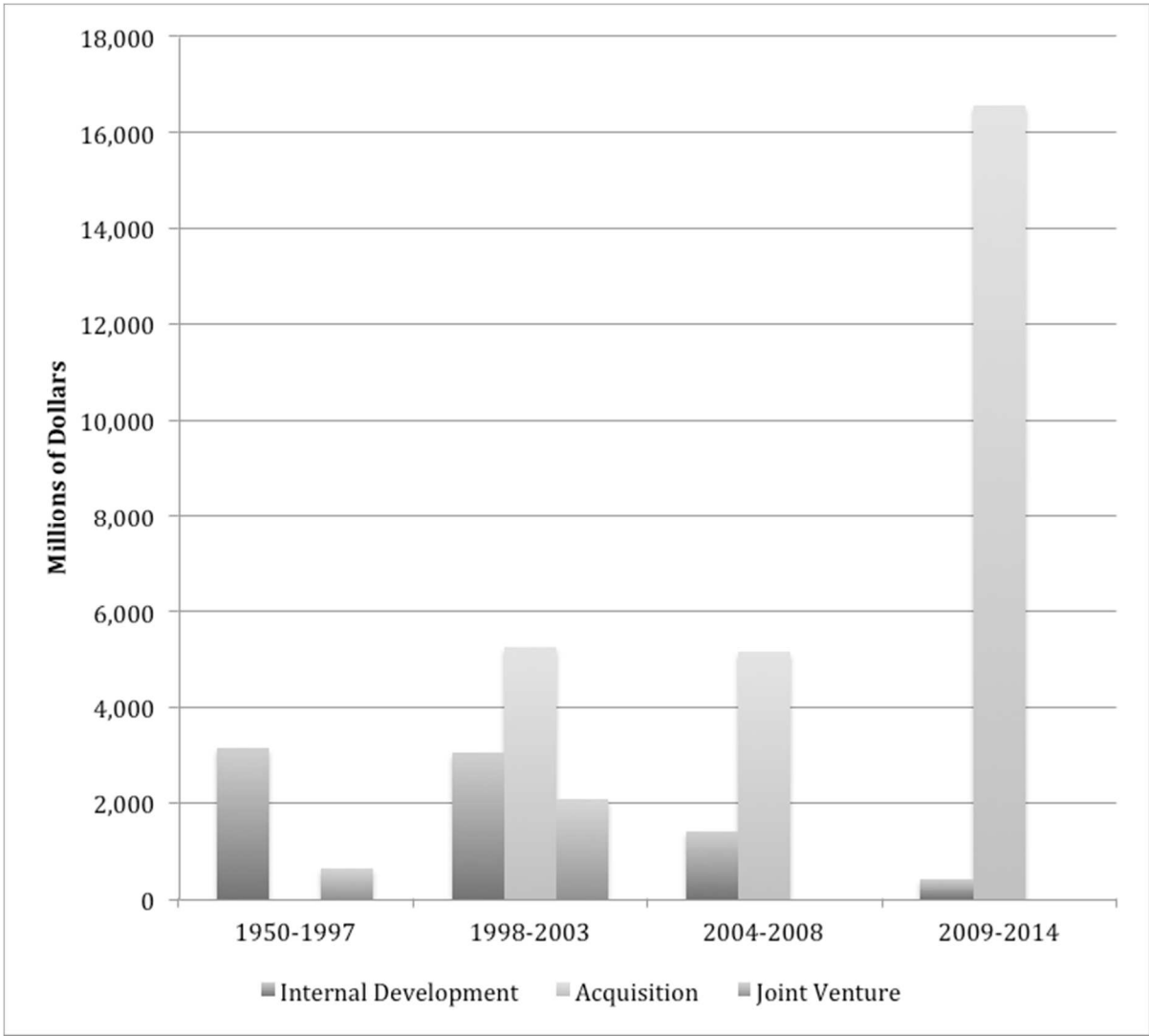


Figure 4.5: Pfizer's 2014 Sales From Internally Developed, Acquired, and Joint Venture Created Drugs Grossing over \$100 Million in Sales, Based on the Year of Approval/Acquisition (Pfizer 2015)

Intangible and Tangible Assets

Intangible assets can be divided into two categories: definite lived and indefinite lived. Indefinite lived intangible assets are those that have no foreseeable limit to the cash flow they grant the company; this includes items such as goodwill and trademarks (FASB 2001). Definite lived intangible assets, such as patents, do have a foreseeable limit due to hard expiration dates²⁵. On a firm's balance sheet, goodwill is removed from the indefinite lived intangible asset category and included as its own section; this is calculated as the sum of the differences between the acquisition value and book value of acquired companies, less impairment. Goodwill can only increase on the balance sheet, then, as a result of acquiring other companies. In the data presented here, I categorize intangible assets in three ways: first, total intangible assets, which includes goodwill, non-goodwill indefinite lived intangible assets, and definite lived intangible assets²⁶. Second, goodwill is considered to be its own category. Finally, total intangible assets are included²⁷. Each of these is represented as a percentage of total assets.

²⁵ While trademarks can expire, they can also be continuously renewed. Patents, on the other hand, may not be renewed and may only be extended under certain circumstances for a predetermined amount of time. This does not prevent the company from altering the product and applying for a new patent, but this would be considered a different intangible asset.

²⁶ This is for consistency, as prior to 2001 companies were not required to separate definite and indefinitely lived intangible assets

²⁷ I use gross intangible assets here, rather than net intangible assets. For accounting purposes, intangible assets are amortized over their useful life, which for all intents and purposes is the intangible equivalent of depreciation. I use unamortized assets instead of amortized, as, from an economic standpoint, the intangible asset does not lose its earning capacity over time in the same way a tangible asset does. A monopoly right in year one generates the same earning capacity as a monopoly right in year two, whereas

Table 4.5 and Figure 4.6 show Pfizer's intangible assets as a percentage of total assets. The pattern shown here fits with what one would expect given Pfizer's merger and acquisition history. From 1995 through 2002, Pfizer's intangible assets decrease, though there is a slight uptick in 2000 when Warner Lambert is acquired. This period, as mentioned, was when Pfizer re-focused on research based pharmaceuticals, building their learning bases in biotechnology. The decrease, then, can be seen as part of an attempt to internally develop their own pharmaceuticals. More important is the diminishing goodwill – goodwill decreased by 47.77% between 1997 and 1998, and 51.21% between 2001 and 2002. Over the course of the whole period, goodwill fell from 20.38% of total assets to 2.59% of total assets, the only important increase being in 2000 when Pfizer acquired Warner Lambert. This changes in 2003 when Pfizer acquires Pharmacia. All three measures show a spike: total intangible assets become 51.34% of total assets, up from 5.15%; non-goodwill intangible assets become 32.67% of total assets, up from 2.56%; and goodwill becomes 18.67% of total assets, up from 2.59%. Between 2003 and 2009, intangible assets as a percent of total assets decline slightly, but for the most part stay stable. The decline is driven primarily by a decline in non-goodwill intangible assets as a percentage of total assets. Goodwill as a percent of intangible assets, though it decreases from 2005 to 2006, stays fairly consistent. The acquisition of Wyeth in 2009 leads to another spike in intangible assets. Total intangible assets increases to 56.37% of total assets, up from 44.54%; non-goodwill intangible

a machine in year one has less wear and tear than the same machine in year two. Using unamortized intangible assets, then, gives a better understanding of the enterprise's accumulation of intangible assets.

Table 4.5: Pfizer's Intangible Assets as a Percentage of Total Assets

Year	Total Intangible Assets	Goodwill	Non-Goodwill Intangible Assets
1995	20.80%	10.38%	10.42%
1996	22.51%	10.49%	12.01%
1997	19.23%	9.65%	9.59%
1998	12.62%	5.04%	7.58%
1999	11.90%	4.34%	7.56%
2000	13.93%	6.24%	7.69%
2001	12.56%	5.31%	7.25%
2002	5.15%	2.59%	2.56%
2003	51.34%	18.67%	32.67%
2004	48.69%	18.28%	30.41%
2005	48.14%	18.85%	29.28%
2006	45.25%	16.25%	29.00%
2007	44.38%	16.20%	28.18%
2008	44.54%	16.54%	28.00%
2009	56.37%	18.01%	38.36%
2010	57.95%	19.75%	38.20%
2011	58.80%	19.90%	38.90%
2012	57.40%	19.83%	37.57%
2013	58.09%	19.76%	38.33%
2014	57.32%	19.51%	37.81%

Source: Pfizer (Various Years)



Figure 4.6: Pfizer's Intangible Assets as a Percentage of Total Assets (Pfizer, various years)

assets increase to 38.36% of total assets, up from 28.00%; and goodwill increases to 18.01% of total assets, a slight increase from 16.54%. Increases are seen in 2010 and 2011 as well, before starting to slowly decrease. The movements in this later period are driven almost exclusively by changes in non-goodwill intangible assets. Goodwill as a percentage of total assets stays more or less constant from 2010 through 2014.

From 1995 through 2014, it should be clear that Pfizer has been accumulating intangible assets at the expense of tangible assets. This comes as Pfizer itself has grown larger – its total assets in 2014 were \$169.3 billion, compared to \$12.8 billion in 1995. The importance of mega-deals is also seen in this data, as the acquisitions of Pharmacia and Wyeth greatly increased the amount of assets held by Pfizer that were intangible. Pfizer's strategy can be seen as one in which acquisitions are primarily driven by the addition of intangible assets, which has resulted in an increasing importance of intangible assets on the balance sheet. In 2014, intangible assets composed 57.32% of total assets, meaning any return on investment is being driven primarily by Pfizer's control over social relations.

Net Tangible Assets

Another measurement that displays the importance of intangible assets is net tangible assets. Net tangible assets are calculated by subtracting total liabilities and total intangible assets from total assets. Because solvency requires that total assets are greater than total liabilities, net tangible assets helps measure the enterprise's reliance on control over social relations *qua* intangible assets to remain a going concern. Based on Pfizer's merger and acquisition history, one would expect net tangible assets to rise

or remain steady in the early period, but begin to fall from 2008 onwards due to the increased emphasis on reducing tangible assets through outsourcing of production activities combined with the accumulation of intangible assets through merger and acquisition.

Table 4.6 and Figure 4.7 show exactly this. From 1995 through 2002, as Pfizer was still in its focus on expanding its research based pharmaceutical business, net tangible assets increase from \$2.8 billion to \$14.8 billion. It drops in 2003 – to \$5.6 billion – as a result of the Pharmacia merger, but then continues to increase until 2006. From 2006 through 2008, net tangible assets decreases from \$20.5 billion to \$13.7 billion as Pfizer begins to sell off its tangible assets while maintaining its intangible property rights. In 2009, net tangible assets becomes negative – dropping to -\$14.7 billion – as a result of the Wyeth acquisition. Unlike the Pharmacia acquisition, where net tangible assets were back to their pre-merger levels by 2005, net tangible assets never fully recovered. Since 2009, Pfizer’s net tangible assets have been negative; in 2014, they were -\$4 billion.

These results, too, lend support to the conclusions that emerged out of Pfizer’s merger and acquisition history. Over time, Pfizer has emphasized the accumulation of intangible assets rather than the maintenance of productive capacity. This has led to a reliance on acquiring medications to sell rather than internally developing their own intangible assets; intangible assets taking on a greater importance in the structure of the balance sheet, rising from 20.8% of total assets in 1995 to 57.32% in 2014; while also reducing Pfizer’s book value to the point where it relies on control over the social

Table 4.6: Pfizer's Total Assets, Total Liabilities, and Net Tangible Assets, 1995-2014 (Millions of 1995 Dollars)

Year	Total Assets	Total Liabilities	Net Tangible Assets
1995	12729.30	7222.70	2858.80
1996	14283.13	7511.13	3557.39
1997	14258.47	6713.11	4803.23
1998	17018.62	8826.40	6045.14
1999	18743.00	10646.91	5865.96
2000	29800.82	15504.25	10144.37
2001	33915.07	18069.33	11586.54
2002	39244.21	22354.88	14819.44
2003	97435.89	42885.98	5607.93
2004	101407.39	45426.88	9240.99
2005	93885.45	41100.27	11400.78
2006	90468.02	34597.48	20460.34
2007	88191.17	38452.23	17696.69
2008	83129.62	40082.44	13740.01
2009	156600.86	90087.65	-14651.20
2010	142051.60	77757.83	-9628.22
2011	134710.29	75509.33	-9409.56
2012	130379.24	73063.69	-5712.05
2013	118674.73	65840.31	-3643.66
2014	114719.04	66397.49	-4021.54

Source: Pfizer (Various Years)

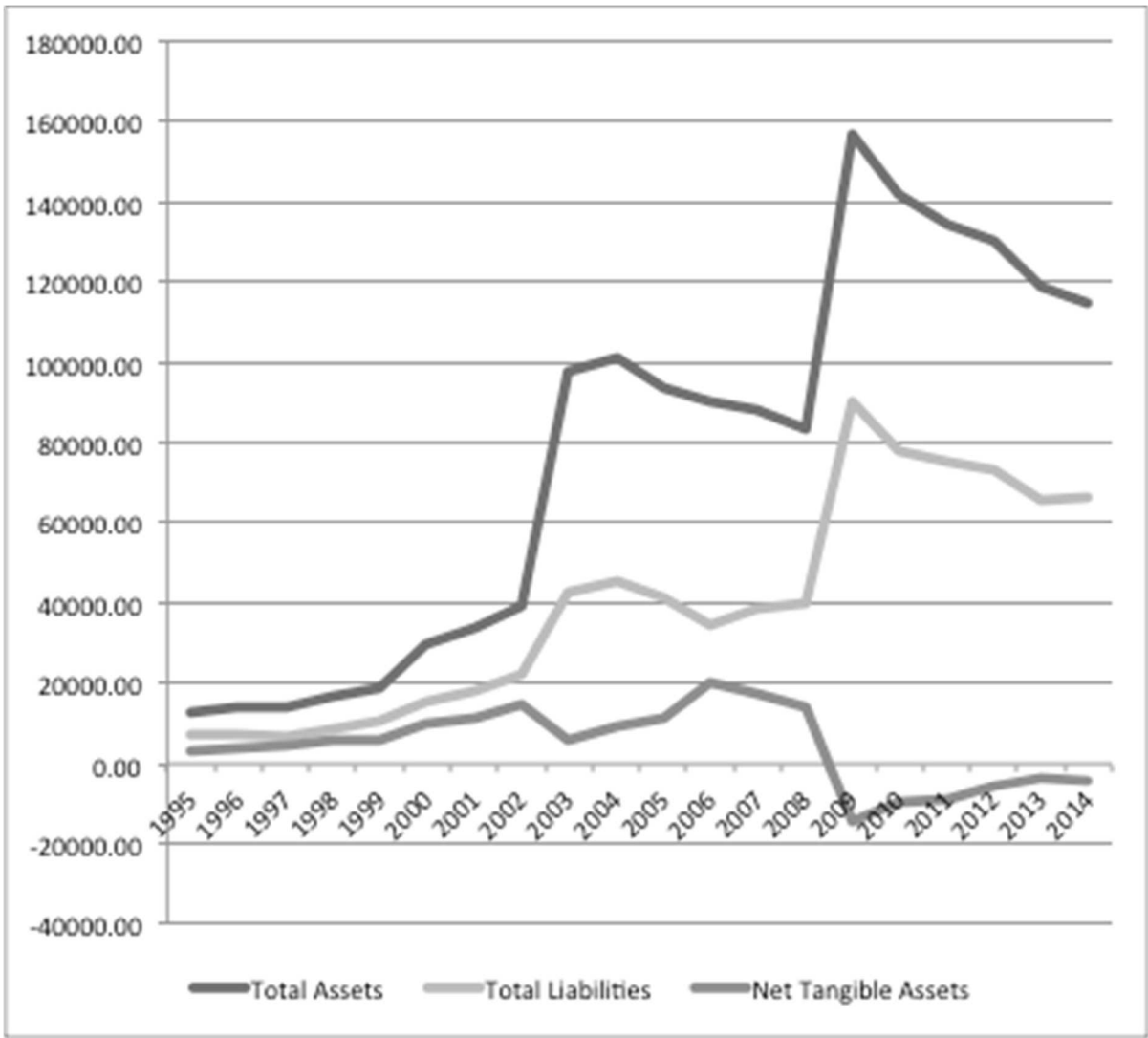


Figure 4.7: Pfizer's Total Assets, Total Liabilities, and Net Tangible Assets, 1995-2014 (Pfizer, various years)

relations, as discussed in the second chapter, to remain solvent. As a result, Pfizer has taken on the characteristic of the transnational corporation described by Serfatti (2008). The primary focus is the acquisition of intangible property rights, with the actual production activities being secondary; they are outsourced and conducted by members of the supporting nexus through cross-licensing and subcontracting agreements. The ability for Pfizer to remain a going concern, then, depends upon its continual accumulation of differential advantages *qua* intangible assets.

Conclusion

This chapter has examined Pfizer's history, beginning with its origins as a nexus member producing chemicals for pharmacists and finishing with it as a core company reliant upon the acquisition of intangible assets. Over time, Pfizer's conduct with regards to acquisitions and divestitures has changed as well. Upon becoming a member of the core post-World War II, it initially branched out very quickly, becoming a conglomerate in the 1970s and 1980s. The new lines of business required different learning bases and organizational capabilities than chemicals and prescription pharmaceuticals, causing Pfizer to miss out on the beginning of the biotech revolution. It refocused in the early 1990s by partnering with periphery companies to access the new paths of pharmaceutical learning. These periphery companies had property rights over screening technologies and strong technological capabilities – they were proficient in the research and discovery of new compounds.

In the 2000s, Pfizer switched strategies; rather than acquire companies with the technological capabilities to aid in the discovery of new molecular entities, Pfizer began

acquiring companies with compounds already in development. Using its strong functional capabilities to facilitate the development and distribution of pharmaceuticals, Pfizer began to accumulate intangible assets and goodwill. Driven by the acquisition of Pharmacia in 2003, intangible assets as a percentage of total assets increased from 13.93% in 2000 to 48.14% in 2005. These acquisitions were primarily speculative in nature, as the compounds acquired still needed to pass through the latest, most costly stages of FDA approval. This proved to be difficult, as between 2000 and 2008, Pfizer only released five new molecular entities. This provoked a change in strategy to the acquisition of companies with already established products. Beginning with the acquisition of Wyeth in 2009 and continuing through 2014, Pfizer acquired companies that had already established products and cut costs by divesting itself of tangible assets. The effect was to further increase intangible asset's share of total assets – from 44.54% in 2008 to 57.32% in 2014 – while also reducing its book value and making Pfizer more reliant on acquired drugs for sales rather than internally developed drugs. Pfizer's net tangible assets being negative throughout this most recent time period reflects its reliance on social control to remain a going concern.

Based on this history and these results, the impetus for M&A for Pfizer can be seen as the generation and acquisition of intangible assets in the form of monopoly rights. Dealings between the core and periphery are – and have been – speculative in nature, where Pfizer acquires the distribution rights to the drug in exchange for financing clinical trials and royalty payments. Thus, the motivation behind pharmaceutical mergers and acquisitions fits within the Veblenian framework. The

view is not towards increasing the productive capacity of the enterprise, but the pecuniary earning capacity *qua* accumulation of intangible assets – indeed, this is seen as Pfizer has been eschewing its tangible assets while accumulating intangibles, leading to a negative book value. In this way, intangible assets function as a type of rent-asset, where Pfizer is earning a return to ownership of the rights of the drugs, rather than their ability to develop and manufacture new drugs. With the separation of business and industry combined with the separation of ownership and control, return to shareholders and the ability to generate pecuniary returns becomes the dominant goal of the business enterprise. Mergers and acquisitions, then, are the tool by which the enterprise acquires patent rights and goodwill that generate the desired returns (Veblen 1904; Nitzan 1998, 2001; Nitzan & Bichler 2009).

CHAPTER 5

CONCLUSION

Summary of Results

The aim of the preceding chapters has been to examine the nature and function of intangible assets as they pertain to the structure, conduct, and financial performance of pharmaceutical enterprises. A principal focus of this dissertation was the emergent properties of an industrial system, grounded in social relationships, in which issues of production, distribution, and control are embedded. Intangible assets are seen as also containing emergent properties that regulate the relations between the community and its joint stock of knowledge by defining property rights within the production process and dictate access to the provisioning system. In developing this framework, I showed how the work of important figures in institutional economics – in particular Veblen, Ayres, and Commons – has translated to the modern economy and the more recent research of Chandler, Lazonick, Serfati, Gagnon, and Dean.

The fundamental focus of the second chapter was to understand intangible assets within the context of the business enterprise *qua* going concern. While tangible assets were seen as emerging out of the technological relations between a community and its joint stock of knowledge, intangible assets emerged out of the relationships between community members. In the first degree of separation – the separation of the community from its joint stock of knowledge – intangible assets establish bargaining transactions between consumers and producers. Access to the provisioning system shifted to being dictated by private owners. In the second degree of separation – the

internal separation of the business enterprise into the going plant and the going business – it was shown that intangible assets instituted rationing transactions that limited the number of sellers of a particular product. For an enterprise to survive, it needed to ensure that the bargaining transactions in which it engages were undertaken at a profitable price. The best way to do this was to limit the number of competing sellers. In this way, intangible assets took on two characteristics to increase the earning capacity of the business enterprise: they lock the community out of its joint stock of knowledge and they dictate competitors' access to markets through monopoly rights.

In the first two degrees of separation, the earning capacity of an enterprise depended upon its ability to sell output. Differential advantages were gained through acquiring monopoly power and cutting costs faster than competitors. With the creation of the joint stock corporation, the enterprise's earning capacity depended upon its ability to expand its asset base and issue incorporeal property. Intangible assets in this third degree of separation become the basis for the capitalization of the enterprise as they represent pure earning capacity through control over market processes, rather than productive capacity. The emphasis on accumulating intangible property rights led to the development of Serfati's Transnational Corporation, which is the dominant form of enterprise within money manager capitalism. With the TNC and its subsidiaries, a distinction is made between the core of the industry and the periphery, with the core dictating the course of action and evolution of the industry and the periphery carrying out much of the day-to-day activities for the business enterprise.

This separation between the core and the supporting nexus was further investigated in the third and fourth chapter of this dissertation. The primary purpose of the third chapter was to investigate the pharmaceutical industry structure, and how the core of the industry has performed over time. The impact of federal regulations on industry structure became clear. The elixir sulfanilamide tragedy – due to lack of safety regulations – led to the creation of the Food and Drug Administration. This, in turn, caused pharmaceutical companies to market their products primarily to doctors to avoid the new labeling requirements, creating a separation between the consumer of the product and the one making the choice of which product would be consumed. Further, in the wake of the thalidomide tragedy in the 1950s, Congress passed the Kefauver-Harris Amendments, increasing the intensity of regulatory approval. In response, pharmaceutical companies focused their energies on creating blockbuster drugs, or drugs that could treat a large number of patients. This created a class of orphan diseases, or afflictions harming too few patients to be profitable for pharmaceutical companies for whom to develop treatments. In response, Congress passed the Orphan Drug Act in 1983, providing incentives for this development.

Simultaneously, developments in the fields of biotechnology and enzymology opened up new paths of research. Much of this research was organized around university laboratories that, with changes in legislation due to the Bayh-Dole Act in 1980 and the Hatch-Waxman Act in 1984, were able to form their own biotechnology companies as a part of the supporting nexus. From this point forward, rather than pharmaceutical companies conduct a majority of research in-house, the preliminary

discovery and early stage clinical testing was outsourced to smaller companies. This created the modern day structure of the pharmaceutical industry, whereby decisions by a central group of companies dictate which products will advance to later stage testing and approval and provide financing, while smaller companies provide the new compounds, screening technologies, and, in some cases, production capabilities.

The existence of intangible assets, either in the form of goodwill or patent rights, has helped reinforce this structure. On the one hand, patent rights owned by the enterprises in the supporting nexus generate income flows to these companies, which can be reinvested for future research. However, intangible assets in the form of, e.g., tightly controlled sales networks and high costs of late-stage research makes it difficult for such enterprises to become part of the core. Rather than innovation leading to a process of creative destruction, it leads to the position of dominant companies being strengthened with new entrants. Further, in order to maintain control over the industry, the focus of the core becomes the accumulation of intangible assets. This allows dominant companies to block research in areas that would compete with their already existing products in a tragedy of the anti-commons process, while also allowing them to increase their earning capacity, as shown when discussing the performance of the core.

The primary tools of the dominant pharmaceutical enterprise for increasing earning capacity are mergers, acquisitions, and strategic alliances. As the fourth chapter has shown in its investigation of the Pfizer Corporation, the fundamental focus in Pfizer's deals was to acquire intangible assets necessary to swell the valuation of the

company. In the 1990s, these deals were designed to gain access to screening technologies for the discovery phase of pharmaceutical research. As the split between the core and the supporting nexus became more pronounced, Pfizer refocused on its sales network, acquiring the rights to drugs in later stages of development. Over time, as Pfizer's transactions in the late 1990s and early 2000s failed to produce marketable products, the company began to outsource its productive activities, selling manufacturing plants and research facilities to third party producers while maintaining its intangible assets. From 2009 through 2014, this strategy becomes clearer, as acquisitions of Wyeth and King Pharmaceuticals reflected the need to acquire established products. As shown, a substantial majority of revenue from Pfizer's top selling drugs in 2014 came from drugs that were acquired, rather than internally developed.

The effect of this strategy has been the increased importance of intangible assets in maintaining Pfizer as a going concern. Intangible assets now compose over half of Pfizer's total assets, while its net tangible assets – the value of the company not dictated by its market capitalization – are negative. To prevent insolvency in this later stage of enterprise development, then, Pfizer must continue to accumulate intangible assets, increasing its earning capacity without increasing its productive capacity.

Paths for Future Research

By emphasizing the importance of intangible assets in the pharmaceutical industry, and more specifically, the way in which intangible assets are used to obtain and maintain differential advantages for core companies, this dissertation may serve as

the base for future research in structure and conduct for the pharmaceutical industry. Two clear lines of research emphasize the nature of the relationships between the core and periphery and current technological advances that, when viewed within the context of existing legal structures, may prevent the greater portion of society from gaining access to pharmaceuticals.

As stated above, the nature of the core of the pharmaceutical industry is to acquire intangible assets from the supporting nexus. This has the effect of turning dominant enterprises into quasi-investment banks – providing the financing for research and development, as well as marketing approved products. Some companies, such as Valeant Pharmaceuticals, have taken this strategy to the extreme, doing very little of their own research and engaging in mergers and acquisitions numbering in the double digits. Future research into the pharmaceutical industry structure, then, should focus on these relationships between the core and the supporting nexus within the context of deliveries of research funding and property rights between the two. Policy should decide if this is an instrumentally efficient way to structure the pharmaceutical industry in terms of the development and production of truly new pharmaceutical products that would maintain the community as a whole as a going concern.

Technological changes and their effects on the legal structure must be investigated. Of key interest here are orphan drug policies and how the advancement of research in pharmacogenics will affect the industry. As Gagnon (2015) has already noted, the blockbuster model of drug development is dying; rather than firms focusing on producing one drug that has a wide reach, they focus on producing niche drugs that

fall under orphan policies and then continually reapply for orphan protection once the drug loses marketing exclusivity. In this way, the effective life of a drug is no longer bound by the life of the patent. Rather, it depends upon the ability for the enterprise to obtain different orphan applications on the drug, expanding the value of the intangible assets involved in producing the drug and the enterprise's control over social knowledge.

Research advances in the area of pharmacogenics has also allowed companies to divide diseases into subcategories, each potentially being classified as an orphan disease. Pharmacogenics, therefore, has the potential to increase the number of orphan diseases, increasing the value of the monopoly rights over those drugs. Orphan drug policies are already problematic¹, but not revising them in the face of these technological developments would be puzzling. The protection provided by orphan policies is already stronger than the patent privilege for non-orphan drugs, and prices for orphan drugs are much higher as well, effectively pricing out of the market many who are suffering from these diseases. Indeed, as Côte and Keating reveal "Orphan drug policies have the paradoxical effect of creating new orphan patients!" (2012, p. 1190) Future research in public policy should examine how orphan drug laws can be rewritten so as to ensure that those who suffer from orphan diseases can access the necessary medications.

¹ For example, when the first treatments for HIV/AIDS were released, they fell under orphan drug protection. However, when the AIDS epidemic hit and the number of patients exceeded the orphan disease limits, the protection for these treatments was not removed.

From a theoretical perspective, this dissertation has also opened two paths of inquiry. First, as Mazzucato (2013) has shown, much of the truly innovative work – the creation of brand new knowledge – has been done with public funds. Baumol (2002) has also shown that much of the research and development done by private enterprises is focused on “routinized innovation” or the adjustments of existing knowledge so that it may be further commercialized. From this perspective, then, it seems that much of what we typically call “innovation” is the result of government finance and public work. However, the Bayh-Dole Act of 1980 has allowed this work done with public funds to be appropriated by individual enterprises. The risk of innovation has been socialized, but the gains have been privatized. Future research should investigate whether changes to legal structures are necessary to ensure that the returns to innovation are distributed in an instrumentally efficient manner.

Second, the nature of the business enterprise within money manager capitalism must be revisited. Specifically, if the focus is on maximizing shareholder value, can the enterprise be thought of as a going concern? As Jo and Henry (2015) have claimed, rather than consider the enterprise itself as a going concern, we must consider the enterprise the tool through which the capitalist class reproduces its dominant relations: “While the existing going concerns die, the capitalist class as a whole survives and grows, insofar as new financial instruments, new concerns, new markets, and new demands are created.” (p. 43) Dean responds to this claim, adding that with the third degree of separation, what has changed is the nature of the hierarchical structure of the business enterprise:

Once it is understood that the modern business enterprise has always consisted of a hierarchy of going concern structures, the base of which is the community itself, it becomes evident that the paradox of stability for the business enterprise exacted at the expense of the stability of its lower going concern structures is inherent to this form of organization. The foundation of capitalism is constructed so, and financialization is only a new accretion to the structure. (p. 17)

Both Dean and Jo and Henry, however, lack the accounting nature of intangible assets. When a company is acquired, it has not vanished; rather its assets have been transferred. The goodwill and appropriated knowledge of the acquired company lives on as a balance sheet entry for the acquiring company. In this way, an enterprise that has sold itself to another is still a going concern in that the social relationships upon which it has capitalized continue to be capitalized upon. It is only when these intangible assets have been impaired and revalued to zero – the equivalent of being returned to the community – does the entity cease to be going. Future research into the “goingness” of the going concern should emphasize the accounting nature of intangible assets.

Intangible Assets, Industrial Organization, and Industrial Policy

In the New Economy Business Model, with the emphasis on maximizing shareholder value, intangible assets become a principal focus for the activities of the business enterprise. Productive capacity is eschewed in favor of maintaining property rights over ideas and control over relations involved in production and distribution. Intangible assets may be seen, then, as the means to dominating the system of social provisioning. With the development of the Transnational Corporation as the dominant owner of such property rights, access to the system of social provisioning is mediated

by a small number of large enterprises that control and dictate the course of action for the economy as a whole.

Any study of industrial organization and any industrial policy proposal, then, must include the nature and use of intangible assets in that particular industry. If an enterprise's fundamental focus is on maintaining and expanding its control over economic and social relations rather than the accumulation of profits through production and sale of output, then return to shareholders as a performance measure should not be seen as a measure of allocative efficiency, but as reflecting the scale and scope of social control. Minsky (1986), in his analysis of the financial system, explains how bad theory can lead to bad policy, culminating in financial instability and depression. On a larger scale, bad theories of industrial organization lead to bad industrial policy, which threatens the viability of an industrial economy as a whole. A good theory of industrial organization is required to make good policy, and a good theory of industrial organization emphasizes the importance of intangible assets.

APPENDIX A

THE DRUG APPROVAL PROCESS

After the thalidomide tragedy and the passing of the Kefauver-Harris Amendments, pharmaceutical companies were required to show both safety and efficacy of new drugs, increasing the costs of research. The approval process may be considered in six steps, shown in Figure 3.A¹. Once a compound has been developed into a potential pharmaceutical product, it begins the process. In the first stage, known as the discovery or pre-human/pre-clinical stage, firms test compounds for basic safety and efficacy, with 21.5% of R&D funds devoted to this stage. Stages two through four are grouped together as the three clinical trial phases; this is the most expensive portion of R&D, composing 56.9% of funds. In Phase I clinical trials, the drug is tested for dosage safety using a small number of participants; increasing doses of the drug are given to participants to determine the body's response and what dosage is safe. This is the cheapest portion of the clinical trials, composed of 8.7% of funds. In Phase II clinical trials, the drug is tested for biological efficacy in a slightly larger number of participants; side effects, effective dosage size, and delivery method are determined in this stage, and it composes 12.5% of R&D funds. In Phase III clinical trials, the drug is tested in thousands of participants across many locations using double-blind experiments for the purpose of determining therapeutic efficacy – does the drug actually treat the disease it is supposed to? This is the longest and most expensive stage

¹ The European Federation of Pharmaceutical Industries and Associations (2013), using data from the PhRMA Annual Membership Survey (2013) estimates the percentage of funds devoted to R&D that are used in each stage. These numbers are included here as well; 3.5% of R&D funds were unclassified.

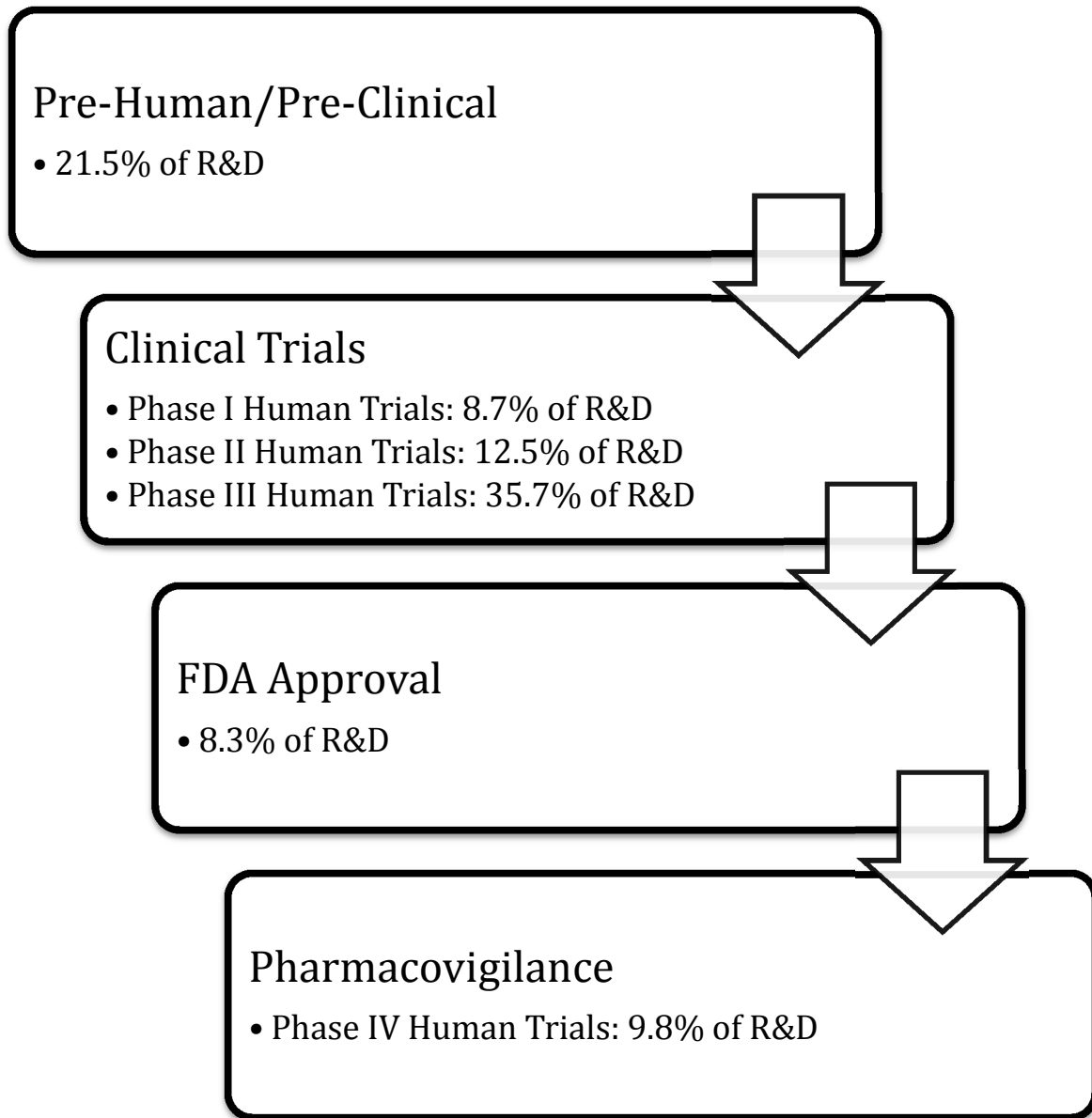


Figure A.1: The Drug Development Process and Percent of Funds Allocated to Each Stage (EFPIA 2013; PhRMA 2013b)

of drug development, requiring 35.7% of R&D funds.

If a drug passes through the three clinical trial stages, it enters the approval stage. During this stage, the FDA reviews the results from the clinical trials and decides whether it should be approved for widespread marketing. When a company applies for approval, they may do so in one of three ways. A biological license application (BLA) is a submission that deals specifically with biological products, or biopharmaceutical. A second type of approval application is the Abbreviated New Drug Application, which deals specifically with generic products. An ANDA allows a generic applicant to bypass the pre-clinical and clinical testing if they can show the generic product is bioequivalent – it performs in the same manner as the brand name drug². The third type of approval – a New Drug Application (NDA) – is the most common. In an NDA, companies submit the results of clinical trials to the FDA. Once the FDA approves the NDA, the drug may be marketed to the public. This leads to the last stage of development, Phase IV trials, or the post-market surveillance phase. Companies monitor the safety and efficacy of the drug, focusing on finding new areas of treatment in which the drug may be useful, leading to product line extensions and follow-on drugs.

² There is some controversy over using bioequivalence to approve generic products. A recent example involves Johnson & Johnson's ADHD medication Concerta, an extended release form of Ritalin. Generic versions were approved based on bioequivalence, but the key to Concerta's efficacy was in the release mechanism that provided symptom relief for 12 hours. Generic versions, despite being bioequivalent in that they provided the same form of treatment, did not have the same release mechanism and provided symptom relief for seven hours. In this case, bioequivalence does not equate to effective equivalence (Thomas 2015).

APPENDIX B

PFIZER DRUGS GROSSING OVER \$100 MILLION IN SALES IN 2014

Table B.1 shows Pfizer's drugs that grossed over \$100 million in sales in 2014. Included are the value of the drugs' sales in 2014; whether the drugs were internally developed; acquired, or the result of a joint venture; the year the drug was acquired; the year the drug was approved by the FDA¹; and the originator of the drug.

¹ For drugs acquired prior to FDA approval, the importance was on the stage in which the drug was acquired. For Lyrica and Sutent, though Pfizer had some hand in their development, Warner-Lambert and Pharmacia did the majority of the development work. Therefore, I consider these to be acquisitions, rather than internal development. For internally developed drugs, acquisition year is left blank.

Table B.1: Pfizer's 2014 Drugs Grossing Over \$100 Million In Sales

Drug Name	Sales (Millions of Dollars)	How The Drug Was Acquired	Year of Acquisition	Year of FDA Approval	Origin
Lyrica ²	5,168	Internal Development	2000	2004	Warner- Lambert
Pprevnar Family	4,464	Acquisition	2009	2010	Wyeth
Enebrel	3,850	Acquisition	2009	1998	Wyeth
Celebrex	2,699	Acquisition	2009	1998	Pharmacia
Lipitor ³	2,061	Joint Venture	2000	1996	Warner- Lambert & Pfizer
Viagra	1,685	Internal Development	1998	1998	Pfizer
Zyvox	1,352	Acquisition	2003	2000	Pharmacia
Sutent ⁴	1,174	Acquisition	2003	2006	Pharmacia
Norvasc	1,112	Internal Development	1997	1997	Pfizer
Premarin Family	1,076	Acquisition	2009	1982	Wyeth
BeneFIX	858	Acquisition	2009	1994	Wyeth
Vfend	756	Internal Development	2002	2002	Pfizer
Pristiq	737	Acquisition	2009	2007	Wyeth
Genotropin	723	Acquisition	2003	1995	Pharmacia
Chantix & Campix	647	Internal Development	2006	2006	Pfizer
Refacto AF & Xyntha	631	Acquisition	2009	2008	Wyeth

² Lyrica was discovered by Richard Bruce Silverman at Northwestern University and licensed to Warner-Lambert's subsidiary Parke-Davis in 1988. Pfizer acquired the rights to the drug when it acquired Warner-Lambert in 2000.

³ Warner-Lambert developed the drug while Pfizer marketed the drug.

⁴ Pfizer acquired the rights to Sutent when it acquired Pharmacia in 2003. Most of the development work was done by the biotech company SUGEN, who was acquired by Pharmacia in 1999.

Table B.1, Continued

Drug Name	Sales (Millions of Dollars)	How The Drug Was Acquired	Year of Acquisition	Year of FDA Approval	Origin
Xalatan & Salacom	495	Acquisition	2003	1996	Pharmacia
Medrol	443	Acquisition	2003	1959	Pharmacia
Xalkori ⁵	438	Acquisition	2009	2011	PF Prism CV
Zoloft	423	Internal Development	1991	1991	Pfizer
Inlyta	410	Internal Development	2012	2012	Pfizer
Relpax	382	Internal Development	2002	2002	Pfizer
Fragmin	364	Internal Development	1994	1994	Pfizer
Cefobid	354	Internal Development	1997	1997	Pfizer
Effexor	344	Acquisition	2009	1993	Wyeth
Rapmune	339	Acquisition	2009	1999	Wyeth
Tygacil	323	Acquisition	2009	2005	PF Prism CV
Zithromax & Zmax ⁶	314	Joint Venture	1986	1991	Pilva & Pfizer
Xeljanz ⁷	308	Joint Venture	1996	2012	Pfizer & NIH
Zosyn & Tazocin	303	Acquisition	2009	1993	Wyeth
EpiPen	294	Acquisition	2010	1987	King

⁵ Pfizer acquired PF Prism CV as part of the Wyeth acquisition.

⁶ Pilva discovered the drug in 1981 and licensed the drug to Pfizer in 1986. Pilva is now owned by Teva Pharmaceuticals.

⁷ The joint venture began in 1996. Pfizer was approached by the National Institute of Health, but did not agree to the venture until NIH policies regarding pricing limits was removed.

Table B.1, Continued

Drug Name	Sales (Millions of Dollars)	How The Drug Was Acquired	Year of Acquisition	Year of FDA Approval	Origin
Toviaz	288	Internal Development	2008	2008	Pfizer
Revatio ⁸	276	Internal Development	2005	2005	Pfizer
Cardura	263	Internal Development	1990	1990	Pfizer
Xanax & Xanax XR	253	Acquisition	2003	1981	Pharmacia
Inspira ⁹	233	Internal Development	2002	2002	GD Searle
Somavert	229	Acquisition	2003	2003	Pharmacia
Diflucan	220	Internal Development	1990	1990	Pfizer
Neurontin	210	Internal Development	1993	1993	Pfizer
Unasyn	207	Internal Development	1986	1986	Pfizer
Detrol/Detrol LA	201	Acquisition	2003	1998	Pharmacia
Depo-Provera	201	Acquisition	2003	1960	Pharmacia
Protonix & Pantoprazole	198	Acquisition	2009	2000	Wyeth
Dalacin & Cleocin	184	Acquisition	2003	1980	Pharmacia
Caduet	180	Internal Development	2004	2004	Pfizer

Source: Pfizer (2015)

⁸ This is another form of Viagra.

⁹ GD Searle is a subsidiary of Pfizer.

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