OPEN SOURCE IN THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

Recent evidence suggests that pharmaceutical companies focus more on managing their intellectual property rights than in developing drugs that cure medical problems. The open source movement offers alternate rules for the process of developing new drugs and managing intellectual property rights. The essence of open source is to radically change the development process before there exists something worthy of being assigned a set of rights. Open source in the pharmaceutical industry also offers the potential to reduce the time it takes to develop breakthroughs, test their viability and safety, and bring them to market.

INTRODUCTION

A contributing factor to the current crisis in health care is the high cost of prescription drugs. Rather than the pursuit of self-interest on the part of pharmaceutical companies leading to greater social welfare, their efforts to maximize profits appears to have led them to focus more on managing their intellectual property rights than in developing drugs that cure medical problems. A number of recent articles have shed light on the cost to society of granting temporary monopolies in the form of patents (Mazzoleni and Nelson, 1998; Merges and Nelson, 1990), and some have suggested ways to reduce these social costs with respect to the pharmaceutical industry (Grabowski and Vernon, 1990; Heller and Eisenberg, 1998).

Changing the assignment of intellectual property rights after a new class of drugs has been developed may promote the diffusion of ideas capable of spurring additional innovation; however, the open source movement in the software industry suggests an alternate avenue for promoting the development of new drugs. Rather than focusing on the assignment of rights after something new has been developed, the essence of open source is to radically change the development process before there exists something worthy of being assigned a set of rights. By altering the development process, open source offers the potential of maximizing the probability of a breakthrough and it has the potential to reduce the time it takes to develop breakthroughs, test their viability and safety, and bring them to market.

To assess the viability of an open source system for the pharmaceutical industry, we begin first by identifying the current market failure that misaligns the incentives between the goals of pharmaceutical firms and the interests of society. We then compare recent approaches to reform the current way intellectual property is assigned with an alternative system that seeks to fundamentally restructure the development process in an effort to maximize social welfare. We then describe the history of the pharmaceutical industry and its transition from a random drug discovery process to a guided discovery process that has occurred because of the developments in the fields of molecular biology and biotechnology. Because a different set of organizational capabilities are needed to conduct a guided discovery process, a natural division of labor in pharmaceuticals has occurred between university and biotechnology researchers and researchers in traditional pharmaceutical firms. This division of labor has created an environment that is conducive to the emergence of open source in the pharmaceutical industry. Finally we analyze the costs and benefits of the current public policy of basic scientific research and then demonstrate how an open source public policy for basic scientific research in the pharmaceutical industry has the potential to maximize the probability of inventing life-saving technologies.

MARKET FAILURE AND THE PHARMACEUTICAL INDUSTRY

Since the end of World War II, the health care system in the United States has experienced new technologies that have revolutionized the ways in which health care is practiced, induced a dramatic increase in the role of private and public health care insurance, and have led to soaring national health care expenditures (Weisbrod, 1991). Previous research has highlighted the clear interplay between market incentives for the pharmaceutical R&D sector to develop particular kinds of new technologies and the long-run growth of national health care expenditures (Kleinke, 2000; Gelijns and Rosenberg, 1994).

In an effort to understand the growth in health care expenditures, it is instructive to categorize medical technologies. Thomas (1975) distinguishes three types of technology in medicine: (1) “non-technology” that tides patients over poorly understood diseases where there is little hope of recovery; (2) “halfway technology” that deals with the incapacitating effects of disease and simply postpones death; and (3) “high-technology,” which comes as the result of a genuine understanding of disease mechanisms and is relatively inexpensive to deliver (p. 40). Weisbrod (1991, p. 533) suggests that we should think of the development of

technology as a dynamic process in which knowledge tends to grow from the first of the three levels to the second and then the third.

Within this framework, as knowledge expands, costs would eventually decline with the adoption of higher-level technologies. It was thought that by diverting R&D resources away from new surgical techniques and toward lower cost substitutes (frequently pharmaceuticals), costs would fall with the development of higher technologies. The predicted systemic rotation from the provision of traditional medical services to the consumption of relatively lower cost pharmaceuticals has occurred (Kleinke, 2001). Indeed, the total national prescription drug expenditure as a percentage of total national heath care expenditure increased from 4.9 percent to 9.4 percent between 1980 and 2000. Contrary to perceived wisdom, however, the nature of technological progress within the pharmaceutical industry has led to a relative increase in halfway technologies and a relative decrease in the discovery of high-technology pharmaceuticals.

The National Institute for Health Care Management has recently reported that there exists an increase of drugs that provide no significant clinical improvement over existing drugs and a decrease of highly innovative drugs that contain new active ingredients that provide significant clinical improvement over existing drugs. Data reported by the National Institute of Heath Care Management reveals that from 1989-2000, 54 percent of drug applications approved by the FDA were for drugs containing active ingredients that were already on the market and only differed from the marketed product in dosage form, route of administration, or were combined with another active ingredients. Eleven percent of approvals were identical to existing products on the market. Each of these drugs received an additional three-year extension of their patent protection under the Waxman-Hatch Act of 1984.

Of the new drug approvals, 35 percent were products with new active ingredients, however; only a subset of these drugs had a sufficient clinical improvement over existing products that the FDA granted them a priority status. Thus, in the aggregate, over the 1989-2000 time-period, only 23 percent of all drugs (238 out of 1035 drugs) approved by the FDA, with new and old active ingredients, were given a priority rating because they provided sufficient clinical improvement over existing products. This data strongly suggest that during the time period that the US has adopted and used the managed care system, it has increased its dependence on drugs (as a substitute for other types of medical services) and that the pharmaceutical industry has not shifted its production from halfway technologies towards the development of "high-technology" pharmaceuticals. Rather, we have observed 77 percent of FDA approved drugs fitting into the category of "redundant technologies" that were developed in an effort to secure economic rents by extending a firm's intellectual property rights.

A flaw of the managed care system, in retrospect, is that its rational objective to control aggregate medical costs has had the effect of substituting away from expensive medical procedures toward drugs; and that process has changed the economic incentives within the R&D sector of pharmaceutical industry such that it has become profitable to develop expensive halfway technologies. Also, the existing set of institutional rules make it very profitable for drug companies to focus more on managing their intellectual property rights – *i.e.*, securing monopoly protection to continue a stream of monopoly rents – by creating new versions of old drugs that have no new medical benefit to the consumer. And last, even after legal monopoly protection does finally expire for many branded drugs, the economic welfare that we have historically expected from the production of generic drugs is now less likely to occur because of an increasing rate of merger activity between generic and branded pharmaceutical companies (Levy, 1999). For all this, it is apparent that a *market failure* has occurred within the high-technology market of the pharmaceutical industry.

INTELLECTUAL PROPERTY AND THE DIVISION OF LABOR

Sir Arnold Plant long ago wrote "the purpose of patents for inventions is … to make it easier for [the inventor] to derive income from it. With … the ultimate aim encouraging invention" (Plant, p. 32). This activity of invention and patenting leads to the division of labor, the growth of economic wealth, and the progress of science, and further these circumstances induce the invention of new processes and devices (Plant, p. 36). The willingness of entrepreneurs to make use of new technology after it has been produced is the process through which the division of labor and the growth in economic wealth is spurred. The aggregate effect of the patent laws, in A.C. Pigou's words, "bring[…] marginal private net product and marginal social net product more closely together" (quoted in Plant 1934, p.39).

At least from the time of Plant and Pigou's observations, conventional wisdom understood the problem of intellectual property covered under patent law to be one of *slippery* knowledge, that is by its very nature non-excludable. Knowledge of an idea, production process, or recipe with this characteristic means that you can know it without me forgetting it (Arrow, 1962). Thus, without some form of property right, there is little incentive for someone else to incur the fixed costs of innovation. Arrow's concern primarily arises with the free entry of competitors. This occurs because free entry allows imitators to produce until they drive the price down and therefore make recovery of R&D costs impossible; a result that completely destroys the

incentive to innovate in the first place (Church and Ware, 2000).

However, while protecting new technologies may promote inventive activity, these new ideas often come at the expense of diffusion (Niman, 1995). Merges and Nelson (1990, 1994) write that broad control over the development of technology by early patentees potentially discourages the many independent efforts that contribute to innovation. The variety of perspectives brought by the division of labor greatly enriches the process of innovation by encouraging rapid trial-and-error learning (Wallace, 2002). Patents, however, are barriers that in many cases slow the pace of learning and stifle the cumulative building process that leads to the development of advanced technologies and processes (Levin, Klevorick, Nelson, and Winter, 1987). Thus, encouraging invention at the expense of diffusion may promote the interests of some, but – contrary to Pigou's analysis – it in many cases does not maximize the interests of society as a whole.

In the biomedical industry, Heller and Eisenberg (1998) write that privatization of upstream research in the US may create a resource that is prone to underuse in a "tragedy of the anticommons." In this setting, privatization takes the form of patents on intellectual property that, in an earlier era, would have been made freely available in the public domain. As Arrow (1962) has taught us, patents and other forms of intellectual property protection for upstream discoveries may fortify incentives to undertake risky research projects and could result in a more equitable distribution of profits across all stages of R&D. However, each upstream patent sets up another tollbooth on the road to product development, creating a social cost by slowing the division of labor and the pace of innovation.

In the pharmaceutical industry, patents can go astray when a proliferation of owners hold upstream intellectual property rights that cause obstacles that have the effect of stifling life-saving innovations further downstream (Heller and Eisenberg, 1998). To be sure, other industries too have a proliferation of intellectual property rights (e.g., automobiles, aircraft manufacturing). These other industries have solved their problem by developing patent pools when a number of licenses under multiple patent rights are necessary to develop important new products. However, patents matter more to the pharmaceutical industry relative to other industries because of their effectiveness in capturing and protecting the competitive advantage gained from new or improved process and products (Levin *et. al.,* 1987). Indeed, only in the pharmaceutical industry are product patents regarded by a majority of respondents, in the Levin *et. al.* high-level R&D executive survey, as strictly more effective than other means of appropriation. Therefore, pharmaceutical firms are less willing to participate in patent pools that have the effect of undermining the gains from exclusivity (Heller and Eisenberg, 1998). The end result in the pharmaceutical industry may be that competitors cannot innovate around a thick group of upstream patents and the discovery pace of "high technology" will diminish.

One potential solution to the problem of the assignment of excludable property rights is to have the government purchase worthwhile patents (Kremer, 1998) and make them available for use by the broader population. Unfortunately, such a policy places the government in the role of picking winners and losers as it attempts to determine which patents to purchase and how much to pay for them (Niman, 1995). An alternative approach is to bypass the issue of patents altogether and move to an open source system where property rights are vested in the broader development community.

One of the principle differences between open source and proprietary software is the assignment of property rights. In the case of open source software, a license such as the General Public License utilized by Linux programmers specifies that all source code must be made freely available. Improvements to the basic code must also be made freely available to the broader development community. Hence software developed under such a license is not assigned an excludable property right.

With the adoption of some form of public license, the diffusion problem associated with the assignment of excludable property rights disappears. However, solving one problem merely leads to another as the incentive problems associated with the development of intellectual property re-emerges. If one cannot receive the fruits of one's own labor by excluding others from benefiting from a new idea, then why make the investment in the first place? However, this incentive problem only reappears when viewing the development of intellectual property from the conventional Arrow perspective. The promise of open source is that it points in an entirely different direction for creating incentives and benefits to the development of intellectual property.

The origins of the advantages associated with such an approach lies with the very foundations of a market economy. One of the hallmarks of the modern economy is that expanding the division of labor creates wealth. Increased specialization enhances productivity that promotes a more efficient use of available resources. Anything therefore that promotes the division of labor creates positive economic benefits for the economy. However, the engine for continued improvement through technological change relies not on the broadest of possible divisions of labor, but rather just the opposite. To benefit from a new idea, one must be able to keep their innovation a secret or rely on the protection of the government through some form of a patent system. Thus, the reward process associated with technological change is one that is most successful by limiting rather than taking advantage of the broadest possible division of labor.

The cost from a social perspective is that new ideas are created, but they are ideas emanating from a limited pool of knowledge and developed with a limited pool of

resources. To capitalize on a new invention, a firm must rely primarily on its own researchers and its own resources in order to maximize the probability of maintaining a secret or being able to obtain a government sanctioned monopoly. Therefore the development of a new idea comes at the cost of limiting the division of labor in order to maximize the potential return on a new idea.

Open source adopts a different approach where it seeks to draw on the greatest possible division of labor in order to maximize the potential value of a new idea. It is similar to existing calls to broaden the diffusion of technology, however, rather than achieving its benefits *ex post* (after the first innovation has been created), it expands diffusion *ex ante* by drawing in as many as possible in the initial development of an idea. The number and abilities of programmers working on the product are not limited to those that exist within the boundaries of a single firm. Rather, each user becomes a potential source of new ideas for future directions in the product and the workload for implementing change is shared between an expanded group of developers.

Because changes to the product originate not from a small group of programmers under the leadership of a management team that thinks it understands the needs of the market, but rather from those who are actually using the product in real world situations, the whole product eventually moves in a direction that is more in tune with the needs of its users than its developers. Thus, open source benefits not only from a greater division of labor, but also from the ability to utilize the superior knowledge associated with decentralization. Changes are driven from a bottom up approach where end-users both initiate and implement modifications based on real needs and not those imagined by a group of managers in a software company who have limited or no knowledge of the various applications for a particular product.

Promoting the development of higher quality software that is of more value not only in terms of its design, but also application, forms the basis for understanding the incentives for participating in the open source movement. Rather than the problem of the "anti-commons," associated with the patent system, open source creates instead what can be called the "joy of commons." In the standard tragedy of the commons story, seas are overfished or pastureland is overgrazed because of a lack of property rights. Value is diminished as too many users utilize a single resource with a limited capacity to serve the needs of everyone. However, within the framework of open source, the common resource becomes more valuable as it is used by a growing number of individuals.

In contrast to the tragedy of the commons where a common resource eventually becomes depleted with overuse, in the joy of commons, the shared product becomes more valuable with increased participation. The additional value is not the result of network effects where something becomes more valuable because of an increase in the *use* of the product; rather, it becomes more valuable because there is greater participation in the *production* of the good. A user in the open source movement becomes a potential contributor either as a co-developer of the product who offers new code to either strengthen or add functionality to the existing code, or as a tester who shares their experiences in order for others to construct needed revisions to the code. This enhanced division of labor and decentralization of the development process work together to improve the product and hence increase its value. As a result, value is created rather than lost with increased participation and hence individuals have a positive incentive to contribute to an open source product because what they receive in turn is something of greater value.

OPEN SOURCE AND THE PHARMACEUTICAL INDUSTRY

Henderson, Orsenigo and Pisano (1999) describe the history of the pharmaceutical industry as encompassing three major epochs. The first, ranging from 1850 – 1945, was a time companies mainly supplied the raw materials found in medications to pharmacists, who following tried and true recipes, handled the final assembly and sale of pharmaceuticals. The second epoch, from 1945 to roughly 1990, was a period where the success of penicillin pointed the way to the internal development and production of new drugs. The third epoch, which is still ongoing, characterizes the transformation of the industry with the emergence of what the authors characterize as the molecular biology revolution that has dramatically changed the way in which the pharmaceutical companies develop new drugs. It is this revolution in molecular biology that offers the potential for paving the way to an open source revolution in the pharmaceutical industry.

In the early days of drug development, pharmaceutical companies employed a technique known as random screening to search for new compounds that might offer possible therapeutic benefits. This approach required a large capital investment to test, categorize and store the results of tens of thousands of screens in the search for positive results. By the 1970s however, many companies were in the midst of making the transition to guided discovery where the process of searching for new compounds was directed by researchers rather than randomly generated as part of a massive screening process. The transition from random to guided discovery required a change in the knowledge base and organizational capabilities required to foster pharmaceutical research.

> So-called random drug discovery drew on two core disciplines: medical chemistry and pharmacology…. Although a working knowledge of current biomedical research might prove useful as a source of ideas as to possible

> compounds to test or as a source of suggestions for alternative screens, by and large it was not critical to employ researchers at the leading edge of their field or to sustain a tight connection to the publicly funded research community…
>
> The ability to take advantage of the techniques of guided search, in contrast, required a very substantial extension of the range of scientific skills employed by the firm; a scientific work force that was tightly connected to the larger scientific community and an organizational structure that supported a rich and rapid exchange of scientific knowledge across the firm. (Henderson, Orsenigo and Pisano, 1999, p. 287).

Such a shift to guided research along with the rise of molecular biology and genetic engineering has lead to large-scale entry into the industry. As noted by Pisano, Shan and Teece (1980), during the period from the mid-1970s to the mid-1980s, over 300 biotechnology firms were founded. By 1990, 700 biotechnology firms existed and a vast majority of those firms were new entrants (*i.e.*, start-ups) to the industry (Zucker et.al., 1998). Such massive entry into the industry can be explained by a number of factors. The transition from random screening lowered the capital requirements for drug discovery by eliminating the need for legions of researchers, extensive facilities to house them, and massive libraries required to keep track of their results. As the nature of the research has shifted to molecular biology, biotechnology companies could leverage the large amount of public spending in support of government and university basic research to support the development of new drugs. Finally, pharmaceutical research has become less "context-specific" (Arora and Gambardella, 1993) as the scientific knowledge embodied in pharmaceuticals has become more generic in nature. This has given rise to the development of a market for research ideas and the development of networks of pharmaceutical companies where the research function has been decoupled from the manufacture, testing and marketing of new drugs.

As a result, Gambardella (1995) describes the emergence of a division of labor in pharmaceutical innovation as the knowledge-base has become more "divisible". With the molecular biology revolution, knowledge discovery and application can be broken into smaller modules split between different groups of researchers. Universities and biotechnology companies can therefore specialize in the discovery and development of new ideas, while the subsequent clinical trials and distribution remain in the hands of traditional pharmaceutical companies who possess the necessary capital and competences required to shepard an idea to the final stage of a marketable product.

Such an expansion in the division of labor has created an environment that is conducive to the emergence of open source – the open dissemination of basic research results – in the pharmaceutical industry. Low capital requirements, the modularity of the development process and the ability to tap into the capabilities of others who can turn research into profits are all necessary preconditions for the emergence of open source. Representing the next stage in the continuum leading to greater specialization, open source offers the possibility of fueling the next major revolution in the discovery and development stage of pharmaceuticals. A revolution not fueled by the new technologies or research methodologies, but rather as the result of organizational changes that further promote the division of labor.

While it may be difficult to imagine how innovation may take place without patent protection, there are examples of the commercialization of basic scientific knowledge that have occurred without patents and licenses. For example, Colyvas et al. (2002) analyze 11 cases of university inventions during the 1980s and discovered the following results. First, in none of the cases did an expectation of financial returns for the scientists, or for the university, appear to have played a significant role in motivating the research. In fact, the principle motive seems to have been to successfully achieve the kind of research results that academic researchers in their fields customarily are congratulated for achieving. Second, the researchers involved were members of a network of scientists that involved people from industry that likely could benefit from successful research results. And in many cases, it is clear that strategically placed people in industry knew of the project from its inception, largely because this network of scientists communicated with each other and thus patents, *per se*, were not needed to help disseminate university research results. Third, for the cases of *embryonic* pharmaceutical inventions – those needing further development – none were exclusively licensed to a firm and in one case *non-licensee* firms invested resources in developing and commercialized products based on the university invention. Apparently these firms believed that if their research was successful, they could get a patent based on their own work and they did not need protection from competitors to be induced to go for the prize. Our open source model for basic scientific knowledge development in the pharmaceutical industry is an attempt to formalize this last case.

THE PUBLIC POLICY OF BASIC SCIENTIFIC RESEARCH

The current economic environment surrounding the development and transfer of basic scientific research at US universities was born in the political arena of the 1980s. The theory underlying the decisions made by policymakers in the 1980s was that university research – particularly in pharmaceuticals – resulted in *embryonic* inventions that would require a tremendous amount of follow-on work by industry. For that type of invention, technology transfer from the university to industry would be helped if the university took out a patent on the invention. The university would then sell a license to an interested firm that would invest resources to further develop the invention. Because of the protection from competition afforded by the license, the private sector would have a greater incentive to bring the invention to market.

Because the U.S. Congress believed that the ability to patent and license would accelerate the commercialization of university inventions (and thus the realization of economic benefits by US taxpayers), Congress passed the Bayh-Dole Patent and Trademark Amendment Act of 1980. Bayh-Dole changed the intellectual property rules at US universities by transferring the ownership right of patents arising from federal research grants from the government to the university. The same logic regarding basic knowledge and technology transfer led to the National Co-operative Research Act of 1984, which reduced the antitrust penalties arising from collaborative research and provided additional incentives for firms to engage in research joint ventures. It also formed the basis for passage of the Omnibus Trade and Competitiveness Act of 1998 which established the US Commerce Department's Advanced Technology Program (ATP) to induce more joint ventures between firms and universities in creating and commercializing generic technology projects. Moreover, the National Science Foundation (NSF) responded to this theory by increasing their funding for Industry-University Co-operative Research Centers designed to promote technology diffusion, commercialization, and integration of research and education.

These initiatives, in addition to a general growth in federal financial support for basic biomedical research in universities beginning in the late 1960s (Mowery *et.al.*, 2001), have lead to a growth in university patents and licenses, and a growth in the incidence of university-industry relationships (Poyago-Theotoky *et.al.*, 2002; Colyvas *et.al.*, 2002). As a result, universities accounted for 49% of the basic research within the US and 13.5% of total US R&D performance in 2000 (National Science Foundation, 2000). The number of patents granted to US universities increased from 300 in 1980 to 3,764 in 2000. As a result of such a growth in patents and licenses, annual university licensing revenue increased from $160 million in 1991 to $1,263 million in 2000. Such revenues now constitute about 4.3% of university R&D expenditures.

The evidence suggests that universities have financially benefited from recent public policies governing scientific research. Specifically, in Jensen and Thursby's (2001) survey of 62 US research universities, university administrators and technology managers revealed the level of their satisfaction with current public policy governing scientific research when they ranked license revenue from patents more important than any other motivation for teaming up with industry. However, this motivation for university-industry alliances is not new. Indeed, it is because of the decentralized structure of US higher education that universities have historically had collaborative research relationships with industry as a mechanism to increase operating revenues and capital reserves (Rosenberg and Nelson, 1994).

Moreover, public policy has not fundamentally changed the incentives motivating university researchers. Faculty have always desired industry support because it contributes to their personal incomes and because it helps contribute to the building blocks for other research, publications, citations and ultimately their eminence in the field of study (Cohen *et.al.*, 1997). One measure of this perspective is also found in the Jensen and Thursby's (2001) survey. They observed university administrators and technology managers reporting that faculty members consider sponsored research more important than the pursuit of patents or the execution of license agreements *per se*.

For university researchers, what did change in the 1980s and 1990s was the availability of venture capital and the opportunity for them to turn "embryonic" molecular or biotechnology inventions into a promising biotechnology firm. Indeed, Zucker *et.al.* (1998) uncovered a tight empirical relationship between the growth of intellectual human capital created by frontier research in these fields and the founding and location of biotechnology firms in the US.

However, there are very real costs associated with a system of property rights vested in patents and funded by venture capitalists. For example, there is an inherent trade-off in the current public policy governing university-industry knowledge and technology transfer (Louis *et.al.*, 2001; Nelson, 2001). It has also been noted that a major drawback to the greater commercialization of university research is the potential degradation of the culture of "open science" (Dasgupta and David, 1994) – the free exchange of ideas among faculty and students – that permeates colleges and universities. Louis *et.al.* (2001) report that academic scientists engaged in entrepreneurial activities are more likely to deny requests from fellow academics for research results than other faculty members who are not engaged in such activity. Thus, these studies indicate that increasing rate of patenting and licensing of basic university research results has hindered (1) the advance of science *per se* and (2) the speed and rate at which new molecular and biotechnology knowledge is disseminated.

The most apparent examples of how patents have limited the diffusion of research results come from the fields

of molecular biology and biotechnology (National Research Council, 1997). Because universities and private firms alike may patent genetic materials and require licensing and royalty payments for their use, the cost of using such basic scientific knowledge has increased, and thus has diminished the rate of its diffusion. As we wrote earlier, the proliferation of patent owners of this "upstream intellectual property" creates obstacles that have had the effect of stifling life-saving high-technology innovations further down stream.

Furthermore, the argument that intellectual property accelerates the commercialization of basic scientific knowledge conflicts with an important strand of economic analysis of the social returns to scientific research which stressed that scientific knowledge is not rivalrous in use (Nelson, 1959; Arrow, 1962). Policies impeding access to a scientific discovery by any party that can make good use of it impose costs on that party and on the economy as a whole. Moreover, the economic theory of scientific research argues that patenting the results of publicly funded research is unnecessary to induce research investment and that any restrictions on use associated with patents reduce the social returns to this public investment (Mowery *et.al*, 2001).

It is for these reasons that a successful open source policy has the potential to fundamentally change the innovation process and thus maximize the probability of inventing life-saving technologies. The economic benefits of an open source model are several. For example, increasing the rate of technological diffusion by lowering obstacles will expand the social knowledge base, increase the probability of high-technology drug production, and lead to human beings living longer and more productive lives – all sources that contribute to increases in economic welfare. The mere existence of more high-technology drugs would lower private health care costs and government expenditures on Medicare and Medicaid, *ceteris paribus*. Pharmaceutical companies would also benefit from the expansion of basic scientific knowledge because they could use it free of charge on the margin to develop "designer" drugs – or drugs that would have been "orphans", but are now profitable because of the lower R&D costs. The increase of, and specialization in, basic scientific research at the university level will also allow pharmaceutical firms to shift out of this activity of production and thereby enabling them to deepen their specialization in other activities of production such as clinical trials and marketing.

The costs of implementing an open source model for basic scientific research are limited. For example, the *ex ante* process of funding university research by the NIH, NSF and other government agencies does not need to change, but rules governing *ex post* methods of knowledge and technology diffusion must change to open source. As a matter of fact, the NIH is already developing a new policy on sharing research data that will expect and support the timely release and sharing of final research data from NIH-supported studies.

The most significant matter that must be addressed is at the university budget level. An open source policy eliminates universities' right to issue licenses and therefore it would eliminate all license revenue from basic scientific research – a source of revenue equal to $1,263 million in 2000. Thus, it appears that universities have the most to lose from the implementation of an open source system. A (quasi) two part-tariff offers a potential solution to this problem.

Because basic scientific research is not rivalrous in use (Nelson, 1959; Arrow, 1962), the marginal cost to society when another researcher (or firm) uses an invented basic technology is zero and therefore the price of a license – part two, of a two-part tariff – should be zero. This pricing outcome is the open source result, where licenses don't exist. However, it is possible to collect revenue without charging a price for marginal use, without affecting marginal behavior, and thus without affecting the socially efficient result. The coordinator and disseminator of basic scientific university data may charge a yearly membership fee – part one, of a two-part tariff – to anyone who wants to access and use the database of basic scientific knowledge. Membership fees could vary according to frequency of use or some other pre-specified set of rules – e.g., the pricing policy could be similar to the pricing strategy of Lexus-Nexus or even Microsoft for large, medium, and small businesses and universities. By allowing universities to charge an upfront membership fee to traditional pharmaceutical firms, and other industrial, academic, or institutional buyers, consumer surplus – a dollar amount equal to or greater than current license revenues – would be transferred to universities' coffers. Once in the hands of the university, revenues would be distributed similar to other sponsored research funds.

However, the question remains: Why would anyone be willing to pay such a fee? The answer can be found in the gains associated from an expanded division of labor. By opening the door to greater collaboration in research effort, newer and more effective classes of drugs can be created at a significantly lower cost. Removing many of the risks associated with the development process, the pharmaceutical company could specialize in manufacturing and/or the marketing and sale of these new classes of drugs thereby offering even greater efficiencies. The loss to the pharmaceutical companies of monopoly rents associated with the taking of patent rights would be offset by the gains that arise from an expanded market. The market will expand in part because a broader division of labor will lead to the development of superior drugs at a lower cost and because of the elimination of monopoly rents associated with the current patent system. By being able to offer better drugs at a lower price, the size of the market for pharmaceuticals will increase dramatically both in terms of the affordability of

the product and the number of individuals who can now take advantage of the lower priced products.

Therefore, while the price that firms charge for pharmaceuticals will fall, as long as the increase in the volume of sales expands sufficiently to generate a level of revenues capable of supporting a dramatically reduced cost structure, the level of profitability will remain the same or may even possibly increase. Over time, competition will lead to the socially optimal result that the fee charged by universities will equal the difference between the revenues that the pharmaceutical companies receive and the rate of return required for those same companies to earn zero economic profits.

CONCLUSION

Changes in the science associated with the development of pharmaceuticals have created a new opportunity for rethinking the assignment of intellectual property rights for the industry. The development of generalized scientific principles is making it possible to expand the division of labor and thereby increase the degree of specialization. The new division of labor between inventors of basic scientific research and those that apply and bring an invention to market has set the stage for the adoption of an open source model in the pharmaceutical industry.

It should be noted that the adoption of an open source system is not something that is entirely alien to the industry. The establishment of a formal open source system would be nothing more than the codification of a trend that currently occurs informally in this industry. For example, several pharmaceutical firms have supported research to identify gene codes on the *condition* that the discovered information be placed into the public domain (National Research Council, 1997).

What would change dramatically under an open source system are the incentives for developing high technology solutions to the problem of disease. Because high-technology pharmaceuticals cure disease, a public policy that would increase the probability of discovering them would have the effect of lowering aggregate health care costs, *ceteris paribus*. By lowering health care costs, more individuals would be able to receive either publicly or privately provided health care.

By reassigning property rights and expanding the division of labor, an open source system can increase the level of social welfare. As long as universities can charge a fee for access to their research and pharmaceutical firms can sell larger quantities of lower priced drugs to a greatly expanded market, then no one would be worse off, while the entire economy in the aggregate would be better off under an open source solution.

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