Recent Changes in Patent Policy and the "Privatization" of Knowledge: Causes, Consequences, and Implications for Developing Countries

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1. Introduction

It is by now almost axiomatic that the long-run economic growth and development of nations, and consequent improvements in standards of living, depend largely on improvements in national technological capabilities. For underdeveloped nations behind the technological frontier, these improvements historically have relied crucially on assimilation and adaptation of knowledge and techniques from developed nations. Much of this knowledge has traditionally been in the public domain. That is not to say that it was freely available-like the "book of blueprints" once famously described by the economist Joan Robinson. Rather, the global pool of knowledge was accessible only to countries that had well developed "national innovation systems," and in particular those with policies and institutions facilitating inward technology transfer. Historically, the countries that were most successful in closing the gap between local technological capabilities and the world technological frontier were precisely those that made such investments.

However, many observers believe that over the past two decades, there has been a shift in the boundaries between the public and private domains in science and technology. In particular, there is concern that knowledge has increasingly become "privatized," limiting developing countries' access to information and technologies that were once in the public domain. Over approximately the same period of time, we have seen significant scientific and technological advances in fields like biotechnology and information/communication technology, which have the potential to benefit developed and developing countries alike. Yet if trends towards privatization limit developing countries' access to these advances, these changes could paradoxically exacerbate rather than ameliorate the global divide in technological capabilities, and hence global inequities in income levels and standards of living.

The main catalyst for these concerns about privatization of knowledge has been a worldwide strengthening of intellectual property rights over the past two decades, and in particular changes in the patent systems of developed and developing countries. Many scholars have condemned what Vandana Shiva (1997) has referred to as "the enclosure of the intellectual commons," and argued that it will hinder knowledge flows to developing countries.
In almost all such treatments, the putative "privatization" of knowledge is treated abstractly, with relatively little attention to the details. In fact, the changes to patent policy and practice over the past two decades have been multi-faceted and variegated. They include changes in developed countries relating to what types of subject matter are patentable, standards of patentability, and the range institutions that can patent, as well as externally-imposed changes in developing countries' patent systems. Assessing the impact of these developments requires examining each independently, as well as the complex interactions between them.

In this paper, I unpack these changes and provide a guide to thinking about their direct and indirect effects on developing countries. To telegraph my conclusions, I find that there has in fact been a privatization of knowledge over the past two decades, and almost all of the policy changes that led to it were based on very weak evidentiary foundations. Notwithstanding, the likely effects of these changes on developing countries (or for that matter developed countries) remain unclear. In part this is because many of the changes are relatively recent: it is just too soon to tell. However, some of the difficulties in assessing the impacts reflect more general measurement problems endemic in science and technology policy research. Because scientific and technological information is intangible, it is difficult to track the effects of changes in science and technology policies: knowledge flows leave few footprints (Krugman 1991).

Despite difficulties in evaluating the effects of the changes, three points do emerge clearly from the paper. First, the growth of patenting of publicly funded research is a legitimate source of concern. Historically, publicly funded research in developed countries, and cooperation between public and quasi-public institutions in developed and developing countries, has been crucial to the development of technologies aimed at developing country needs. The growth of patenting threatens to limit public research organizations' willingness and ability to disseminate the fruits of their research widely, which could create transaction costs in the research process itself. This remains a crucial topic for future research. Second, while many observers believe that the TRIPs-mandated changed in patent policies in developing countries will have the most dramatic and drastic effects on developing countries, the discussion below suggests that developing countries do have considerable latitude in how they implement the TRIPs requirements, and rather than simply mimic developed country patent standards, they should explore how they can structure these standards to minimize potential harms and maximize benefits. Indeed, developing countries have the historically unique opportunity to take the lead in developing patent systems that appropriately balance the tradeoffs between incentives for knowledge creation and the rate of knowledge diffusion, a balance which many developing countries are striving to regain. Third, and most importantly, many of the potentially negative effects of the various policy changes described in the paper will be felt only by countries which already have local innovative capabilities. For others, weak innovation systems and limited social absorptive capabilities, rather than the privatization of knowledge, remain the main impediment to knowledge flows.

The paper proceeds as follows. Immediately below in Section 2, I set the stage by discussing the role of patents in mediating the boundaries between the public and private domains, and review economic theory and evidence on whether and when patents promote innovation. In Sections 3 through 5, I review the history of three recent changes to the U.S. patent system that are often indicted as part of the privatization of knowledge: the expansion of patent eligible subject matter (Section 3), changes in patent standards and the rights afforded to patent-holders (Section 4), and the growth of patenting of "public" research (Section 5). These sections also review empirical evidence on the impacts of these changes in developed countries, and consider possible direct and indirect impacts on developing countries. (Though these sections focus primarily on changes in the U.S., similar changes have occurred or are currently being considered in other developed countries.) In Section 6, I examine the causes and consequences of the TRIPs agreement. In Section 7, I conclude.

2. The Patent System

2.1 Patents and the Boundary Between the Public and Private Domains

Science and technology, and information more generally, differ in several respects from other commodities. From an economic perspective, the most important dimension is that science and technology are non-rival: they can be used simultaneously by many users at once, and they do not deplete upon use. Another (related) characteristic of scientific and technological information is that the marginal cost of creation often significantly exceeds the marginal cost of reproduction. That is, production of the first unit is expensive, requiring significant investment in research. But upon creation, additional units can be created and disseminated at lower cost. An implication of low marginal cost of reproduction and dissemination is that is can be difficult to exclude others from the use of information, once created. That is, to an extent, science and technology are characterized by limited excludability.

Non-rivalry and limited excludability are two defining characteristics of what economists call "public goods." Beginning with the classic works of Nelson (1959) and Arrow (1962), economists have recognized that these features (and others) imply that in many circumstances, market actors will lack incentives to invest in the creation of science and technology even when such investment would be socially beneficial.

As Paul David (1994) discusses, governments traditionally have employed several mechanisms to ameliorate this "market failure": two of the most important are patronage and (intellectual) property. Patronage refers to direct government funding of research, i.e. using grants to subsidize those engaged in production of science and technology. Where markets will not fund the research, governments do so directly. Property on the other hand gives private actors exclusive rights to their intellectual creations. Intellectual property rights are legal rights to exclude others from the use of new knowledge, effectively allowing for private control of the latent public good, for a limited period of time.

Neither patronage nor property policies are perfect: each have their relative costs and benefits. Patronage based systems are difficult to administer because the government is less informed than the potential investigator about the true expected costs and benefits of a project, and the investigator requesting funds has incentives to exaggerate each. Moreover it is often difficult for funding agencies to monitor the activities of research performers, and in this context grant recipients may have incentives to shirk (David 1994, Wright 1983).

Intellectual property based mechanism can avoid these problems created by information asymmetries, since (at least in principle) under these systems investigators are rewarded if and only if they develop useful knowledge. But a cost of using intellectual property based mechanisms is that they remove knowledge from the public domain, i.e. they turn a latent public good into a private one. Recall that once produced, the marginal cost of reproduction and dissemination of knowledge is typically lower than the initial production cost. Reflecting this property, from a social perspective it would be desirable to allow for broad use of new information, once produced. That is, there are social "costs" involved in limiting the use of new information, once developed.

Most economists have focused on the costs created by non-competitive pricing of goods and services embodying the technology: these are known as "deadweight losses" created by restricting the use of information that could, in principle, be used by many more actors. This concern is reflected in recent disputes over pricing of HIV treatments in Sub-Saharan Africa, or laws on production by "generic" pharmaceutical manufacturers in the United States. In both cases, critics of intellectual property rights argue that patients are suffering and lives being lost because of the high prices of drugs that could be produced more cheaply, in the absence of intellectual property rights.

Thus, intellectual property rights are a double-edged sword. On one hand, they can create incentives for the generation of new knowledge. On the other, by subsequently removing it from the public domain (for a limited period of time) they create social costs by limiting its dissemination and use. That is, intellectual property rights trade-off incentives for creation versus benefits from dissemination. Indeed, much of the policy discussion about intellectual property rights centers on the degree of excludability that they should confer: too little could thwart incentives for creation, and too much could increase social costs resulting from limited use.

In addition to the "costs" discussed above, scholars more recently have begun to focus on another drawback of strong excludability: its effects on subsequent knowledge production. For example, Nelson (1992) argues:

> " … the going public of a new technology not only increases society's ability to use it in its present form, but also widens the range of parties who are in a position to further improve it, variegate it, more generally contribute to its advance. While analysts have argued the case both ways, I maintain that by and large the experience is that technical advance proceeds much more rapidly when a considerable number of parties are engaged in competitive efforts, than in a context where one or a few parties are in a position to control developments" (60).

These types of costs have figured prominently in recent debates about patenting of "science" and patenting by universities, discussed in Sections 2 and 5 below.

The social costs from lack of dissemination, as well as the more dynamic costs on further knowledge creation, almost certainly are greater for research that has a broader range of uses or range for development. It may not be surprising, then, that most western societies have traditionally relied on patronage based mechanisms to stimulate the creation of more "fundamental" research, and intellectual property based mechanisms to create incentives for more "applied" research[1]. As David (1994) points out, while patronage based systems typically have been associated with full public disclosure of findings (reinforced by the norms of open science; see Dasgupta and David 1994) property based solutions inherently restrict the use of information.

2.2 An Overview of the U.S. Patent System

Intellectual property rights thus demarcate the boundary between the public and private domains in science and technology. As Nelson (1992) explains, science and technology are not pure public goods but "latent" public goods, meaning that their public and private aspects are determined, in large part, by government regulations on intellectual property rights. Much of the recent discussion about "privatization" of knowledge focuses on changes in the domain, scope, and strength of one type of intellectual property mechanism-the patent system. The next section provides an overview of the origins and functions of the patent system in the United States.

Though one can make various philosophical and/or ethical arguments about what aspects of science and technology should be public and which private, the rationale embodied in the U.S. patent system is explicitly a utilitarian one, namely that patents are necessary to stimulate innovation. Thus in Article I, Section 8 of the U.S. Constitution, the Framers gave Congress the right to issue patents "To Promote the Progress of Science and the Useful Arts." The spirit of U.S. patent law has always been about the difficult task that Thomas Jefferson once referred to as "drawing a line between the things that are worth to the public the embarrassment of an exclusive patent, and those which are not," (*The Writings of Thomas Jefferson*, 335). Restrictions on patent eligible subject matter and criteria defining standards for patentability illustrate attempt to draw these lines.

Section 101 of the patent code limits patent eligibility: an "invention" can be patentable only if it is a "new and useful process, machine, manufacture, or composition of matter" (35 USC § 101). Historically, laws of nature, physical phenomena, and abstract ideas have not been patentable, on the basis that they are already in the public domain, and that allowing for property rights on them would serve no socially useful purpose.[2]

In order to be patentable, an invention must also be shown to be both "novel" (35 USC § 102) and "non-obvious" (USC 35 § 103). Under the novelty bar, an invention cannot be patented if it was known or previously used. Under the non-obviousness bar, an invention cannot be patented if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains" (35 USC § 103a).

The novelty and non-obviousness bars reflect the utilitarian character of patents. As noted above, patents create welfare losses, and thus from an economic view are only necessary in order to promote invention and dynamic gains in welfare (Arrow 1962). The novelty and non-obviousness bars draw these lines between the public and private domains. The novelty bar ensures that patents are not granted on things that have already been invented, and are already in the public domain.[3] The non-obviousness bar also fences off the public domain by precluding the granting of patent monopolies for inventions that were easily accessible based on the information already in the public domain, i.e. cases where "the cost and risk of independent research to obtain an invention are low enough that an ordinary researcher would be expected to incur them at about the same time without the additional incentive of a patent" (Schlicher 1992, 5-3).

Inventions that meet these criteria (in addition to several other technical requirements) are granted patents: the right to exclude others from the use of an invention for a limited term, currently 20 years from application date in the United States.

The criteria for patentability, and the courts interpretations thereof, effectively draw the lines between the public and private domains to which Jefferson referred. Much of the recent concerns about the "privatization" of science and technology relate to legislatively or judicially imposed changes in these standards in developed countries, and in particular in the United States. Another set of concerns relate to exogenously introduced changes to patent systems in developing countries which require them to extend patent protection to technologies that these nations formerly considered to be in the public domain. The causes and consequences of these changes are reviewed in Sections 3 through 5 below.

But first, to provide context for thinking about these changes, immediately below we review the empirical evidence on the relationships between patents and innovation.

2.3 Patents and Innovation

As indicated above, the assumption underlying the U.S. patent system (and the patent system of most other developed countries) is that patents are necessary to promote innovation. Because patents promote innovation and "dynamic" economic benefits, society is willing to endure the various costs associated with keeping new information out of the public domain for a limited period of time. Interestingly, however, the empirical evidence on whether patents actually do promote innovation is mixed, and recently there have been concerns that patents may actually hinder rates of innovation in some contexts.

2.3.1 Do Patents Promote Innovation?

Several studies conducted over the past two decades show that in most industries, patents are not the only way, and rarely the most important way, for firms to appropriate the returns from their research. Mansfield et al. (1981) find that it is typically difficult and costly for competitors to imitate new products or processes invented by a firm. Contrary to the assumption that new technologies are "public goods" freely available to all, the authors find that on average imitation costs are 65% of the costs of invention, and the time it takes to imitate a technology is 75% of the time it took to develop it in the first place. Moreover, they find that in most industries, with the exception of pharmaceuticals, imitation costs are *not* affected by the presence or absence of patents. In a follow-up study, Mansfield (1986) surveyed 100 firms in 12 industries, asking them to estimate the share of successful inventions that would not have been developed absent patent protection. In most industries, respondents replied that only a trivial share of inventions would not have been developed without patent protection. Again, pharmaceuticals and chemicals are exceptions: here, fully 30% of inventions would not have been developed absent patent protection.

These studies thus suggest that outside of pharmaceuticals/chemicals, firms have and rely largely upon other ways to appropriate the returns from their R&D. This issue was further illuminated by two surveys of firm R&D managers during the 1980s and 1990s, one conducted by researchers at Yale (Levin et al. 1987) and one by researchers at Carnegie Mellon University (Cohen et al. 1997). In each, firm R&D managers were asked to rank the relative importance of various channels though which they could appropriate returns from their R&D: patents, secrecy, lead time, complementary sales/service, complementary manufacture, or proprietary know-how. The results from these surveys are broadly consistent with those from Mansfield's studies. In most industries, for both product and process innovations, the other mechanisms (in particular lead time, complementary sales and manufacturing capabilities, and secrecy) were ranked as more important than patent protection. Also consistent with Mansfield's results, both the Yale and Carnegie Mellon studies found that the pharmaceuticals industry is an exception: here, patenting is an important mechanism for appropriating returns.

The reasons why the pharmaceuticals industry is "exceptional" have not been fully explored. Almost certainly, one reason is that the costs of creation of a new pharmaceutical compound are particularly high relative to costs of imitation, and reverse engineering of a new compound is often trivial. In addition, the ability to specify patentable compounds precisely (via chemical nomenclature) may make it more difficult to "invent around" patents in pharmaceuticals (and chemicals based industries more generally) than in other fields, making patent protection more attractive relative to other means of appropriability (cf. Levin et al. 1987).

Another important insight that comes from juxtaposing the results of the Yale and Carnegie Mellon studies is that the effectiveness of patent protection as a means of appropriating returns from R&D has not increased between 1984 (when the Yale study was conducted) and 1994 (when the Carnegie Mellon study was conducted). Yet, over the same period of time, the number of patents granted to U.S. firms, as well as their propensity to patent (patents per R&D dollar) have increased dramatically. Several scholars have suggested that this apparent "patent paradox" (Kortum and Lerner 1999, Hall and Ziedonis 2001) may reflect a growth of strategic patenting, rather than patenting to prevent imitation of their inventions. For example, Hall and Ziedonis (2001) find that following the 1982 formation of the Court of Appeals for the Federal Circuit (see Section 4 below), which increased the rights of patent-holders and the presumption of validity of issued patents, firms in the semiconductor industry began stockpiling large portfolios of patents in order to extract royalties from other (potentially infringing) firms and to use as bargaining chips in negotiations when they were threatened with infringement suits. Related to this, Cohen et al. (1997) suggest that the growth of patenting may reflect defensive patenting, i.e. patenting to protect a firm from litigation by another firm which later patents a similar technology. Though more work on this front is needed, in such cases where patenting is driven by "strategic" rationale rather than a need to prevent imitation of new technologies, the social welfare effects of patents are almost certainly negative.

2.3.2 Can Patents *Deter* Innovation?

Thus the evidence that patents promote innovation is weaker than conventionally believed. Indeed, recent theoretical scholarship and limited empirical evidence suggest that in some cases patents could actually *deter* innovation. Specifically, where intellectual patent claims are fragmented or patents are granted on early stage inventions, patents may actually increase the costs of future research and product development, and thus slow down the rate of innovation.

A first concern arises in contexts where "downstream" research or product development relies on access to many patented technologies held by different owners, i.e. "upstream" patents are highly fragmented and there are numerous potential claimants to particular lines of product development or research. In such cases, the costs of obtaining access to these rights could prevent the downstream research or product development from going forward. This potential "tragedy of the anticommons" was first suggested by Heller and Eisenberg (1998), who highlight implications for biomedical research and development. For example, Heller and Eisenberg (1998) suggest that the growth of patenting on gene fragments could hinder development of therapeutic proteins and diagnostic tests in cases where these "downstream" products rely on multiple patents, and it is difficult and costly for developers to gain rights to use these patents. In addition, they also suggest that in cases where future research relies on access to patented "research tools" owned by many different parties, the costs of obtaining access to these tools may considerably slow down the progress of research and innovation. Importantly, and as the examples cited above suggest, Heller and Eisenberg note that such "tragedies" are much more likely today than previously, given the changes to definitions of patent eligible subject matter, standards of patentability, and the range of institutions active in patenting and licensing that we discuss below.

A pre-requisite for this "tragedy of the anticommons" is difficulty in bargaining for access to the "upstream" patents, which Eisenberg and Heller believe is pervasive. Note however, that preliminary interview based research by Walsh et al. (2002) suggest that though transaction costs do complicate bargaining, they are rarely so large to be show-stoppers, and in most cases valuable research and development projects do go forward even in the presence of many upstream rights-holders. However, more research on this front is needed.

The potential tragedy of the anti-commons results when there are many claimants to technologies that are inputs into future research or product development. A similar but conceptually distinct concern arises with patents in the context of sequential or cumulative innovation, i.e. where "[t]oday's inventions provide not simply to capability to produce new or better products or to produce them more effectively today, but also concepts and starting places for inventive efforts tomorrow" (Merges and Nelson 1994). In such cases, Merges and Nelson (1994) suggest that innovation tomorrow would be occur more quickly if "today's" inventions were broadly available, because (they argue) innovation takes place more effectively in the context of multiple, rivalrous sources of invention. Consequently, excessively strong patent rights on inventions today-in particular on "fundamental" and "science based" inventions that lay the seeds for many inventions tomorrow-could stifle the rate of innovation. Scotchmer (1991) discusses similar arguments.

2.3.3 Patents and Innovation: Reprise

Thus, despite decades of theoretical and empirical research on this issue, the relationships between patents and innovation, and answer to the question of whether patents promote innovation, remain uncertain. In most industries, patents are not the most important means through which firms appropriate returns from their R&D. However, this does not mean that patents do not induce R&D investment: the presence of patent protection may still induce R&D that would not have otherwise been undertaken. In addition, note that in pharmaceuticals, one of the fields of the fields where concerns about "privatization" of knowledge (particularly with respect to its impact on developing countries) have been particularly pronounced, there is consistent evidence that patents are important means through which firms protect their R&D investments.

One of the reasons it is difficult to evaluate whether patents stimulate innovation is that "innovation" is difficult to observe and measure directly. As the discussion in subsequent sections illustrates, these measurement issues make it extremely difficult to assess the effects of recent changes to the patent system-"privatization"-even in a developed country context.

However, one of the few empirical findings consistently found in empirical studies is that in many industries patents are not the most important mechanisms through which firms appropriate the returns from their research. Instead firms rely on mechanisms like secrecy, lead time, and complementary investments to protect their inventions. In such industries, the lines between the public and private domains may not be affected much by strengthened patent protection. Instead, the degree to which developing country firms can access the global "pool" of knowledge will depend more on their ability to reverse engineer, imitate, and otherwise assimilate and adapt developed country technologies. This in turn, depends on their levels of social absorptive capability and other broad characteristics of their innovation system. Thus it is important to keep the recent changes in patent policies and practices, described in the following sections, in perspective.

Over four decades ago, Fritz Machlup (1957), in concluding his magisterial review of the patent system, argued that "No economist on the basis of present knowledge could possibly state with certainty that the patent system, as it now operates, confers a net benefit or net loss upon society." Based on the review of the empirical evidence above, it is clear that the same is true today, though we do have a better understanding of inter-industry differences in the importance of patent protection in stimulating innovation. Machlup also suggested that because of this lack of understanding:

> "If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, based on our present knowledge, to recommend abolishing it"

Despite Machlup's cautions, since the time he wrote (in particular since the late-1970s) we have seen what appears to be a dramatic strengthening of patent rights in the United States and other developed countries, as well as pressures to mimic these systems in developing countries. The causes and consequences of these changes are discussed in the following sections.

3. Recent Changes in Patent Policy and Practice: Changes in Patent Eligible Subject Matter

Perhaps the most important of the recent changes to the patent system are changes in patent eligibility, i.e. changes in subject matter deemed patentable. As suggested in Section 2, the patent statute limits patentable subject matter to "any process, machine, manufacture, or product of matter" (35 U.S.C. Section 101). Historically, these limitations were interpreted by the courts and by the patent office to exclude from patentability living organisms and algorithms; these exclusions reflected the basic principle underlying the patent law that living organisms and algorithm belonged in the public domain. However, important court decisions during the early 1980s-as well as growing sophistication by patent attorneys (Merges 1999)-led to a relaxation of these standards. These changes fueled the growth of patenting in biotechnology and software: each is discussed in turn below.

3.1 Biotechnology

Historically, the patent offices and the courts interpreted the patent statute as prohibiting the patenting of living organisms, or more generally "products of nature." In large part, this prohibition was based on the logic of the patent system discussed above: patenting "products of nature" would unnecessarily remove from the public domain things that are already known or accessible. This was the essence of the logic underlying made by the Supreme Court in 1948 decision delivered by Justice Douglas, who wrote for the majority that certain bacterial cultures could not be patented because:

> "Patents cannot issue for the discovery of the phenomena of nature. . . . the qualities of the bacteria, like the heat of the sun, electricity, or the qualities of metals are part of the storehouse knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."[4]

This longstanding interpretation[5] was amended, if not reversed, in the noted 1980 Supreme Court decision *Diamond v. Chakrabarty*, where the court ruled that certain genetically modified organisms were patentable because, though they were living organisms, they did not occur "in nature" but rather their existence required human intervention. As such, according to the decision, they were "manufactures" or "compositions of matter" and were thus patent eligible. With the *Chakrabarty* decision, patentability effectively was extended to "anything under the sun that is made by man."[6]

The *Chakrabarty* ruling coincided with the emergence of the biotechnology industry, which had been made possible after key discoveries in the early 1970s allowed for the introduction of foreign genes into cells. In the decades following this ruling, there was a dramatic growth in patenting of cloned genes and DNA sequences, and products produced using these sequences, including therapeutics and crops. The number of biotechnology patents issued in the United States increased from less than 1000 per year in 1976 to approximately 8000 in 1999, and patents on genomics alone increased from 100 to over 5000 over the same period.[7]

This growth of patenting in biotechnology, and patenting of genes and gene sequences in particular, has been the source of considerable debate and controversy. While defenders of patenting genes argue, much in the spirit of the *Chakrabarty* decision, that absent patents the benefits from genetic engineering would not occur in the first place, others have raised ethical and economic objections to patenting the genome (see Nuffield Council on Bioethics, 2001, for an excellent overview).

One of the most important concerns about the rise of biotechnology patenting reflects the fact that the composition of this patents has changed over the past two decades (Eisenberg 2002). During the 1980s, the bulk of biotechnology patents were on genetically engineered therapeutics. However, since the 1990s we have seen the rise of patenting on DNA sequences developed via high-throughput sequencing (Eisenberg 2002).

One set of concerns reflects the belief that many of these DNA sequences do not meet the novelty and non-obviousness requirements, and thus should not be patented. We discuss this issue in more detail in Section 4. More importantly, as discussed above, some claim that much of the value of DNA sequences derives not from particular products that will be developed from them, but rather from the information embodied in them, which is often useful in subsequent research. Patents on these "research tools," it is feared, could lead hinder downstream research and product development, i.e. increased patenting of DNA sequences could be creating an "anti-commons" (Eisenberg 2002, Eisenberg and Heller 1998) If true, this would be particularly troubling because many of these patents derive from publicly funded research, a context where the traditional argument for patent protection does not hold, as we discuss in Section 5 below. Note that this discussion already suggests that concerns about "privatization" reflect the interaction of a range of policy shifts, rather than any one alone.

3.2 Software

Another area where there has been an apparent change in patent eligibility is computer software. Historically, the United States Patent and Trademark Office resisted granting patents on computer programs and other algorithms on the basis that they are essentially mathematical formulae, similar to laws of nature. Thus in Gottschalk v. Benson the court ruled that a computer program algorithm was not patentable because:

> Mathematical inventions should be treated like scientific truths and laws of nature, and scientific truths and laws of nature are unpatentable subject matter.

The non-patentability of laws of nature, much like the non-patentability of products of nature that traditionally limited patenting on organisms, reflected the underlying principle of patent law that it would be inefficient to create monopolies over information already in the public domain (see Samuelson 1990, page 1097).

The rise of software patenting followed several judicial opinions in the 1980s that certain types of software could be patentable, the most important of which was the Supreme Court's 1980 decision in *Diamond v. Diehr*. There, the court affirmed the argument in *Gottschalk v. Benson* that laws of nature are not patentable, but argued that applications of laws of nature (and mathematical formulae) were patentable. Though this distinction has been questioned by some (Samuelson 1990), since this decision the Patent Office relaxed its traditional reluctance to patenting computer software related inventions.

The most tangible result of this change was a dramatic growth of software related patents over the 1980s and 1990s. Graham and Mowery (2002) show that between 1987 and 1999 alone, the share of all U.S. patents accounted for by software patents more than doubled, increasing from 1.8% to 5.0%.

The growth of software patenting has been accompanied by several sets of concerns. First, the rise of patenting (driven primarily by electronics systems firms rather than software firms) ran counter to the traditional mode of software development, where information was shared generously and often freely. Related to this point, some fears that patents on software would hinder product development, arguing that software development is a cumulative and collective process, and patents would introduce significant transaction costs of the type discussed in Section 2 above (cf. Merges and Nelson 1994). Thus Richard Stallman, founder of the Free Software Foundation, recently wrote that the proliferation of software patenting:

> "will turn software into a quagmire. Even an innovative program typically uses dozens of not-quite-new techniques and features, each of which might have been patented. Our ability to use each wrinkle will depend on luck, and if we are unlucky half the time, few programs will escape infringing a large number of patents. Navigating the maze of patents will be harder than writing software"
> (http://www.fsf.org/philosophy/patent-reform-is-not-enough.html)

Many scholars also believe that a significant portion of the software patents do not meet the "novelty" and "non-obviousness" requirements, but rather represented a privatization of information and techniques that were already known and in the public domain, or minor variations thereof, as we discuss in Section 4 below.

3.3 Changes in Patent Eligibility: Reprise

When considering the effects of "privatization" of knowledge on developing countries, it is important to bear in mind that it is not patents per se, but rather the standards of patentability that draw the lines between the public and private domains. In this section, we showed that these standards have in fact changed in the U.S. over the past 20 years (as they have in other developed countries). The definition of patent eligible subject matter has expanded, to include types of information that have historically been considered part of the public domain.

Much of the concern about the potential effects of these changes on developing countries has been in relation to biotechnology, for several reasons. First, there is much enthusiasm that biotechnology will yield clues to treating diseases plaguing developed countries, e.g. that recent advances in genomics will prove to be a boon to vaccine development. Second, some believe that genetically modified crops might be the only feasible way to reduce malnutrition and hunger in many developing countries in the decades to come. Moreover, the growth of patenting of genetically engineered pharmaceuticals and agricultural biotechnologies in developing countries may increase their costs and reduce the extent of their dissemination.

However, it is important to remember that in biotechnology (like pharmaceuticals more generally) patents are an important mechanism used by firms to appropriate the returns from their R&D. Thus the extension of patent protection to biotechnology is likely encouraging R&D in this field. Put differently, absent patent protection (i.e. if we returned to a pre-Chakrabarty world) it is possible that much of the biotechnology research currently being undertaken by private firms would cease, though the extent to which this is so remains an important empirical question.

The growth of patenting of *inputs* into biotechnology research and product development, including so-called "research tools," also is cause for concern. If the "tragedy of the anticommons" is a real and widespread phenomenon, the productivity of R&D and rate of product development itself could be negatively affected. This too warrants future investigation, and is revisited below in the discussion of patenting publicly funded research.

Finally, though much of the public controversy about changes in patent eligibility and development has focused on the biotechnology industry, the recent changes affecting software patentability may also be relevant. One reason is in fact related to biotechnology: Eisenberg (2002) suggests that there may currently be a movement towards patenting DNA sequences encoded in computer readable media, in order to obtain capture the "informational" value of these sequences. This change, if it in fact occurs, would not be possible absent the changes relating to software patenting discussed above. In addition, Paul David (2002) argues that the growth of patenting (and other forms of IPRs) on databases may increase costs for scientists in developing countries to access information and hinder collaborative research programs between scientists in developed and developing countries, another means through which changes related to software patenting could effect knowledge flows and development.

4. Recent Changes in Patent Policy and Practice: Strengthening the Rights of Patentholders and a Reduction in the Non-Obviousness Standard

4.1 The CAFC and Strengthening of the Rights of Patentholders

In addition to changes in patent eligibility, there has also been concern that the monopoly rights of patent-holders have become stronger over the past two decades, at the expense of the public. The catalyst for these changes is widely believed to be the Federal Courts Improvements Act of 1982, which created the Court of Appeals for the Federal Circuit (CAFC). The CAFC is a central court which handles all appeals (from the district courts) on cases of patent infringement and validity. Prior to its creation, such appeals were heard by the various regional circuits. Standards of patent validity and infringement differed significantly across the circuits, and some earned a reputation for being "pro-patent" and others "anti-patent." This lack of uniformity predictably led to "forum-shopping" by litigants. The primary impetus for the creation of the CAFC was to eliminate these inconsistencies and thus make litigation more predictable.

While it may have reduced uncertainties in litigation, most scholars believe that the creation of the CAFC effectively led to a "pro-patentholder" bias in appeals. Merges (1992) notes that:

> While the CAFC was ostensibly formed strictly to unify patent doctrine, it was no doubt hoped by some (and expected by others) that the new court would make subtle alterations in the doctrinal fabric, with an eye to enhancing the patent system.

Immediately following its formation, the CAFC made a number of changes to law and doctrine which strengthened the rights of patent-holders, including improving the presumption of validity for patents already issued, and increasing remedies available to patentholders in the case of infringement (Turner 2002).

The effects of these changes are seen in litigation outcomes. Jaffe (2000) reports that before the creation of the CAFC, district court rulings that a patent were valid and infringed were affirmed 62% of the time on appeal, while after 1982 such rulings were affirmed valid 90% of the time. In addition, before its creation only 12% of district court rulings that a patent was not infringed or invalid were overturned, while since the 1982 this number has increased to 27%. These and other statistics (Jaffe 2000, Lanjouw and Lerner 2001) suggest that the creation of the CAFC did indeed strengthen the rights of patentholders.

4.2 Reduction in the non-obviousness standard

Another important change over the past two decades has been an apparent decline in the "quality" of patents in the United States in recent years, specifically a lowering of the non-obviousness bar. Inasmuch as the purpose of this bar is to protect the public domain--by preventing monopoly rights over information that was obvious based on what was already known--this change too can be seen as a "privatization" of knowledge. Most of the concerns about a diminished non-obviousness standard center on fields where patent eligibility itself has changed: biotechnology and software. In addition, some observers have pointed to a more general lowering of the non-obviousness bar, driven by changes at the patent office and the formation of the CAFC. These concerns are discussed in turn immediately below.

In biotechnology, much of the concern reflects the growing tendency for the patent office to allow for patents on new DNA sequences developed using routine (and at least in a colloquial sense, obvious) methods (Rai 1999, Eisenberg and Merges 1995). Specifically, the current standard for obviousness on DNA sequences is whether or not the sequence was disclosed in previous prior art. However, many sequences that are being patented were isolated using routine methods that are widely known and practiced. In such cases, allowing for patents seemingly flies in the face of the spirit of the non-obviousness criterion, to prevent privatization of information readily accessible based on the information in the public domain. Thus Rai (1999) questions the USPTO's standard for non-obviousness of DNA sequences, noting that "under this logic, DNA sequences can be non-obvious no matter how easy it is to isolate the sequences" (834).

Another new technological area where there have been concerns about weakened standards for non-obviousness is software. Much of the concern here is anecdotal stories of software patents that were granted even though a technology was widely known and/or being used previously: witness the recent uproar over Internet-based patents on "business methods" (see Merges 1999). In addition, several observers have presented more quantitative evidence that many software patents are overlooking prior art that would render the inventions obvious and thus unpatentable. In particular, Merges (1999), Riddles and Pomerance (1998) and others present evidence that software patents tend to cite very little non-patent prior art relative to patent based prior art. This fact provides *prima facie* evidence that patent examiners are not conducting proper searches of the prior art, since before the 1980s very few software patents were granted: most of the prior art was instead published in printed sources, or was embodied in computer code. The reasons provided for the lack of adequate searches include "newness" of the technological field and inexperience of patent examiners with software, as well as the related fact that patent examiners do not have access to common sources of non-patent prior art.

Though many of the concerns about the non-obviousness requirement have focused on particular technologies, some evidence indicates that the problem is more general. Merges (1999) provides some evidence that the growth in the number of new patent applications received by the patent office have far outpaced growth in the number of patent examiners and resources provided to examiners, making it more difficult for examiners to perform complete searches of the prior art. Merges (1999) also suggests that patent examiners face strong incentives to grant patents, and much weaker incentives to deny them, which may also have contributed to the growth of "questionable" patents over the past decades.

Finally, the formation of the CAFC may also have been a contributing factor. Among the doctrinal changes introduced by the CAFC were certain modifications that made the test for non-obviousness weaker, in practice making many more inventions qualify for patentability than previously (Hunt 1999, Lunney 2001).[8] Some evidence on the effects are presented in Lunney (2001), who shows that while before the formation of the CAFC obviousness was a basis for invalidity in 67%-80% of the cases where a patent was found invalid, this proportion dropped after 1982, and in the most recent cohort (1994-5) obviousness served as a basis for invalidity in only 20% of cases that were held invalid.

Though there is fairly strong evidence that there has been a change in the non-obviousness requirement, the effects of this change are less clear. To the extent that it has facilitated the patenting and restricted access to information readily available from the public domain, it could be creating static costs from non-competitive pricing as well as well as more dynamic costs by hindering downstream research. On the other hand, the lowering of the bar could also have increased R&D, at least in industries where patents serve as important inducements to innovative activity. Part of the difficulties of assessing the effects of this change may be illuminated by better theoretical models, but much of the frustration derives from more general problems with measuring innovation and evaluating changes in science and technology policy, discussed above.

Notwithstanding the lack of systematic empirical evidence, most observers do believe that these changes are real and have at least the potential of causing significant harm, especially in industries where innovation is cumulative. Several solutions have been proposed, many of them targeting practices and policies at the USPTO itself, e.g. enacting stricter non-obviousness criterion, requiring inventors to conduct prior art searches, development of new and better prior art databases, increasing resources for examiners, and hiring examiners with more field specific expertise.

In addition, several scholars (e.g. Merges 1999) have suggested that the establishment of a European style post-grant opposition system could help to ameliorate some of the "problems" in the U.S. system. Under opposition systems, third-parties (including competitors) can challenge the validity of a patent after it is issued. If they are able to produce evidence that the patented invention lacks novelty or non-obviousness in light of the prior art, then the European Patent Office will amend or revoke the patent (see Graham et al. 2002, Hall et al., 2003). Thus under such a system, even in the face of limits on patent examiners' field-specific knowledge of the prior art (or access to prior art databases), "low quality" patents can be eliminated ex post.[9]

4.3 Strengthening the Rights of Patentholders and a Reduction in the Non-Obviousness Standard: Reprise

Earlier, I suggested that the boundary between the public and private domains is a choice variable, determined in part by standards of patentability. This section showed that there has been a reduction in the non-obviousness standard as well as a strengthening of the rights of patent holders in the United States, each of which has effectively reduced the size of the public domain.

The most significant impacts of these changes on developing countries, like the changes in patent standards discussed in Section 3, will occur if they negatively affect the rate of creation of knowledge useful to developing countries, either via directly hindering the rate of commercial product development or indirectly via encumbering the process of upstream research.

However, the changes discussed in this section need not have an impact on the diffusion of technology, since even under the new TRIPs rules (see Section 6) developing countries have latitude in determining standards of non-obviousness and strength of patent protection within their own borders. By choosing stringent standards of patentability, they could limit the number of "junk" patents that could impede invention, imitation, and use within their own borders.

Related to this point, and particularly salient in relation to growing concerns about biopiracy and patenting of traditional knowledge (Shiva 1997), developing countries may find it in their interest to develop databases documenting traditional uses of natural resources to (e.g. therapeutic applications of particular plants) to establish them as prior art which would compromise their patentability not only indigenously, but also in developed countries. However, the effectiveness of such a strategy in protecting the public domain remains unclear. Studies of firms which created databases of "defensive publications" for similar reasons may indirectly shed some light on this issue.[10]

5. Recent Changes in Patent Policy and Practice: Patents and Public Research[11]

Yet another change often associated with the privatization of knowledge is the growth of patenting and licensing of publicly funded research, i.e. research funded by the government itself. In large part, this change reflects the effects of the Bayh-Dole Act of 1980, which allowed contractors (initially, only universities, non-profit organizations, and small businesses) to retain title to patents resulting from publicly funded research and to license them on an exclusive basis.

Based on the theory of the patent system developed in Section 2, allowing for patents on publicly funded research is--at least at first glance--peculiar. Patents and Patronage (i.e. public funding of research) were presented as two distinct mechanisms to induce investment in socially useful R&D. Given this, it would seem rather strange for the government to *both* pay for research via taxpayer funds, and then *also* allow for the performers of the research to take out patents. Based on the logic presented above, once the government has funded the research it would be foolish to tolerate the welfare losses resulting from patenting, and more sensible to disseminate the research outputs widely.

Indeed, throughout much of the postwar era, there was considerable opposition to patenting publicly funded research, based on the argument that doing so was unnecessary and would effectively compel the public to pay twice for the same research: first by funding it and second by paying monopoly (or at least non-competitive) prices. This presumption changed with the Bayh-Dole act. The reasons for this shift in government patent policy are discussed in Section 5.1.

The main impact of Bayh-Dole was in its impact on public research organizations, primarily research universities. University research is often thought of as "public knowledge" (Ziman 1968) for several related reasons. A first is that, in the postwar era in the United States, the public sector has been the primary funder of university research. Second, academics and they universities that employ them have traditionally faced strong incentives to get their research outputs into to public domain (Merton 1973, Dasgupta and David 1994). The passage of Bayh-Dole has led to some fears that these norms of "open science" are being compromised, and that traditionally "public knowledge" is increasingly subject to patent protection. On the other hand, some observers believe that the Bayh-Dole act led to a dramatic increase in technology transfer from universities to industry, resulting in large economic benefits and the growth of science-based industries like biotechnology. In Section 5.2, we review what is and what is not known about the impact of Bayh-Dole on university research and technology transfer.

5.1 Patents and Publicly Funded Research: The Bayh-Dole Act

Congress debated the issue of who should retain rights to patents resulting from publicly funded research for decades before the passage of Bayh-Dole, and federal patent policy was a central point of contention during the debates of the 1940s over the organization of postwar U.S. science and technology policy. One side of the debate over patent policy was represented by Senator Harley Kilgore (D-W.Va.), who argued that the federal government should retain title to patents resulting from federally funded research and place them in the public domain (Kevles 1977). According to Kilgore, allowing private contractors to retain patents represented a "giveaway" of the fruits of taxpayer-funded research to large corporations, reinforcing the concentration of technological and economic power. The opposing position was articulated by the Director of the wartime Office of Scientific Research and Development, Vannevar Bush, who argued that allowing contractors to retain patent rights would preserve their incentives to participate in federal R&D projects and to develop commercially useful products based on government-funded research.

The postwar debate highlighted the central issues in controversies over government patent policy for the next three decades. Supporters of the retention of intellectual property rights by government agencies argued that allowing contractors (rather than government agencies) to retain title to patents resulting from federally funded research favored large firms at the expense of small business. Moreover, they asserted, such a policy would harm consumers who would have to pay monopoly prices for the fruits of research they had funded through their taxes. Supporters of allowing contractors to retain title to patents resulting from federally funded research argued that failure to do so would make it difficult to attract qualified firms to perform government research and that absence of title would reduce incentives to invest in commercial development of these inventions.

Another contentious issue in these debates about government patent policy was the desirability of a "uniform" patent policy across all federal agencies. Each of the major federal R&D funding agencies had established its own patent policy following World War II, and the resulting mix of agency-specific policies created ambiguities and uncertainties for contractors and for government employees. Despite numerous congressional hearings on this issue, no legislation was adopted during the 1950-75 period, because of the inability of supporters of opposing positions outlined above to resolve their differences. The legislative deadlock was reinforced by statements on federal agencies' patent policies issued by Presidents Kennedy and Nixon in 1963 and 1971 respectively. Both Presidents' statements asserted that agency-specific differences in patent policy were appropriate, in view of the differences in their missions and R&D programs.

These debates over federal patent policy largely ignored U.S. universities during the 1940s and 1950s. After all, U.S. universities have never accounted for more than one-third of federal R&D spending during the postwar period, and first exceeded 20% of federal R&D funding only in 1978 (a National Science Board 2002). It is interesting, then, that a major impetus for a movement towards a uniform federal patent policy which allowed contractors to retain to publicly funded inventions came from issues facing universities.

It is not widely appreciated that before Bayh-Dole, universities could retain title to patents resulting from federally funded research either via 1) petitioning for title on a case by case basis or 2) Institutional Patent Agreements (IPA) offered by some agencies (including the National Science Foundation and the Department of Health, Education, and Welfare) which allowed institutions blanket rights to any patents resulting from agency funds. Indeed, complaints by universities that the Department of Health, Education, and Welfare was considering curtailing its IPA program in the late 1970s (interestingly, in response to fears that exclusive licenses were contributing to rising healthcare costs) provided the primary impetus for the introduction of Bayh-Dole (Sampat 2002).

In response to these complaints, in 1978 Senator Dole and Senator Birch Bayh (D-Indiana) introduced S. 414, the University and Small Business Patent Act. The Act proposed a uniform federal patent policy that gave universities and small businesses blanket rights to any patents resulting from government-funded research. The bill lacked provisions that were typically included in IPAs, any language expressing a federal preference for non-exclusive licensing agreements.

As we noted earlier, many members of Congress had long opposed any federal grant of ownership of patents to research performers or contractors (Broad, 1979).But Bayh-Dole attracted little opposition. The bill's focus on securing patent rights for only universities and small business weakened the argument (*a la* Kilgore) that such patent-ownership policies would favor big business. The bill's introduction in the midst of debates over U.S. economic competitiveness also proved crucial to its passage. An article in *Science* discussing the debate on the Bayh-Dole bill observed that:

> The critics of such legislation, who in the past have railed about the 'giveaway of public funds' have grown unusually quiet. The reason seems clear. Industrial innovation has become a buzzword in bureaucratic circles … the patent transfer people have latched onto this issue. It's about time, they say, to cut the red tape that saps the incentive to be inventive (Broad 1979, p. 479.)

Considerable testimony and commentary during these hearings focused on lagging U.S. productivity growth and innovativeness, suggesting that government patent policy contributed to these woes. In their opening statements in the Senate Judiciary Committee hearings on the bill, Senators Bayh and Dole each pointed to two problems with federal patent policy as of 1979: the "policy" in fact consisted of more than 20 different agency-specific patent policies; and most federal agencies made it difficult for contractors to retain title to patents.

As was the case with many of the other initiatives during the late 1970s and early 1980s that strengthened or extended patent rights, the evidentiary foundation for the passage of Bayh-Dole was weak. Witnesses supporting the Bayh-Dole argued that when government (rather than contractors) retained title to patents resulting from public funds, commercialization rates were lower. These claims were based on a selective and largely incorrect interpretation of data from the 1968 Harbridge House Report and a 1976 Report of the Federal Council on Science and Technology, as discussed in Eisenberg (1996) and Sampat (2002). In addition to this statistical evidence, witnesses supporting Bayh-Dole also appealed to anecdotal evidence from university administrators that absent intellectual property rights, firms would lack incentives to commercialize "embryonic" inventions developed at universities.

In contrast to the debates about university patenting earlier in the century (Mowery and Sampat 2001), none of the witnesses in these hearings discussed the potential risks created by university patenting and licensing for the "disclosure" and other norms of academic science, nor were any potentially detrimental effects of patenting and licensing for other channels of university-industry technology transfer considered. A journalist covering the hearings observed that "although the Dole-Bayh bill is receiving nearly unprecedented support, some congressional aides point out that it still leaves unanswered fundamental questions about patents in general and patents on university campuses in particular" (Henig, 1979, p. 284).

The Bayh-Dole Act was passed overwhelmingly in both the House and the Senate in the winter of 1980 with minimal floor debate, and President Carter signed the Act into law in December 1980. Bayh-Dole became effective on July 1, 1981, creating a uniform federal patent policy for universities and small businesses that gave them the rights to any patents resulting from grants or contracts funded by any federal agency

Much of the discussion of Bayh-Dole rightly focuses on its impact on universities. The Act's provisions facilitated university patenting and licensing in at least two ways. First, they replaced the web of IPAs and case-by-case petitions with a uniform policy. Second, the Act expressed Congressional support for active university involvement in patenting and licensing, activities which they had traditionally avoided for fears that they would undermine academic commitments to "open science." These effects, and the effect of Bayh-Dole on university-industry technology transfer, are discussed in the following section.

5.2. University Patenting and Patenting "Science"

5.2.1 Patents in Perspective

Though in the Bayh-Dole hearings universities were characterized as "ivory towers" unconcerned with practical applications, in fact American research universities were important economic institutions of the twentieth century. In a range of industries, from agriculture to aircraft to computers to pharmaceuticals, university research and teaching activities have been extremely important for industrial progress. Most economic historians agree that the rise of American technological and economic leadership in the postwar era was based in large part on the strength of the American university system.

The economically important "outputs" of university research have varied over time and across industries. The literature suggests that universities' economic contributions come in a variety of forms. For example:

- Universities create economically useful scientific and technological **information**, which helps increase the efficiency of applied R&D in industry, by guiding research towards more fruitful departures.
- They develop **equipment and instrumentation**, which is used by firms in their production processes or their research.
- Universities provide **skills** or **human capital** to students and faculty members, as well as help create networks of scientific and technological capabilities.
- Universities create **prototypes** for new products and processes.

The outputs of university research are useful not only to industry, but also feed into future academic research. Academic research is a cumulative process that builds upon itself: recall Sir Issac Newton's famous aphorism, "if I have seen further, it is by standing on the shoulders of giants."

The relative importance of the different channels through which these outputs diffuse to (or alternatively, "are transferred to") industry also has varied over industry and time. The channels include, *inter alia*, labor markets (hiring students and faculty), consulting relationships between university faculty and firms, publications, presentations at conferences, informal communications with industrial researchers, formation of firms by faculty members, and licensing of university patents.

This diversity of outputs of university research, and the diversity of channels of university-industry knowledge and technology transfer, are necessary to keep in mind when evaluating the effects of Bayh-Dole. Patents are only part of a much broader picture.

Moreover, they are not the most important part. According to the results of a recent survey of firms in the U.S. manufacturing sector (Cohen, Nelson, and Walsh (2002), firms report that in most industries, the primary channels through which they learn from university research are publications, conferences, and informal information exchange. Patents and licenses rank near the bottom of the list.[12] A recent study by Agrawal and Henderson (2002), focused on two major academic units at the Massachusetts Institute of Technology (MIT), provides corroborating evidence. Faculty members report that a very small fraction of the knowledge transfer from their laboratories to industry (7%) occurs via patenting. Other channels-Agrawal and Henderson focus on publications--are more important.

It is interesting that the most important channels of university-industry knowledge transfer--publications, conferences, and informal information exchange--are those associated with what the sociologist of science Robert Merton has termed the norms of "open science" (Merton, 1973), which create powerful incentives for academics to publish, to present at conferences, and to share information with (academic and non-academic) colleagues (Dasgupta and David, 1994).

Thus in addition to the fact that academic research is largely funded by the public sector, another "public" aspect of research carried out by university scientists is that the norms of open science have traditionally compelled researchers to disseminate outputs quickly and widely into the public domain. Conversely, fears that the growth of patenting and licensing activities might create counter-incentives to keep information secret and to limit disclosure form the basis for another potential source of the "privatization" of public science.

5.2.2 University Patenting Before Bayh-Dole

Indeed, throughout much of the twentieth century, universities were reluctant to become directly involved in patenting and licensing activities precisely because of fears that such involvement might compromise, or might be seen as compromising, their commitments to open science and their institutional missions to advance and disseminate knowledge. Consequently, many universities avoided patenting and licensing activities altogether, and those that did get involved typically out-sourced their patent management operations to third party operations like the Research Corporation, or set up affiliated but legally separate research foundations to administer their patents.

As discussed in more detail in Mowery and Sampat (2001a), the Research Corporation originated from the research of Berkeley chemist Frederick Gardner Cottrell, to administer his patents on the electrostatic precipitator, a pollution control device. Cottrell intended to license his patents and use the proceeds to support scientific research. Implementation of this plan, however, required the development of an organization to manage the licenses. Cottrell first considered using the University of California as a licensing manager, but rejected this possibility because of concern about the effects of licensing on the culture of scientific research at the University. He later recalled:

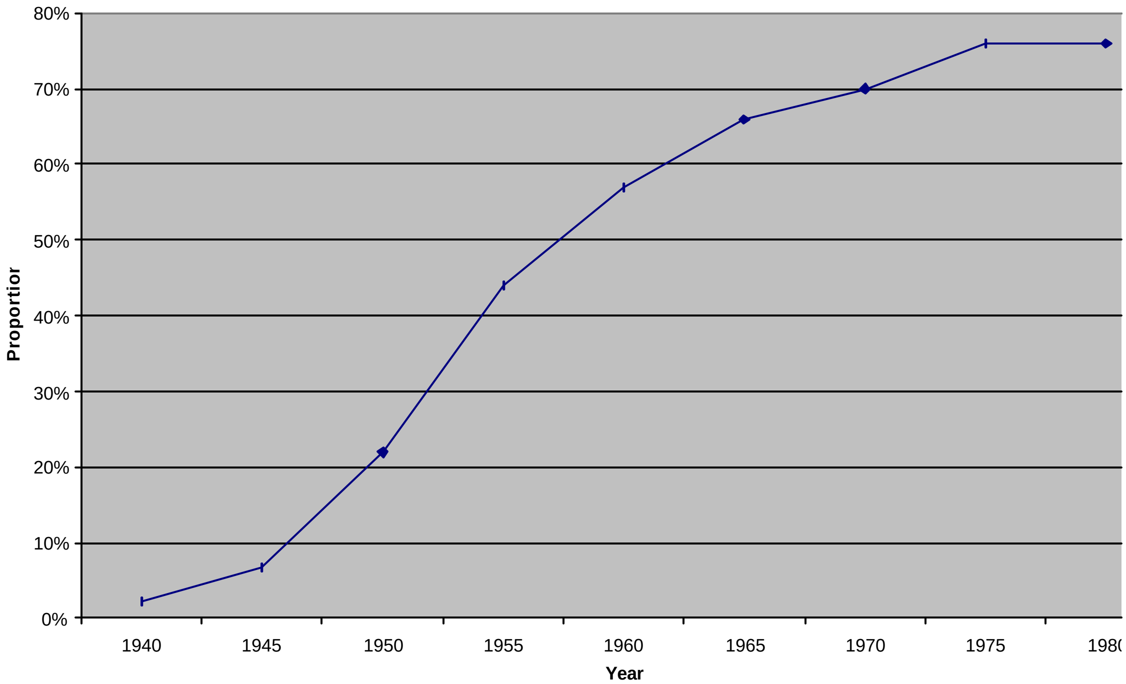
> A danger was involved, especially should the experiment prove highly profitable to the university and lead to a general emulation of the plan. University trustees are continually seeking for funds and in direct proportion to the success of our experiment its repetition might be expected elsewhere . . . the danger this suggested was the possibility of growing commercialism and competition between institutions and an accompanying tendency for secrecy in scientific work. (Cottrell, 1932, p. 222).

Instead, in 1912 he founded a non-profit third party technology transfer agent, the Research Corporation, to administer the precipitation patents. When he founded the Research Corporation, Cottrell also thought that it might also serve a broader purpose, namely to license patents developed by:

> the ever growing number of men in academic positions who evolve useful and patentable inventions from time to time in connection with their regular work and without looking personally for any financial reward would gladly see these further developed for the public good, but are disinclined either to undertake such developments themselves or to place the control in the hands of any private interests (Cottrell, 1912, p. 865).

This vision was fulfilled in 1937, when the Massachusetts Institute of Technology (MIT) signed the first "invention administration agreement" with Research Corporation. Under the terms of the agreement, MIT would disclose to Research Corporation inventions that it deemed potentially patentable. Research Corporation agreed "to use its best efforts to secure patents on inventions so assigned to it and to bring these inventions into use and derive a reasonable income therefrom" and further to "use its best efforts to protect these said inventions from misuse and to take such steps against infringers as [it] may deem for the best interest of the parties hereto, but with the general policy of avoiding litigation wherever practicable." All services were provided at the expense of Research Corporation. Any license income net of expenses were to be divided according to a formula by which MIT split net royalties with Research Corporation on a 60/40 basis. Research Corporation was to use its portion of the earnings to support it grants activities. Over the post-war era, and especially after World War II, universities continued to sign similar invention administration agreements (IAAs) with Research Corporation. This is illustrated in Figure 1, which shows the proportion of Carnegie research universities[13] with such agreements, from 1940-1980.

Figure I: Proportion of Carnegie Research Universities with IAAs with Research Corporation: 1940-1980



While most major universities contracted with the Research Corporation before 1980, some, especially state schools, took another approach, setting up legally separate but affiliated research foundations to manage patents. The first and most prominent of these was WARF, the Wisconsin Alumni Research Foundation, founded by members of the University of Wisconsin in 1924. Steenbock demonstrated a method of increasing the vitamin D content of food and drugs via the process of irradiation. Steenbock, despite the criticism of many in the medical community and his colleagues at the University, wished to patent his findings. In particular, he argued that in this case patenting was necessary for quality control, i.e. to prevent the unsuccessful or even harmful exploitation of the invention by unqualified individuals or firms. He believed that incompetent exploitation of the process, which might discredit the research results and possibly the university, could be avoided by patenting and thus gaining the right to exclude (Apple 1996).

Once the decision to acquire the patent had been made, the question how to administer it remained. Steenbock offered to assign the patent to Wisconsin for management. However, the University was not convinced that creation of an administrative organ to handle patents was worth the necessary political and financial risk (Apple 1996). Thus a different solution was developed. Steenbock convinced several alumni to create the Wisconsin Alumni Research Foundation (WARF), a university affiliated but legally separate foundation that would accept assignment of patents from University faculty, would license these patents, and would return part of the proceeds to the inventor and the University. According to Apple (1996) the idea was that "[w]ith this structure, business matters would not concern or distract the university from its educational mandate; yet academe could reap the rewards from a well-managed patent whose royalties would pay for other scientific work" (42). Over the course of the twentieth century, a number of other institutions established similar foundations.

Via contracting out to the Research Corporation or establishment of WARF like organizations, universities hoped to insulate themselves from the business side of patent activities. While most major universities employed one of these two options in the pre-Bayh-Dole era, there was considerable variance in their formal patent policies, i.e.. faculty disclosure policies and sharing rules. (See Mowery and Sampat 2001b for specifics.) In the postwar era, many universities had "hands off" policies, refusing to take out patents as institutions but allowing faculty members to patent and retain title if they desired. Thus before 1980, Columbia University's policy left patenting up to the inventor and administration up to Research Corporation, stating that "it is not deemed within the sphere of the University's scholarly objectives" to hold patents. Others required faculty members to report inventions to university administration, and still others required faculty disclosure only in cases of sponsored research. Notably, several major universities (including some with "hands off" policies) explicitly forbade the patenting biomedical research, evidently based on the belief that restricting the dissemination of health-related inventions was undesirable. At Harvard, Chicago, Yale, and Johns Hopkins and Columbia, and Chicago, these prohibitions were not dropped until the 1970s.

In the 1970s, university patent policies and procedures began to change under the weight of several forces, described in detail in Mowery et al. (1999), Mowery and Sampat (2001a, 2001b), and Sampat and Nelson (2002). The most important source of these changes was the emergence of commercial applications resulting from the growth of "use oriented" basic research (Stokes, 1997) in fields like molecular biology. This was occurring at the same time as federal and other sources of funds for university research were declining, leading some universities to become increasingly interested in patenting as a source of income. In addition, by the mid-1970s many universities had become frustrated with the Research Corporation's failure to return license revenues under Invention Administration Agreements (Mowery and Sampat, 2001a). This led many institutions to reconsider their patent policies and procedures, and to get more directly involved in patenting and licensing. Thus by the mid-1970s, Research Corporation's *Annual Report* noted that most major institutions were considering setting up internal technology transfer offices (Mowery and Sampat, 2001a).

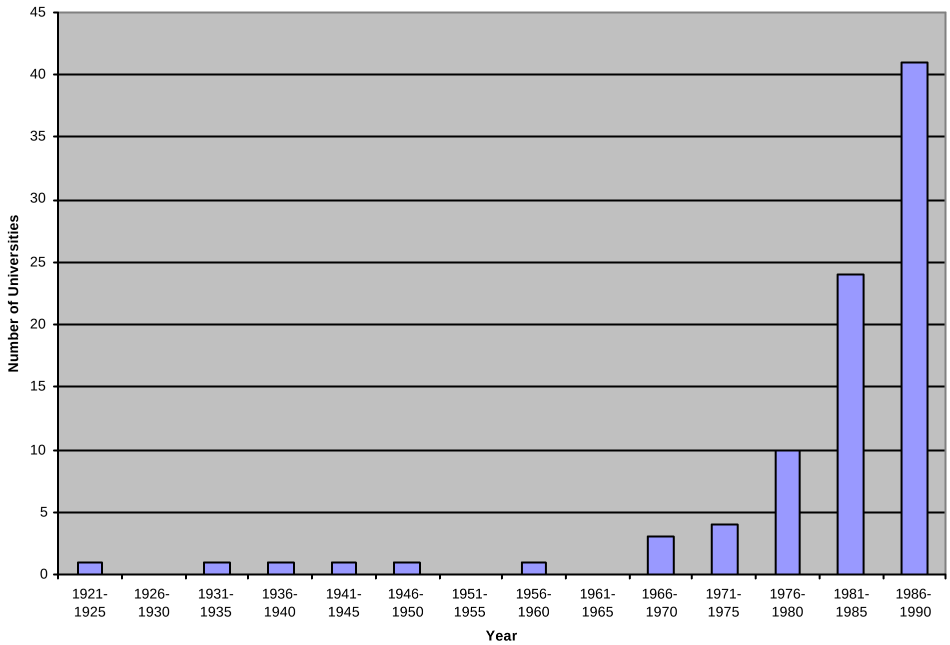
In light of the historical reluctance of universities to become directly involved in patenting and licensing activities, these changes were fairly dramatic. Entry by universities into patenting and licensing activities, which began in the 1970s, was magnified and accelerated by the Bayh-Dole act.

5.2.3 The Effects of Bayh-Dole: Growth of Patenting and Licensing

As suggested above, Bayh-Dole did not legalize anything that was previously illegal. But it did reduce the costs and bureaucratic hurdles universities faced in patenting and the results of publicly funded research, and in licensing these patents exclusively.[14] More importantly, it gave strong Congressional endorsement to the position that direct involvement in patenting and licensing, activities universities had traditionally avoided, was appropriate and indeed enhanced "technology transfer" and social benefits from university research.

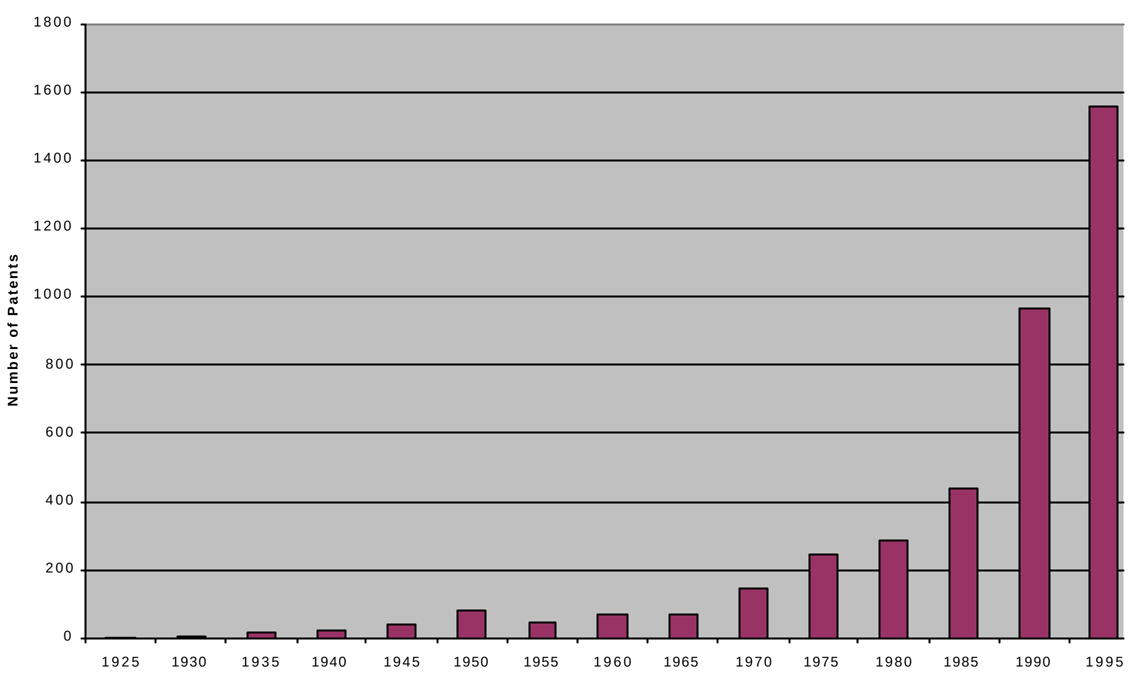
In the wake of Bayh-Dole, universities increasingly became directly involved in patenting and licensing, setting up internal technology transfer offices to manage licensure of university patents. Figure 2 shows the distribution of years of "entry" by universities into patenting and licensing, defined as the year in which the universities first devoted .5 FTE employees to "technology transfer activities" (AUTM, 1998). Consistent with the discussion above, few universities were involved in patenting and licensing early in the century. Entry began during the 1970s, but accelerated after Bayh-Dole.

Figure 2: Year of "Entry" into Technology Transfer Activities



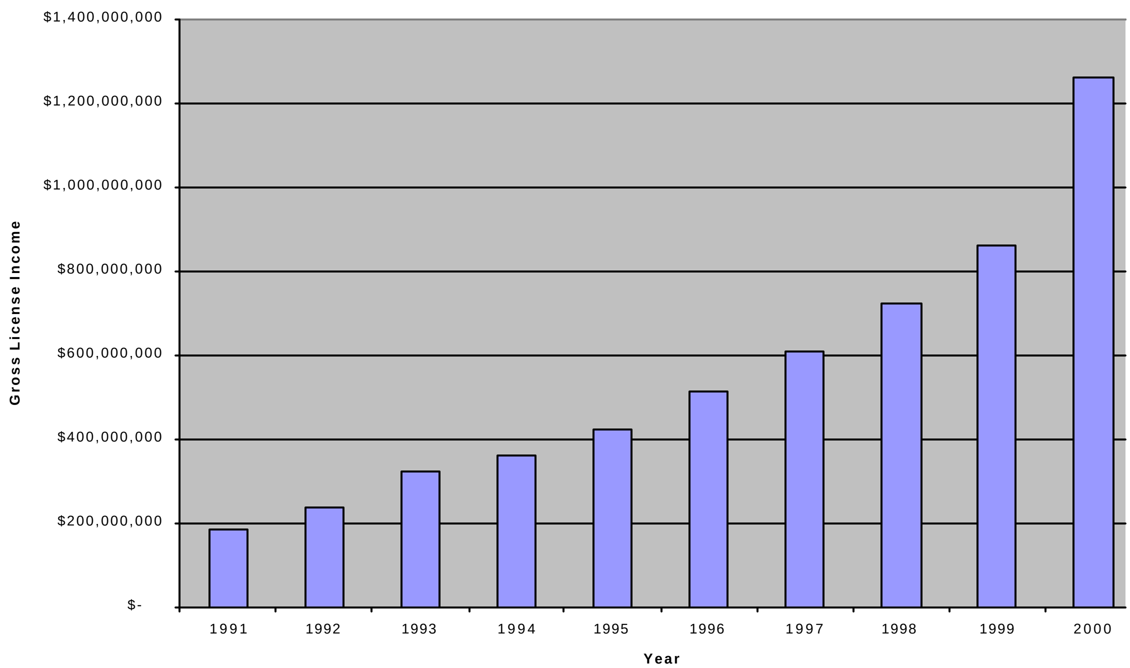
University patenting exhibits a similar trend. Figure 3 shows the total number patents issued to Carnegie research universities over the 1925-1995 period. Here again, growth began during the 1970s, but accelerated after 1980.

Figure 3: Patents Issued to Research Universities, By Year



Time series on license revenues are more difficult to obtain, as they were not systematically collected until the early 1990s. In 1991, according to a survey by the Association of University Technology Managers (AUTM), universities earned nearly $200 million in license revenues, and this figure has increased nearly seven-fold since that time, as seen in Figure 4:

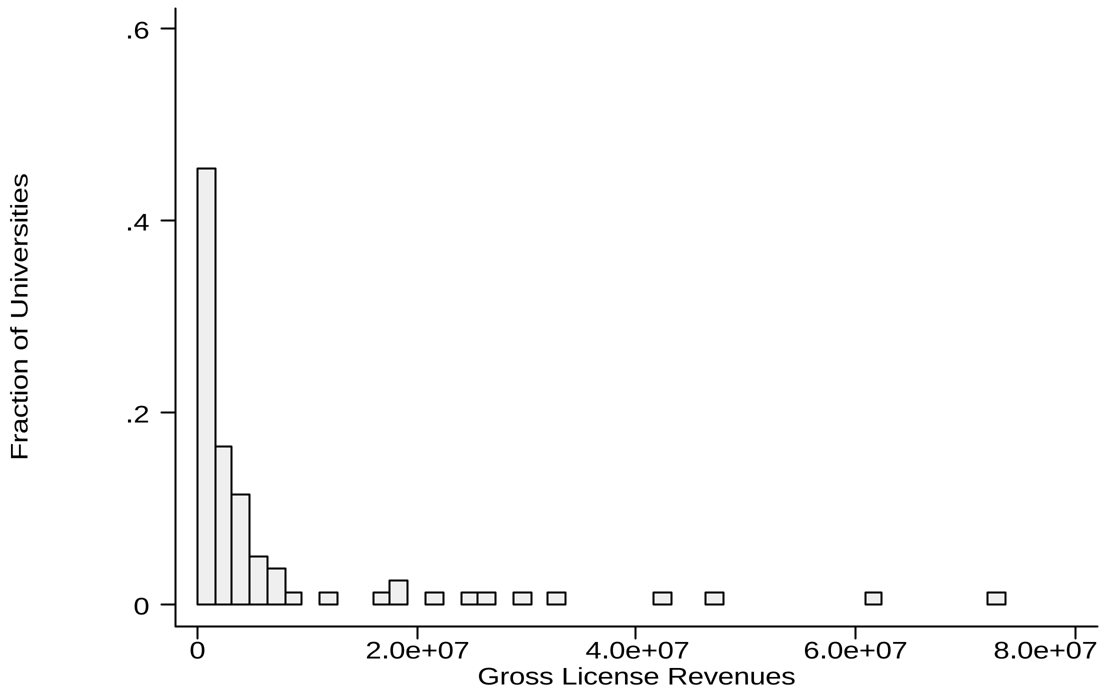
Figure 4: Gross University Licensing Income, 1991-2000
(Source: AUTM 2002)



These trends in license revenues are at least part of the reason that some policymakers and university administrators believe that Bayh-Dole was a success, and form the basis for the widespread movement to emulate Bayh-Dole in other OECD countries (OECD 2002). Yet they should be put in perspective. Overall, license revenues by universities generate less than 5% of all research funds at AUTM universities (AUTM 2002). Note also that this figure was calculated before subtracting the inventors' share of royalty income (typically 30-50%) and before subtracting costs of patent and license management, which can be significant.[15]

In addition, a handful of universities account for the lion's share of licensing revenues. Figure 5 shows the distribution of licensing revenues in 1998 across the Carnegie research universities. Note that few universities are making large revenues: in fact, 10% of these universities account for over 60% of total licensing revenues. Moreover, the numbers in Figures 4 and 5 are gross revenue figures, and do not include costs of patent and license management. It is likely that after taking costs into account, the majority of American research universities are losing money on their patenting and licensing activities (cf. Trune and Goslin 1997).

Figure 5: Distribution of University License Revenues



5.2.4 Social Welfare Effects of Bayh-Dole[16]

Of course, the primary purpose of Bayh-Dole act was not to make universities rich, but rather to promote "technology transfer" of federally funded university inventions. And a number of observers in the United States and abroad have looked to the patenting and licensing trends displayed above (or similar figures) and pronounced Bayh-Dole a resounding success.[17] Implicit in this interpretation is the assumption that the commercialization and development underlying these trends would not have occurred absent Bayh-Dole, or more generally absent university patenting and licensing.

This assumption is bound to be valid in some cases, but certainly not in all. The importance of patents and licensing for development and commercialization of university inventions was not well understood during the Bayh-Dole hearings, and is not well understood today. Universities can patent any inventions developed by their faculty members, and certainly do not limit their patenting to cases where commercialization would go forward even absent patenting and licensing.[18] For example, the Cohen-Boyer recombinant DNA technique was being used by industry even before the University of California and Stanford began to licensure; patenting (and licensing widely) allowed the universities to generate income, but did not facilitate technology transfer. In a recent oral history, Neils Reimers, the manager of the Cohen-Boyer licensing program, made this point explicitly, noting that

> [W]hether we licensed it or not, commercialization of recombinant DNA was going forward. As I mentioned, a nonexclusive licensing program, at its heart, is really a tax ... [b]ut it's always nice to say "technology transfer" (Reimers, 1998).

In this case, technology transfer occurred in spite of, not because of, university patenting and licensing activities. A preliminary estimate suggests that such cases account for at least 15% of cumulative royalty revenues earned by *all* research universities in the post-Bayh-Dole era. Here, the university revenues are "taxes" on industry (to use Reimers' language) and ultimately consumers, rather than indicators of the extent of technology transfer.

In cases such as these, where universities are patenting inventions that would have been utilized or developed even absent intellectual property rights, society suffers the standard losses from non-competitive pricing. Further, restrictive access to university inventions may result in too few sources of further experimentation and development, in a context when multiple, rivalrous development efforts may be more socially desirable (see Merges and Nelson, 1994). The share of these cases and the extent of these costs are unknown: because they involve counterfactuals they are difficult to identify and measure. But a proper evaluation of the welfare effects of Bayh-Dole would have to take these costs into account.

Such an evaluation would require additional empirical evidence on a number of other fronts, as well. As discussed above, universities contribute to technical change in industry and economic growth through a number of channels. An extremely important issue that we know little about is whether and how universities' increased patenting and licensing activities are affecting these other channels. Given that publication, conferences, and informal information exchange are important channels of university-industry knowledge and technology transfer--and universities historically have avoided direct involvement in patenting and licensing precisely because of fears that these activities might adversely affect the operation of these channels associated with "open science"--any assessment of Bayh-Dole that fails to mention these potential effects is necessarily incomplete. Several preliminary projects by the present author attempt to assess this issue-one using data on the "science" base of university patents before and after Bayh-Dole, and another on information from university invention disclosures on the relationship between patenting, publishing, and presentation--but much more work remains to be done on this front.

A related concern is that universities are increasingly patenting inputs into academic research, rather than technologies, and that restrictive licensing of "research tools" may be creating friction in the process of academic research itself. That is, universities may increasingly be both victims of and culprits in the "tragedy of the anticommons" discussed in Section 2 above. This is another potential dimension that needs to be considered before one can make a judgment about whether the net effect of Bayh-Dole, and increased university patenting and licensing more generally, has been positive or negative.

5.3 Patents and Public Research: Reprise

Many of the concerns about the effects of increased patenting and licensing of "public" research in developed countries on developing countries has been focused on the impact of these activities on prices of therapeutics developed based on publicly funded research. Specifically, some observers have argued that university patenting has contributed to high costs of "essential therapies" like HIV treatments, making them unaffordable in many countries where they are most needed. However, there is little evidence of this, and economic theory suggests that under plausible assumptions university patents would have only negligible effects on final drug prices (Thursby and Thursby 2002). Moreover, if these therapies would not have been commercialized absent the university patents and exclusive licenses-the theory underlying Bayh-Dole-this concern is moot. However, I argued above that there is little evidence on the importance of patents and licenses for commercialization of publicly funded inventions, and more research is needed on this front.

More vital are the concerns that these activities could actually hinder the process of research itself as well as development of products based on publicly funded research: the tragedy of the anti-commons scenario. This is a legitimate source of concern. Given that the private sector devotes little attention to most applications that have only a developing country market (Kremer 1999), it is important to ensure that public sector efforts in this area are not hampered by excessive patenting. Historically, public sector efforts (together with those philanthropic foundations) have led the way in developing and diffusing technologies aimed at meeting developing countries' needs: consider the Green Revolution. In the current environment, excessive emphasis on patents by universities and publicly funded researchers threatens to reduce the productivity of such investments by increasing transaction costs. It is particularly disconcerting that, at least based on anecdotal evidence, these "problems" are apparently most prevalent in biotechnology, a field which may offer unprecedented opportunities for meeting the medical and agricultural needs of developing countries.

Clearly, before we can knowledgably discuss solutions to such problems, more research needs to be done on their extent and nature. However, note that simply addressing some of the broader concerns discussed in previous sections, in particular retarding the growth of "non-obvious" patents in the United States, could go a long way towards reducing the negative impacts of increased patenting of "public" research on developing and developed countries alike.

Finally, note that despite only limited evidence of its "success," there is currently a widespread movement to emulate Bayh-Dole in other OECD countries (OECD 2002). If the history of diffusion of science and technology policies is any guide, this movement will also soon spread to developing countries themselves. For example, there is currently a movement to mimic Bayh-Dole in South Africa, in an attempt to improve the "entrepreneurial" nature of that nation's universities. Such pressures should be avoided. Universities and other "public" research organizations are society's most effective vehicles of disseminating new knowledge broadly: this is their comparative advantage. In developing countries, policies like the Morrill Act of 1890--which created incentives for U.S. universities to create and diffuse knowledge targeted at local agricultural and industrial needs-would yield far greater social returns than Bayh-Dole type legislation.

6. Recent Changes in Patent Policy and Practice: TRIPS

The changes discussed in Sections 3-5 focused on patent policy and practice in developed countries, in particular the United States. While some of these changes could affect developing countries directly (e.g. by making it more difficult for public agencies to sponsor technology development efforts specific to the needs of developing countries; see immediately above), the main effects are more likely to be indirect. In particular, if these changes to U.S. patent policy and practice encourage the creation of knowledge and information that would be useful to developing countries, the latter could benefit. Conversely, if they hinder rates of innovation in developed countries, in the long run these changes could harm developing and developed countries alike. As suggested above, much more research needs to be done on these changes before we can predict the effects with confidence.

One direct effect of the recent changes in U.S. patent policy and practice could occur if developing countries attempted to, or were required to, emulate them. There is some concern that similar changes will be forced onto developing countries under the auspices of the Trade Related Intellectual Property Rights (TRIPs) agreement signed as a pre-condition to entry into the World Trade Organization (WTO). And even if the specific changes discussed above are not adopted by developing countries, most observers believe that TRIPs will lead to a "strengthening" of patent rights in developing countries, including the expansion of the level, scope, and duration of patent protection afforded to both domestic and foreign innovators.

Historically most "underdeveloped" nations have developed by assimilating and/or adapting technologies created in developed countries, which were typically available publicly. Increasingly, in the post-TRIPs era, developing countries will increasingly have to pay for these frontier technologies or may be excluded from using them. Thus TRIPs too has been indicted as part of the growing trend towards privatization of public knowledge.

The following sections review what is known about TRIPs, and discuss its implications for knowledge flows and development. Section 6.1 provides some historical and empirical background on the effects of patents on technological learning and economic development. Section 6.2 discusses the TRIPs agreement and assesses its potential costs and benefits.

6.1 Patents and Development: Background

Assessing the impact of TRIPs on knowledge flows to developing countries requires first an understanding of the effects of patent policy, and in particular "stronger" patent systems, on economic development. In Section 2, I suggested that it is difficult to say anything concrete about the effects of patents on innovation and learning in developed countries. It may not be surprising that the effects in a developing country context are also not well understood: there the data constraints are even more binding.

However, several empirical and historical studies have addressed this issue, and are reviewed immediately below.

6.1.1 Empirical Studies

Several recent "macro" level studies have examined the the effects of patent protection on growth rates. For example, Gould and Gruben (1996), using a sample of 79 countries find that their index of the "strength" of patent protection is not significantly related to growth rates, after controlling for other intervening variables. However, Gould and Gruben do find a positive and statistically significant effect of intellectual property protection on growth in open economies, suggesting that intellectual property regimes interact with other elements of the economy and "innovation system" in affecting growth (cf. Dahlman and Nelson 1995). However, such studies are confounded by the fact that levels of development and GDP may simulataneously affect intellectual property regimes. Thus the theoretical literature on patents and development suggests that the relationship between patent strength and levels of development should have an inverted U-shaped relationship: countries will adopt strong patents at very low and high levels of development, but weak patents at intermediate stages, where countries can benefit the most from imitation and copying (Chin and Grossman 1990). Empirical results from Maskus and Penubarti (1997) support this hypothesis, though much more work on this front is necessary.

In addition to these studies conducted at a relatively high level of abstraction, several scholars have also examined whether and how patents affect the different channels of "inward" technology transfer discussed in Paper 1, including international trade, foreign direct investment, and technology licensing. A brief and selected review of these studies follows; Maskus (2000) offers a more detailed overview.

The existence of patents or the strength of patent rights in developing countries could affect trade based technology transfer primarily via affecting the decisions of developed country firms to export to a developed country. Specifically, firms may be less willing to export to countries with weak patent protection for fears that firms in the importing nations will imitate the inventions and cut into their profits. Thus Maskus and Penubarti (1995, 1997) find that the strength of intellectual property protection in a developing country has a statistically significant effect on the volume of exports to that country in many industries, and this effect is particularly strong in "patent sensitive" industries like pharmaceuticals. Smith (1999) finds broadly similar results, namely that the strength of patents in a developing nation affects its volume of imports. However, she finds that this effect is accounted for mainly by developing countries with strong absorptive capacity, i.e. that in countries with no ability to imitate developed countries' inventions, the volume of imports is not related to the existence or strength of patents. These results suggest that different aspects of the national innovation system-here patent policies and policies/institutions affecting a nation's "absorptive capacity"-interact to affect knowledge flows.

Another channel of technology transfer is foreign direct investment (FDI), where firms from developed countries invest in production facilities in developing countries. The seminal paper on patents and FDI is Mansfield (1994), who surveyed 100 U.S. firms about whether the strength of intellectual property rights in a country matter in their decisions to engage in FDI there. In most industries, 48% or more of the respondents answered that their FDI decisions do depend on the level of intellectual property rights protection, with the highest proportion of affirmative responses in pharmaceuticals and chemicals.

However, the empirical literature examining the relationships between the strength of patent protection (or intellectual property protection more generally) on the actual level of FDI flows is mixed, as Correa's (2000) review shows. Partly, this reflects the fact that the determinants of FDI flows reflect a range of country-specific factors that are difficult to measure. In addition, as Maskus (2000) suggests, this issue is complicated by the fact that developed country firms may view FDI and technology licensing as alternative measures of transferring technology to developing countries. With licensing, firms in a developed countries can allow those in developing countries to use a technology. For a variety of reasons, licensing is often more efficient in the presence of strong patent rights (see e.g. Arora 1995). Paradoxically, this may mean that if patent rights are weakened, firms will choose to produce directly in developing countries via FDI rather than license to a developing country firm: weaker patent rights could thus induce more flows of FDI.

6.1.2 Historical Studies of Patents and Development

Overall, the results of empirical studies of the effects of stronger patents on growth, development, and different channels of technology transfer provide little guidance on thinking about the probable effects of TRIPs. Historical studies of the roles of patents in the process of development also do not provide definite conclusions, but it is interesting that almost every historical study of patents and development suggests that most countries that have closed the gap between local technological competencies and the world technological frontier have done so via copying and imitation, and with relatively weak patent systems, and in particular little respect for the intellectual property rights of innovators from developed countries.

Most of the historical literature on patents and development examines countries that are currently developed, and attempts to assess whether and how their patent systems contributed to their development. For example, Khan (2002) examines patent rights in the United States, France, Great Britain, and Germany while they were developing. She shows that each of these countries occasionally strengthened or weakened the strength of intellectual property rights in accordance with their national needs and interests. This provides prima facie evidence that the developed countries push towards a strong "harmonization" of intellectual property rights is, if not harmful, at the very least hypocritical. She shows that several of these countries at some point in time excluded certain types of inventions from patentability, e.g. France had prohibitions on medical patenting, Britain on chemical products patenting, and Germany on patents for food products, pharmaceuticals, and chemical compounds. Thus is particularly interesting insofar as a major force underlying developed countries advocacy of TRIPs was to ensure patentability in all fields, as discussed below. Based on her historical surveys, Khan concludes of the current TRIPs induced harmonization:

> For many of today's developing countries, intellectual property harmonization has meant the exogenous introduction of rules and standards that may be ill-suited to their particular circumstances. In direct contrast, the major lesson that one derives from the economic history of Europe and America is that intellectual property institutions best promoted the progress of science and arts when they evolved in tandem with other institutions and in accordance with the needs and interests o social and economic development in each nation" (10).

In a useful overview of the roles of patents in more recent development experiences, Nagesh Kumar (2002) examines the roles that patents played-and did not play-in the development of the 4 East Asian Tigers: Taiwan, South Korea, Hong Kong, and Singapore. The interesting thing about these countries is that each rapidly closed the gap between their own technological capabilities and the world technological frontier, perhaps more rapidly than any other countries in the history of the world.

Much of the technological development in each of these nations was based on adopting, adapting, and assimilating technology that was already being used in the developed world. Surveying these experiences, Kumar concludes that "the soft intellectual property regimes" in these countries were important to their success. Similar conclusions have been reached by other scholars who have studied the development of these East Asian nations, including Frischtak (1989). Indeed, Evenson (1999) writing during the TRIPs negotiations suggested that the push (by developed countries) for stronger intellectual property rights (in developed countries) was in large part a response to the success of countries like these, noting that:

> "to see that this battle over IPRs has some bearing on the general process of development, one need only note that the U.S. Department of Commerce's list of pirating nations is almost exactly the list of countries that most economists would consider as having made significant progress in economic development over the past thirty or forty years" (325)

Thus these historical accounts suggest that countries can and have developed with relatively weak patent protection, an important point to keep in mind in assessing the likely affects of TRIPs.

6.2. Causes and Consequences of TRIPS

6.2.1 A Brief Political History

The political history of TRIPs has been covered at length elsewhere, including Watal (2000), Yusuf (2000), Stewart (1993), and Evans (1994). As such, I provide only a brief sketch, following the excellent account in Watal (2000).

One of the factors that led to the introduction of TRIPs into the negotiations on the GATT (General Agreement on Tariffs and Trade) was concern by developed countries that global intellectual property rights were in danger of being weakened as a result of lobbying by developing country coalitions before the WIPO (World Intellectual Property Organization), the United Nations' organization charged with administering international intellectual property rights treaties including the Paris Convention (on industrial property, including patents) and the Berne convention (on copyright).

In part to fend off these threats-but also reflecting the increased ability of newly industrializing countries to compete on global markets, concerns about the about the loss of American technological leadership, and a perceived weakness of dispute settlement mechanisms under WIPO-various business groups lobbied for the introduction of minimum intellectual property standards into the Uruguay Round of the GATT negotiations. Perhaps not surprisingly, representatives from the pharmaceutical industry were particularly insistent on introduction of strong standards in developing countries, and extension of patents to all technological fields. Before TRIPs, most developing countries restricted patenting on pharmaceutical products (Siebeck et al. 1990).

GATT is a multilateral trading agreement which aims to set ground rules for free trade and non-discriminatory trade between nations. Intellectual property rights were introduced as "trade related" issues because, it was claimed, weak intellectual property standards could distort international trade flows. In addition, developed countries may also have found the GATT an attractive mechanism to governing international intellectual property rights because of various advantages it offered relative to prior intellectual property treaties, including that it had an effective dispute settlement mechanism and, because it was linked to trade, a credible means of punishment for nations that violated the terms of the agreement. During the negotiations, developed country representatives also argued that stronger intellectual property rights would help spur technology transfer and economic development (Lanjouw 1998), despite relatively weak empirical/historical support for this claim.

Under the TRIPs agreement, minimum standards of intellectual property rights are "harmonized" across nations, with the new minimum standards much closer to the previous intellectual property standards in developed countries than those in developing countries (see below). The reasons why developing countries agreed to TRIPs-which strengthens minimum standards of intellectual property protection are complicated, and a full review is beyond the scope of this paper. They include, *inter alia*, the fact that some developing countries had grown frustrated with bilateral action on intellectual property issues from the United States, some had already begun to strengthen their intellectual property regimes as a result of these bilateral actions, and that developing countries had much to gain from the GATT generally via increased access to developed countries' markets, and were willing to make certain concessions on intellectual property issues. In addition, Watal (2000) suggests that for a range of reasons, developed countries were more united in their support for higher intellectual property standards than developing countries were in opposition to these changes, characterizing the negotiations that led to the passage of TRIPs as as "the relatively united assault by the North against the largely weak and divided South" (98).

6.2.2 TRIPs mandated changes in developing countries' patent laws

TRIPS was signed in 1994, and became effective in 1995. It is widely seen as having strengthened global intellectual property rights, and patent rights in particular. One of the basic principles of TRIPs is so-called "national treatment," or the requirement that nations provide equal treatment under their intellectual property laws to foreigners as they do to domestic rights holders. This limits countries' abilities to freely imitate foreign inventions but still create patent based incentives for indigenous innovations, as many nations (including presently "developed" nations) had done in the past (Kumar 2002; Khan 2002).

Beyond this, TRIPs does not impose strict harmonization, but rather a set of minimum standards on intellectual property rights that countries must adhere to, as a precondition for membership to the WTO. Moreover, I will argue below, it includes considerable leeway in patent eligibility and standards for patentability-and thus the strength of a nation's patent system--a point often overlooked by its critics.

The specific changes imposed by TRIPs are reviewed in detail in a number of sources, including Correa (1998) and Maskus (2000). Here I simply provide a brief (and selected) overview, discussing the TRIPs requirements on patentable subject matter, patent standards, and the rights afforded to patentees.

As suggested above, one of the reasons the developed countries pushed for inclusion of

TRIPs into the WTO was frustration with developing countries' limitations on granting patents in some fields, in particular pharmaceuticals. Perhaps the most important feature of TRIPs is the imposition of a broad requirement of patentability. Article 27.1 states that "patents shall be available for any inventions, whether products or processes, in all fields of technology". As Correa (2000) points out, before the Uruguay Round more than 50 countries excluded patent protection in at least one field. Moreover, as discussed above, many of today's developed countries limited patentability in some fields while they were developing. In some cases, e.g. India's limitation on product patents in pharmaceuticals, such limitations have arguably stimulated learning and innovation by domestic industry (see Lanjouw 1997).

Thus, at least at first glance, the expansive definition for patentable subject matter required by Article 27.1 is a dramatic change. However, subsequent sections of the TRIPS agreement allow countries to exclude certain types of patents in special cases. Article 27.2 allows countries to exclude from patentability inventions that would threaten the public interest[19] or morality, so long as these inventions are not allowed for distribution and/OR sale in the country. This exclusion obviously affords countries considerable flexibility, though this exception could not be used to restrict patentability *carte blanche* in particular sectors (e.g. pharmaceuticals), unless products from these sectors were not offered for sale in the country.

In addition, Article 27.3 allows countries to exclude from patentability "diagnostic, therapeutic, and surgical methods for the treatment of humans and animals" as well as "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes." The exact interpretation of what is and what is not excludable by these criteria is open to debates, but many observers believe this ambiguity provides some opportunity for countries to tailor their fine-tune their patent systems to local needs and requirements (Correa 2000, Watal 1999, Maskus 2000).

Moreover, as Correa (2000) indicates, though TRIPs requires patentability of all types of inventions (subject to the exceptions above), it also leaves open the definition of what an "invention" is. As discussed in Section 3 of this paper, several judicial decisions in the 1980s as well as creative claim drafting by attorneys have recently expanded the realm of patentability in the United States to new areas, including genetically engineered organisms and software. However, it appears that under TRIPs developing countries may be able to exclude "products of nature" and "algorithms" from patentability on the basis that these are not "inventions"-which would be consistent with legal doctrine in the United States and many other developed countries before 1980. More legal scholarship on this front is needed to explore such options.

Article 27.1 of TRIPs also lays out the criteria for patentability of an invention, including (essentially) that inventions be novel, useful, and non-obvious.[20] However, these standards are not defined in detail, and as the review of the evolution of these standards in the United States (above) makes clear, they are subject to interpretative flexibility.

One area where TRIPs rules unambiguously strengthen patent protection is the imposition of a minimum standard of patent length of 20 years from the date of filing. This patent length exceeds even that of most developed countries before TRIPS, including the United States. However, even here developing countries are not without options, as they can affect "average" patent length indirectly via their fee and patent fee structures.

Most observers believe that TRIPs represents an unequivocal "strengthening" of intellectual rights in developing countries. But, as the discussion above suggests, developing countries have a number of alternatives which could limit the degree to which intellectual property rights are strengthened, including their legal definitions of "inventions" and interpretations of the novelty, utility, and non-obviousness requirements. In particular, developing countries need to be careful not to mimic recent changes strengthening patents in the United States and other developed countries, as the effects of these changes remain unclear at best.[21]

However, it is almost certainly true that under TRIPs the rights of patent holders will be strengthened relative to the status quo ante, especially in fields like pharmaceuticals where developing countries now have to grant patents. In the next section, I discuss the theoretical and empirical literature on the effects of those changes.

6.2.3 The Effects of TRIPs on Developing Countries: Some Theory and Evidence

Given the relatively short period of time since the TRIPs mandated changes in patent law took effect-in many developing countries they will not be fully instituted for some time-any empirical evidence on the effects of TRIPs must be taken as preliminary. It is just too soon to tell. Nevertheless, several recent exercises have attempted to assess the effects on innovation, and are reviewed below.

A first effect of TRIPs could be on indigenous innovation in developing countries: stronger patents, by allowing potential domestic innovators to appropriate a higher share of the social returns from their R&D, could increase incentives for R&D and ultimately increase the rate of innovation. Unfortunately, the review in Section 2 of the evidence on patents and innovation in a developed country context made clear, the evidence that patents stimulate R&D and innovation is weak. Having said that, in industries where patents *are* important appropriability mechanisms, such as pharmaceuticals, stronger patents may indeed stimulate indigenous innovation in developing countries. However, whether they do so will be mediated by a range of other aspects of the innovation system: even in industries where they are necessary, stronger patents are unlikely to be sufficient to stimulate indigenous innovation. In particular, the various components of social absorption capability discussed in Dahlman and Nelson (1995) are also required.

A second effect of TRIPs on the technological capabilities of developing countries could occur if stronger patents stimulated formal "technology transfer" via traditional channels, e.g. trade, FDI, and licensing. Here, too, the empirical results reviewed above did not point in a clear direction: there is no consensus on whether or how patents affect these channels of technology transfer. What is clear, however, is that the effects are likely to be mediated by other institutions, including again the "absorptive capacity" of the potential recipients.

Thus there is little strong evidence that stronger patents induced by TRIPs will induce greater indigenous innovation in developing countries or greater technology transfer to these countries. In fact, claims that TRIPs will have these effects (typically by representatives of developed countries) smack of paternalism, neglecting the fact that absent TRIPs developing countries could have instituted stronger patent regimes if they thought these changes were beneficial.

At the same time, there are many concerns that TRIPs will make inward "technology transfer" via informal channels, e.g. reverse engineering and copying, more costly for developing countries by limiting imitation. These concerns are particularly worrisome in light of the strong evidence from the historical literature that in many currently "developed" countries, imitation was key to closing the gap between domestic capabilities and the international technological frontier. Note however, that this concern is only valid with respect to the handful of developing countries that indeed have the capabilities to imitate and assimilate developed countries' knowledge-absent the various components of "absorptive capacity" these knowledge flows would not have occurred even in the absence of TRIPs.

A related concern is that allowing developed country firms to retain monopolies on knowledge that was previously imitated will restrict access to and increase the costs of products embodying these technologies. This fear has been most pronounced in the context of pharmaceutical technologies. (Recall that prior to the 1990s, many developing countries did not allow for patents on pharmaceutical products.) Several studies (Watal 1999, 2000) have suggested that these changes will indeed increase costs of drugs in developing countries. But here again, the effect will be felt most dramatically in countries that have indigenous imitative and productive capability. Elsewhere, domestic sources would not have been able to supply the pharmaceutical products in the first place.[22]

In pharmaceuticals and other industries, at least in the short run, the effects of TRIPs do appear to be a transfer of rents from consumers and firms in developing countries to those in developed countries. This conclusion is also supported by the theoretical literature: see Panagariya (1999) for a review. However, the extent of these transfers likely will vary by industry, being largest in industries where patents are difficult to invent around, like pharmaceuticals and chemicals. And again, they also depend on particular countries' broader innovation systems: in countries where there is little ability to imitate and assimilate in the first place, one cannot attribute difficulties in "technology transfer" to TRIPs alone.

6.2.4 "Appropriate (v.) Technology" or "Appropriate (adj.) Technology"? The Potential Impact of TRIPS on Stimulating R&D for Neglected Diseases

Another less widely appreciated potential benefit from TRIPs could be via its affects on the incentives of *developed country* firms. That is, instead of simply allowing firms in developed countries to appropriate technologies that were formally available to developing countries via the public domain, stronger patent rights may create incentives for developed country firms to engage in R&D relevant to the problems of developing countries, i.e. invest in R&D on appropriate technologies from the developing countries' perspectives.

These effects would naturally be strongest in industries where patents are important inducements to R&D, and thus it may not be surprising that much of the discussion about this "indirect" effect of TRIPs has focused on the pharmaceuticals sector, and on whether post-TRIPs changes in patent laws will help to stimulate R&D for neglected diseases. Developing countries' demands for pharmaceuticals may differ from developed countries' demands for several reasons, including lower incomes, different demographics, and generally poor health delivery infrastructures (Lanjouw 1997).

In addition to these factors, the global burden of many diseases is concentrated heavily in developing countries, e.g. malaria, chagas, bilharzias, river blindness, dengue, and worms. Lanjouw (1997), Lanjouw and Cockburn (2001) and Lanjouw (2002) argue that absent patent protection in developing countries, there will be little incentive for firms in developed countries to invest in R&D for such technologies. Compare this to the case of diseases which are prevalent in both developing countries and developed countries. For such "global diseases" (Lanjouw 2002), profits from (typically patent protected) developed country markets may be sufficient to induce firms to undertake R&D, even absent patent protection and the possibility of profits in developing countries. In such cases, TRIPs would simply make diffusion of these products more costly.

However, for diseases and conditions that do not have markets in developed countries, TRIPs may also have an important effect on creation incentives. Lanjouw and Cockburn (2001) find some evidence that after it became clear that something like TRIPs would take effect, there was an increase in allocation of research to products specific to developing countries, though the authors caution that this evidence is preliminary. Assessment of the effects of TRIPs on stimulating R&D for neglected diseases is difficult because a range of factors confound this relationship (see Lanjouw and Cockburn 2001 for a nuanced discussion), and in any case may not be possible until a sufficiently long period of time has elapsed for the effects of these policies changes to be seen.

Recent scholarship suggests that patent based incentives for stimulating R&D for diseases specific to developing countries may be inefficient relative to other mechanisms, e.g. vaccine purchase commitments (see e.g. Kremer 2000). Others have noted that for many years, philanthropic foundations, international agencies, and governments have subsidized R&D on problems specific to developing countries (Panagriya 1999) and question why public and quasi-public funding-rather than patent based incentives--cannot be used to stimulate R&D for neglected diseases today. This is a valid question, though it is worth noting that the trends towards encouraging patents on publicly funded research is spreading broadly among OECD countries, as noted above, and in the next decades we will almost surely see a movement towards emulation of Bayh-Dole type initiatives in developing countries. As such, and in contrast to a previous era, it is no longer safe to assume that publicly funded research either in developed or developing countries will be disseminated freely-if current trends continue it will increasingly result in patents, absent explicit requirements to the contrary by research funders.

6.3 TRIPS: Reprise

Of the array of changes in patent policy in practice over the past two decades, the TRIPS mandated changes in developing country patent policies will have the most direct effects on learning and innovation in developing countries. The discussion above highlights four distinct ways in which TRIPs could affect developing countries: via affecting the rate of innovation in developing countries, the rate of diffusion of new knowledge from developing countries to developed countries, and the rate of creation of knowledge in developed countries targeted to the needs of developing countries.

In Section 2, we observed that the evidence that patents promote innovation, even in a developed country context, is weak. At best, we know that patents are important in some industries, and less important in others. Machlup's statement that for countries that do not have a patent system it would be "irresponsible" to recommend instituting one was as true in the 1990s as it was in the 1950s: there was no evidentiary basis for the claim that TRIPs induced stronger patent protection in developing countries will promote indigenous innovation. Nevertheless, the genie is out of the bottle, and the challenge for developing countries is to develop patent systems that balance incentives for indigenous knowledge creation while at the same time do not hamper diffusion. We suggested above that developing countries have considerable latitude in choosing standards of patentability and thus how they draw the lines between what is public and what is private. They should do so not based on developed country patent doctrines-which have probably gone too far in restricting the public domain-but rather in view of their own social and economic circumstances. Developing countries can and should seize the opportunity to take the lead in creating patent systems that strike a proper balance between creation and diffusion incentives, rather than mimicking developed country patent standards.

The choice of standards of patentability will also determine the degree to which developing countries are able to imitate developed country technologies. Under TRIPs, they cannot exclude from patentability entire sectors, as many countries (including currently developed countries) did in the past. However, stringent requirements for patentability could protect their ability to freely use and apply knowledge that has historically been in the public domain, limiting the degree of monopoly power afforded to developed country firms. Similarly, developing countries can take the lead on codifying and developing databases of non-patent prior art, including "traditional knowledge", to preclude patenting of information already in the public domain. Finally, introducing rigid patent fee structures could also effectively limit the length of monopoly power granted to developed country innovators.

However, there is a risk in going too far in weakening patent protection in developing countries, since in some industries the strength of patent protection may be an important facilitator of other channels of technology transfer, namely international trade and FDI (though the evidence on this is mixed). More importantly, in certain industries-particularly pharmaceuticals--strong patent protection may be necessary to stimulate developed country research in areas critical to developing countries. This remains an open empirical question.

Finally, it is crucial to bear in mind that many of the negative effects of TRIPS will only be felt in developing countries that already have indigenous innovative capabilities. Those that do not-and this is likely the majority of developing countries-would be better served by focusing on policies to strengthen their innovation systems and their social absorptive capability, rather than being pre-occupied by the potential negative effects of TRIPs.

7. Conclusions

As the preceding sections made clear, there appears to have been a dramatic shift in the boundaries between the public and private domains in science and technology over the past two decades. This shift is not the result of any one policy change, but rather reflects the complex and sometimes subtle interaction of the range of changes in patent policy and practice discussed above. Though virtually none of these changes was based on clear evidence that they would promote innovation and/or learning in developed or developing countries, the net effects of these changes on developing countries is unclear, reflecting both data constraints and lack of targeted empirical research on these issues. As such, in this section I present recommendations for future data collection efforts and empirical research using existing data that would help to illuminate these issues.

Much of the difficulty in assessing the effects of these changes in patent policy and practice reflects lack of reliable data on the innovative and learning activities of firms in developing countries. For example, as Lanjouw and Cockburn (2000) found, it is difficult to examine how TRIPs mandated changes are affecting indigenous innovative efforts without reliable indigenous R&D data. More generally, firm level R&D surveys aimed at collecting internationally comparable indicators would help benchmark the technological capabilities and activities of developing countries, allowing for a better assessment of what types of policies and institutions facilitate innovation and learning. Such surveys could also be designed to gather information on the relative importance of different channels of inward technology transfer (cf. Cohen et al. 2000), which would provide a more nuanced picture of how important the recent changes in patent policy and practice are likely to be, and how this varies across firms and technological fields. There are several good models for such surveys of R&D Activities in developed countries (e.g. the NSF R&D Expenditure Survey) that could be adapted to a developing country context. Though administration of such surveys is expensive, they would be invaluable for purposes of policy evaluation and design, and likely would yield high social returns over the long run.

In addition to firm level surveys, investments in making machine readable data on patenting in developing countries could also help to improve understanding of innovation in learning processes, and would be useful to empirical researchers and policymakers alike. Though there are well known limitations of using patent data as indicators of innovative activity (Griliches 1990), efforts over the past decade by researchers at the National Bureau of Economic Research (NBER) in creating computerized patent databases (Jaffe and Trajtenberg 2002) have led to a resurgence of empirical work on technical change, and are likely to dramatically improve our understanding of the U.S. innovation system. Though several scholars have attempted to use these U.S. patent data to track international technological competencies and international knowledge flows (Hu and Jaffe 1998), inferences based on such exercises are limited since U.S. patent data only contain information on technologies that foreign firms intend to market in the U.S. Creating similar databases based for developing countries, and linking to the NBER patent data would significantly increase our understanding of who is patenting what and where, and citation data would allow researchers to identify international knowledge flows and their determinants. To facilitate this (at a minimum) data should be collected at the patent level on assignees, inventors, international patent classification, and prior art citations.

In addition, making data on patenting in developing countries more accessible would facilitate evaluation of the policy changes surveyed above, TRIPs in particular. Moreover, broader access to information on the extent and distribution of patent ownership in particular fields would allow agencies and organizations funding research directed at developing countries' needs to avoid "patent thickets" ex ante or to negotiate access before funding the research, avoiding potential tragedies of the anti-commons downstream.

On a related note, creation of better databases of non-patent prior art, including indigenous prior art which is traditionally not codified, would help to prevent developed country firms from patenting knowledge which already is effectively in the public domain in developing countries. This is of course a central worry of those concerned about "biopiracy" (e.g. Shiva 1997). Such codification and database creation efforts could help to assure that patents are limited to knowledge that is truly novel and non-obvious. As suggested above, more qualitative and quantitative work on the use and effectiveness of "defensive publications" in the United States (like the IBM Technical Disclosures) would provide a better understanding of whether and under what conditions such databases could help to protect "freedom to operate" and the public domain.

In addition to investments in creating new data sources, three areas of future research using data that currently exist (or are readily available) are particularly promising and important.

First, more qualitative and quantitative research is required on the effects of increased patenting and licensing of publicly funded research. As I suggested above, these changes could affect developing countries indirectly, via affecting the rate knowledge creation and commercialization generally, or more directly, via affecting the creation and/or diffusion of knowledge and technologies targeted specifically at developing countries' needs. How have these changes affected "technology transfer" from universities to industry? How have they affected the conduct and operation of scientific research? Recent research (e.g. Henderson et al. 1998, Sampat et al. 2003, Sampat 2002) shows that analysis of university patent and patent citation data can shed light on these issues, but much more work needs to be done. In addition, there has been no systematic research on the effects of the post-Bayh-Dole regime on public initiatives targeting problems specific to developing countries. This is an important question, insofar as the public sector has traditionally been an extremely important source of knowledge and technology for developing countries, and public sector patenting is most prominent precisely in the technological field which many believe offers the most potential benefit to developing countries: biotechnology. Here, too, simple analysis of patent data could inform the debate. For example, tracing the extent of patenting and the nature of licensing of research funded by the NIH and directed at diseases borne in developing countries would be illuminating. More generally, patent data combined with grant and burden of disease data could be used to assess the relative responsiveness of the public and private sectors to developing country specific diseases.

Second, and related to this, much more research is required on the extent of the "tragedy of the anti-commons." Though this potential "tragedy" has sparked much concern, recent interview-based research by Walsh et al. (2002) suggests that it is rarely a stumbling block to future research or downstream commercialization. Given the importance of this issue, it would be useful to administer a broader survey to firms and academics on the nature and extent of bargaining problems created by upstream and/or fragmented patent rights, and the magnitude of associated costs. Equally important, such a survey could help to indicate the circumstances under which agents are able to "contract out" of these tragedies, and those where bargaining breakdowns are more likely and where external intervention, e.g. via patent-pooling arrangements, would prove useful.

A third fruitful area for future research is on the impact of recent changes in patent law, in particular TRIPs, on stimulating R&D for neglected diseases. The pioneering work by Lanjouw and Cockburn (2001) represents a useful first step in this direction, though as I indicated above the true effects of TRIPs on developed country firms may take some years to observe. A promising line of research which could indirectly shed some light on this question is examining the impact of the U.S. Orphan Drug Act of 1983 which provided 7 years of exclusive marketing protection for drugs effective against rare diseases or conditions. In preliminary work, Lichtenberg (2000) found that since the passage of this act the number of such drugs approved for marketing has increased 12-fold. However, Lichtenberg's work does nor control for changes in scientific opportunity or the possibility that firms are simply adding "orphan" indications to existing drugs. In principle it is possible to account for these other factors, and doing so would help answer the question of whether (and when) stronger patent protection helps to stimulate R&D for diseases with small markets in developed countries. More generally, such research could help inform the debate on the relative efficacy of "push" versus "pull" mechanisms for addressing the problems unique to developing countries (cf. Kremer 2000).

But empirical studies like those suggested above have their limits, as the survey in the previous sections made clear. Since such studies are often at a high-level of abstraction and subject to major data constraints, they alone will not allow for a comprehensive assessment of the effects of the recent "privatization" of knowledge on developing countries. As such, they should to be complemented by more "appreciative" studies, combining historical and qualitative data with empirical evidence. A useful model is the recent "Matrix" project led by Richard Nelson and David Mowery, which brought together a team of leading researchers to examine the source of industrial leadership in seven industries in seven countries (Mowery and Nelson 1999). A similar study of a set of industries in selected developing countries could help to uncover whether and how the various recent changes discussed above are affecting knowledge flows, learning, and innovation in developing countries.

Moreover, such a study would show how these changes interact with the broader innovation systems in developing countries. All of the available historical and empirical evidence suggests that "inward technology transfer" depends on the complex interaction of a range of policies and institutions. This suggests that if we really want to understand knowledge flows and global inclusion, we need to expand our focus beyond patents alone. This expanded focus would complicate the issue considerably, but in the long run yield greater returns.

References

Arora, A. (1995). "Licensing Tacit Knowledge: Intellectual Property Rights and the Market for Know-How." Economics of Innovation and New Technology 4(1): 41-59.

Arrow, K. (1962). Economic Welfare and the Allocation of Resources for Invention. The Rate and Direction of Inventive Activity. R. R. Nelson. Princeton, Princeton University Press.

Broad, W. (1979). "Patent Bill Returns Bright Idea to Inventor (in News and Comment)." Science 205: 473-476.

Chin, J. C. and G. M. Grossman (1990). Intellectual Property Rights and North-South Trade. The political economy of international trade: Essays in honor of Robert E. Baldwin. R. W. Jones and A. O. Krueger. Oxford and Cambridge, Mass., Blackwell: 90-107.

Cohen, W. M., R. R. Nelson, et al. (2000). Protecting Their Intellectual Assets: Appropriability Conditions and Why U S Manufacturing Firms Patent (or Not). National Bureau of Economic Research Working Paper: 30.

Cohen, W. M., R. R. Nelson, et al. (2002). "Links and Impacts: The Influence of Public Research on Industrial R&D." Management Science 48(1): 1-23.

Correa, C. M. (2000). Intellectual property rights, the WTO and developing countries: The TRIPS Agreement and policy options. Penang, Malaysia, Third World Network; London: Zed Books; distributed by St. Martin's Press New York.

Dahlman, C. J. and R. Nelson (1995). Social Absorption Capability, National Innovation Systems and Economic Development. Social capability and long-term economic growth. B. H. Koo and D. H. Perkins. New York, St. Martin's Press; London: Macmillan Press: 82-122.

Dasgupta, P., and Paul David (1994). "Towards a New Economics of Science." Research Policy 23(5): 487-521.

David, P. A. (1993). Intellectual Property Institutions and the Panda's Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History. Global dimensions of intellectual property rights in science and technology. M. B. Wallerstein, M. E. Mogee and R. A. Schoen. Washington, D.C., National Academy Press: 19-61.

David, P. A. (2002). "A Tragedy of the Public Knowledge Commons? Global Science, Intellectual Property and the Digital Technology Boomerang." Working Paper, Stanford University.

Dupree, A. H. (1957). Science in the Federal Government, a history of policies and activities to 1940. Cambridge, Mass.,, Belknap Press of Harvard University Press.

Eisenberg, R. (1996). "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research." Virginia Law Review: 1663-1727.

Eisenberg, R. (2002). "How Can You Patent Genes." American Journal of Bioethics 2: 3-11.

Eisenberg, R. S. and R. P. Merges (1995). "Opinion Letter as to the Patentability of Certain Inventions Associated With the Identification of Partial cDNA Sequences." Am. Intell. Prop. L. Ass'n Q.J. 23: 3.

Evenson, R. E. (1990). Intellectual Property Rights, R&D, Inventions, Technology Purchase, and Piracy in Economic Development: An International Comparative Study. Science and technology: Lessons for development policy. R. E. Evenson and G. Ranis. Westview Special Studies in Science and Technology Boulder, Colo., Westview Press in cooperation with the Economic Growth Center Yale University: 325-55.

Frischtak, C. R. (1990). The Protection of Intellectual Property Rights and Industrial Technology Development in Brazil. Intellectual property rights in science, technology, and economic performance: International comparisons. F. W. Rushing and C. G. Brown. Westview Special Studies in Science, Technology, and Public Policy Boulder, Colo. and London, Westview Press: 61-98.

Gambardella, A. (1995). Science and innovation : the US pharmaceutical industry during the 1980s. Cambridge ; New York, Cambridge University Press.

Gould, D. M. and W. C. Gruben (1996). "The Role of Intellectual Property Rights in Economic Growth." Journal of Development Economics 48(2): 323-50.

Graham, S., B. H. Hall, et al. (2002). "Post-Issue Patent "Quality Control": A Comparative Study of US Patent Re-examinations and European Patent Oppositions." NBER Working Paper w8807.

Griliches, Z. (1990). "Patent Statistics as Economic Indicators: A Survey." Journal of Economic Literature 28(4): 1661-1707.

Hall, B., S. Graham, et al. (2003). "Prospects for Improving U.S. Patent Quality via Post-grant Opposition." NBER Working Paper w9731.

Hall, B. H. and R. H. Ziedonis (2001). "The Patent Paradox Revisited: An Empirical Study of Patenting in the U S Semiconductor Industry, 1979-1995." RAND Journal of Economics 32(1): 101-28.

Heller, M. A., and R.S. Eisenberg (1998). "Can Patents Deter Innovation? The Anticommons in Biomedical Research." Science 280: 298.

Henig, R. (1979). "New Patent Policy Bill Gathers Congressional Support." Bioscience 29(May): 281-284.

Hu, A. and A. Jaffe (2001). "Patent Citations and International Knowledge Flow: The Cases of Korea and Taiwan." NBER Working Paper w8528.

Hunt, R. (1999). "Patent Reform: A Mixed Blessing for the U.S. Economy?" Federal Reserve Bank of Philadelphia Business Review November/December.

Jaffe, A. B. (2000). "The U S Patent System in Transition: Policy Innovation and the Innovation Process." Research Policy 29(4-5): 531-57.

Jaffe, A. B. and M. Trajtenberg (2002). Patents, citations, and innovations : a window on the knowledge economy. Cambridge, Mass., MIT Press.

Jefferson, T., A. A. Lipscomb, et al. (1905). The writings of Thomas Jefferson. Washington, D.C.,, Issued under the auspices of the Thomas Jefferson memorial association of the United States.

Kevles, D. (1977). "The National Science Foundation and the Debate over Postwar Research Policy, 1942-45." Isis 68: 5-26.

Kevles, D. (1999). "Patenting Life: A Historical Overview of Law, Interests, and Ethics." Working Paper: Yale Law School.

Kortum, S., and J. Lerner (1999). "Which is Behind the Recent Surge in Patenting?" Research Policy 28: 1-22.

Kremer, M. (2000). Creating Markets for New Vaccines Part I: Rationale. National Bureau of Economic Research Working Paper: 43.

Krugman, P. R. (1991). Geography and trade. Leuven, Belgium Cambridge, Mass., Leuven University Press; MIT Press.

Lanjouw, J. O. (1998). The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering?" National Bureau of Economic Research Working Paper: not available.

Lanjouw, J. O. (2002). "A Patent Policy for Global Diseases: U.S. and International Legal Issues." Harvard Journal of Law and Technology, Forthcoming.

Lanjouw, J. O. and I. M. Cockburn (2001). "New Pills for Poor People? Empirical Evidence after GATT." World Development 29(2): 265-89.

Lanjouw, J. O. and J. Lerner (2001). "Tilting the Table? The Use of Preliminary Injunctions." Journal of Law and Economics 44(2): 573-603.

Levin, R. C. and et al. (1987). "Appropriating the Returns from Industrial Research and Development." Brookings Papers on Economic Activity 3(0): 783-820.

Lichtenberg, F. R. (2001). "The Effect of New Drugs on Mortality from Rare Diseases and HIV." NBER Working Paper w8677.

Lunney, G. (2001). "E-Obviousness." Michigan Telecommunications and Technology Law Review 7: 363-421.

Machlup, F. (1958). An Economic Review of the Patent System: Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, U.S. Senate, study no. 15. Washington, D.C., USGPO.

Mansfield, E. (1986). "Patents and Innovation: An Empirical Study." Management Science 32(173-181).

Mansfield, E. (1994). "Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer." Discussion Paper, International Finance Corporation.

Mansfield, E., M. Schwartz, et al. (1981). "Imitation Costs and Patents: An Empirical Study." Economic Journal 91(364): 907-18.

Maskus, K. E. (2000). Intellectual property rights in the global economy. Washington, D.C., Institute for International Economics.

Maskus, K. E. and M. Penubarti (1995). "How Trade-Related Are Intellectual Property Rights?" Journal of International Economics 39(3-4): 227-48.

Maskus, K. E. and M. Penubarti (1997). Patents and International Trade: An Empirical Study. Quiet pioneering: Robert M. Stern and his international economic legacy. K. E. Maskus and et al. Studies in International Economics. Ann Arbor, University of Michigan Press: 95-118.

Merges, R. (1999). "As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform." Working Paper: University of California, Berkeley - School of Law (Boalt Hall).

Merges, R. and R. Nelson (1994). "On Limiting or Encouraging Rivalry in Technical Progress: The Effect of Patent Scope Decisions." Journal of Economic Behavior and Organization 25: 1-24.

Merges, R. P. (1992). Patent law and policy : cases and materials. Charlottesville, Va., Michie Co.

Merton, R. K. (1973). The Sociology Of Science : Theoretical And Empirical Investigations. Chicago, University of Chicago Press.

Mowery, D., and Bhaven Sampat (2001). "Patenting and Licensing University Inventions: Lessons from the History of the Research Corporation." Industrial and Corporate Change 10: 317-355.

Mowery, D. C. and R. R. Nelson (1999). Sources of industrial leadership : studies of seven industries. Cambridge, UK ; New York, Cambridge University Press.

Mowery, D. C. and B. N. Sampat (2001). "University Patents, Patent Policies, and Patent Policy Debates,1925-1980." Industrial and Corporate Change 10: 781-814.

Mowery, D. C. and B. N. Sampat (2001). "University Patents, Patent Policies, and Patent Policy Debates,1925-1980." Industrial and Corporate Change 10: 781-814.

National Science Board (2002). Science and Engineering Indicators: 2002. Washington, D.C., U.S. Government Printing Office.

Nelson, R. R. (1959). "The Simple Economics of Basic Scientific Research." Journal of Political Economy 67: 297-306.

Nelson, R. R. (1992). What is 'Commercial' and What is 'Public' About Technology, and What Should Be? Technology and the Wealth of Nations. N. Rosenberg, R. Landau and D. C. Mowery. Stanford, CA, Stanford University Press.

Nuffield Council on Bioethics (2002). "The Ethics of Patenting DNA." Working Paper.

OECD (2002). Benchmarking Science-Industry Relationships. Paris, OECD.

Panagariya, A. (1999). "TRIPs and the WTO: An Uneasy Marriage." Working Paper, University of Maryland.

Rai, A. K. (1999). "Intellectual Property Rights in Biotechnology: Addressing New Technology in Symposium Issue, Genetic Technology: Social Values and Personal Autonomy in the 21st Century." Wake Forest Law Review 34.

Reimers, N. (1998). Stanford's Office of Technology Licensing and the Cohen/Boyer Cloning Patents, An Oral History Conducted in 1997 by Sally Smith Hughes, Ph.D., Regional Oral History Office. Berkeley, CA, The Bancroft Library.

Riddles, A. M. and B. Pomerance (1998). "Software Patentee Must Conduct Own Search: Prior-Art Searches Made By The Patent Office Often Are Not Thorough Enough To Be Trusted." National Law Journal.

Sampat, B., D. Mowery, et al. (2003). "Changes in University Patent Quality After the Bayh-Dole Act: A Re-Examination." Forthcoming, International Journal of Industrial Organization.

Sampat, B. N. (2002). "Private Parts: Patents and Academic Science in the Twentieth Century." Prepared for AAAS/CSPO Symposium for the "Next Generation" of Leaders in Science and Technology Policy.

Sampat, B. N. and R. R. Nelson (2002). "The Emergence and Standardization of University Technology Transfer Offices: A Case Study of Institutional Change." Advances in Strategic Management 19.

Sampat, B. N. (2003). "The Social Welfare Effects of the Bayh-Dole Act of 1980: A Survey of the Empirical Literature." Working Paper, Georgia Institute of Technology.

Samuelson, P. (1990). "Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions." Emory Law Journal 39: 1025-1154.

Schlicher, J. W. (1992). Patent law : legal and economic principles. Deerfield, IL, Clark Boardman Callaghan.

Scotchmer, S. (1991). "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law." Journal of Economic Perspectives 5(1): 29-41.

Shiva, V. (1997). Biopiracy : the plunder of nature and knowledge. Boston, MA, South End Press.

Siebeck, W. E., R. E. Evenson, et al. (1990). Strengthening protection of intellectual property in developing countries: A survey of the literature, World Bank.

Smith, P. J. (1999). "Are Weak Patent Rights a Barrier to U S Exports?" Journal of International Economics 48(1): 151-77.

Stokes, D. E. (1997). Pasteur's Quadrant: Basic Science and Technological Innovation. Washington, D.C., Brookings Institute.

Thursby, J., R. Jensen, and M. Thursby (2001). "Objectives, Characteristics and Outcomes of University Licensing: A Survey of Major U.S. Universities." Journal of Technology Transfer 26: 59-72.

Thursby, M. and J. Thursby (2002). "University Licensing under Bayh-Dole: What are the Issues and Evidence?" Working Paper, Georgia Institute of Technology.

Trune, D. and L. Goslin (1998). "University Technology Transfer Programs: A Profit/Loss Analysis." Technological Forecasting and Social Change 57: 197-204.

Walsh, J. P., A. Arora, et al. (2002). "Research Tool Patenting and Licensing and Biomedical Innovation." Unpublished working paper, Heinz School of Public Policy, Carnegie-Mellon University; forthcoming in W.M. Cohen and S. Merrill, eds., The Patent System in the Knowledge-Based Economy. Washington, D.C.: National Academies Press.

Watal, J. (2000). "Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India under the WTO TRIPS Agreement." World Economy 23(5): 733-52.

Watal, J. (2001). Intellectual property rights in the WTO and developing countries. The Hague ; Boston, Kluwer Law International.

Weissman, R. (1996). "A Long, Strange TRIPS: the Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries." U. Pa. J. Int'l Econ. L. 17: 1098+.

Wright, B. D. (1983). "The Economics of Invention Incentives: Patents, Prizes, and Research Contracts." American Economic Review 73(4): 691-707.

Ziman, J. M. (1968). Public knowledge: an essay concerning the social dimension of science. London, Cambridge U.P.

1 See however Stokes (1996) for an excellent discussion of the problematic nature of the basic-applied dichotomy.

2 Thus the Supreme Court ruled in Funk Brothers Sees Co. v. Kalo Inoculant that certain bacterial strains were not patentable because "[P]atents cannot issue on the discovery of phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of the laws of nature, free to all men and reserved exclusively to none" (33 U.S. 127, 76 USPQ, 1948).

3 A. Hunter Dupree (1957) writes that when he was Patent Commissioner, Jefferson "was always on guard to restrict patents to real novelties and to protect the public from having familiar devices long the common property of all men subject to a levy by the patentee" (12).

4 Funk Brothers Seed Co. v. Kalo Inoculant Co, 333 U.S. 127, (1948);

5 According to Kevles (2001), the "product of nature" doctrine dates back to an 1889 ruling by the Commissioner of Patents.

6 Diamond v. Chakrabarty, 447 U.S. 303 (1980)
7 Definitional difficulties and the somewhat blunt structure of patent classification systems make it difficult to count "biotechnology" patents precisely. The trends cited above are meant to be illustrative rather than definitive, and are drawn from data presented in http://www7.nationalacademies.org/step/12 and http://healthresearch.georgetown.edu.
8 Cooley (1994) notes "Many patent attorneys believe that the obviousness defense is dead and that the cause of death lies in the decisions of the Court of Appeals for the Federal Circuit" (quoted in Hunt 1999, p. 9).
9 The U.S. currently has a procecedure which allows third parties to request reexamination, but there are substantial disincentives for third-parties (such as competitors or users of the technologies) to initiate a re-examination proceeding, and it is rarely used (Merges 1999, and Graham et al. 2002 for a comparison of re-examinations and oppositions).
10 For example, from 1958-1998 IBM issued "technical bulletins" to prevent patentability of certain areas of research, to preserve the firm's freedom to use. Over the years, over 48,000 references to these disclosures were made in U.S. patents, making them the third most highly cited source of non-patent prior art in U.S. patents.
11 This section draws heavily from Sampat (2002).
12 There is, however, considerable inter-industry variance. Patents and licenses are considerably more important channels in pharmaceuticals than in other industries. However even in pharmaceuticals, the other channels historically have been extremely important (Gambardella 1998).
13 In its 1973 report, the Carnegie Commission on Higher Education classified the nation's 173 doctorate granting institutions as Research Universities and Doctoral Universities. Institutions that awarded at least 50 doctorates in 1969-1970 and were among the 50 leading recipients of federal financial support in at least two of the three years 1968-1969, 1969-1970, 1970-1971 were classified as "Research University I" (RU1). Institutions that awarded at least 50 doctorates in 1969-1970 and ranked in between 50th and 100th in federal financial support in two of the three years were classified as "Research University 2" (RU2). I treat the union of the RU1s and RU2s as "Carnegie Research Universities".
14 In the pre-Bayh-Dole era, universities without IPAs had to request permission for licensing exclusively on an invention by invention basis. Those with IPAs ere required to consider non-exclusive licensing first. Bayh-Dole included no such provision, and as such made licensing inventions exclusively easier.
15 Mowery and Sampat (2001a) show that the high costs of patent management made it difficult for the Research Corporation to generate positive net income from patenting and licensing university inventions.
16 For a more formal assessment of the social welfare effects of Bayh-Dole, see Sampat (2003).
17 See, for example, the recent assessment by Howard Bremer, available online at http://www.cogr.edu/Bremer.htm.
18 According to a recent survey of 76 major university technology transfer offices, licensing incomeis the most important criterion by which technology transfer offices measure their own success (Thursby, Jensen, and Thursby 2001).
19 The specific language used in Section 27.1 is the French phrase order public, which may be actually narrower than "public interest." Correa (2000) notes that "Under the Guidelines for Examination of the European Patent Office, for instance, ordre public is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behaviour" (193).

20 Specifically, it states that patents will be granted for inventions which are "new, involve and inventive step, and are capable of industrial application". In the parlance of most European patent offices, "inventive step" corresponds to non-obviousness and "capable of industrial application" to utility.

21 See also Weissman (1996) for a discussion of alternatives available to developing countries under TRIPs.

22 However, another extremely important set of issues relates to the effects of TRIPs on the ability of a country without indigenous manufacturing capability to import drugs from low-cost generic producers elsewhere. For example, see http://lists.essential.org/pipermail/ip-health/2003-March/004508.html.