

Intellectual Property Rights (IPR): Issues for Researchers in Biology

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Agenda Outline

- A Walk into a Molecular Biologist's Lab
- Some IPR Fundamentals
- Patenting Research Tools in Biology
- Economic Costs and Benefits of Patenting
- Some Questions to Ponder

A Walk into a Molecular Biologist's Lab...

- A dazzling variety of biological materials, texts, software, and instruments.
- A sequencing machine sits on a bench. Racks of clones fill the freezers.
- Laboratory notebooks, computer printouts, reprints, and draft manuscripts cover the desks.

A Walk into a Molecular Biologist's Lab...

- Where did all this stuff come from?
- Some of it was purchased in open markets
- Some of it was produced locally in the laboratory
- Some of it came from colleagues

A Walk into a Molecular Biologist's Lab...

- Where will all this stuff go?
- Most of them are of little interest to anyone outside the laboratory but a few are of intense interest to people in the world outside
- Some of the items will be submitted to scientific journals

A Walk into a Molecular Biologist's Lab...

- Some might be included in patent applications
- Some might be shared with colleagues
- Some might be kept quietly in the laboratory, no one being told about their existence.

A Walk into a Molecular Biologist's Lab...

- How can one develop a sociological explanation of the traffic patterns of resources in and out of scientific laboratories? How can one explain the process that shapes who gets what, when, and under what kinds of terms and conditions? This formulation of the problem of scientific exchange focuses attention on the particular entities, or resources, that are involved in exchanges—entities that received little notice in early sociological work on scientific exchange.

Some IPR Fundamentals

- In order to assess the significance of recent developments, it is necessary to understand something about patents and their relationship to other forms of intellectual property protection
- The term intellectual property is used to refer to a wide range of rights associated with inventions, discoveries, writings, product designs, and other creative works.

Some IPR Fundamentals

- Some of these rights, such as patents, have more of the attributes of property than others, such as trade secrets. Some of these rights, such as patents, are protected under Central law, while others, such as trade secrets, are a matter of State law.

Some IPR Fundamentals

- A patent confers a right to exclude anyone else from using an invention, even an innocent infringer who independently develops the same invention without any knowledge of the patent holder's rights

Some IPR Fundamentals

- Trade secrets, in contrast, receive more limited protection and may not be enforced against innocent infringers. Although trade secret rights are weaker than patent rights, the availability of legal protection for trade secrets under state law provides an alternative to protection that some inventors might choose in situations where patent protection is unavailable

Some IPR Fundamentals

- Given commercial interest in the development and dissemination of research tools, in the absence of patent protection, firms may be more likely to resort to trade secrecy
- But secrecy only works for inventions that can be exploited commercially without disclosure, such as manufacturing processes. Many inventions and discoveries are self-disclosing once they are put on the market in the form of a product, and thereafter may only be protected through a patent

Some IPR Fundamentals

- From the perspective of an innovating firm, disclosure of underlying technology might help in the marketing of a new product, and from a broader social perspective, secrecy might impede further technological progress in the field.

Some IPR Fundamentals

- For some inventions, patents provide an alternative strategy for protecting intellectual property rights that does not require (and indeed does not permit) secrecy. To get a patent, it is necessary to file an application that includes a full disclosure of the invention and describes how to make and use it.

Some IPR Fundamentals

- A patent gives an inventor the rights to exclude others from making, using and selling the invention for a limited term, 20 years from the application filing date in most of the world. During the patent term the inventor may choose to make, use, and sell the patented invention herself (assuming this does not violate the patent rights of others or any applicable laws), or to license others to do so on an exclusive or non-exclusive basis, or even to suppress the use of the invention entirely. One thing an inventor who wants a patent cannot do is keep the invention secret.

REQUIREMENTS FOR PATENT PROTECTION

- The basic requirements for patent protection are novelty, utility, and non-obviousness
- *Novelty* means that the invention did not exist before. Determining whether an invention is new requires searching through certain categories of prior art to determine the state of knowledge in the field at the time that the invention was made. Sources of prior art include prior patents, publications, and inventions that were previously in public use. If an invention was already known or used before the time that the inventor claims to have made it, the public gains nothing by conferring a patent. The patent will take something away from the public that it was previously free to use without in any way enriching the public storehouse of knowledge

REQUIREMENTS FOR PATENT PROTECTION

- The prior art is also relevant to the standard of *non obviousness*. This standard asks whether the invention constitutes a significant enough advance over what was known previously to justify patent protection
- This requirement is satisfied if, at the time the invention was made, it would not have been obvious to a person of ordinary skill in the field and who was knowledgeable about the prior art.

REQUIREMENTS FOR PATENT PROTECTION

- The *utility* requirement limits patent protection to inventions with practical applications, as opposed to basic knowledge. The meaning of this requirement has varied over the years from a minimal standard that the invention not be positively harmful to people to a stricter requirement in recent years of safety and effectiveness that has sometimes approached what the FDA would require for approval of a new drug.

REQUIREMENTS FOR PATENT PROTECTION

- The conceptual underpinnings of the utility requirement are not always clear, but in theory it can be justified as a means of distinguishing between basic research discoveries that are more likely to be effectively utilized if left in the public domain and more practical technological applications that may require a patent to ensure adequate incentives for commercial development.

REQUIREMENTS FOR PATENT PROTECTION

- The Supreme Court has stated that discoveries whose only value is as an object of scientific inquiry do not satisfy the utility standard, suggesting that utility could be an important limitation on the use of the patent system to protect research tools.

RESEARCH TOOLS IN MOLECULAR BIOLOGY

- Molecular biology provides a useful focal point for examining the effect of intellectual property on the dissemination of research tools. It is a dynamic and productive field of research that provides a wealth of new discoveries that are simultaneously inputs into further research and also candidates for commercial development.

RESEARCH TOOLS IN MOLECULAR BIOLOGY

- The obvious implications of discoveries in molecular biology for human health raise the stakes of striking the right balance between public access and private property, particularly when public attention is riveted upon the rising costs of health care. And it profoundly affects the interests of two different types of commercial firms—young biotechnology firms and large, integrated pharmaceutical firms—both of which are sensitive to intellectual property but for

different reasons

RESEARCH TOOLS IN MOLECULAR BIOLOGY

- **Young biotechnology firms typically need to raise funds to keep their research operations moving forward before they have products to sell to consumers. For these firms, an intellectual property portfolio might be critical at an early stage in their R&D to give them something to show investors as evidence of their potential for earning high returns in the future**

RESEARCH TOOLS IN MOLECULAR BIOLOGY

- **With this purpose in mind, they are likely to seek patents on discoveries that are several stages removed from a final product that is ready to be sold to consumers**

RESEARCH TOOLS IN MOLECULAR BIOLOGY

- **Established pharmaceutical firms are also very sensitive to intellectual property rights, but for different reasons and at a different stage in the R&D process. Pharmaceutical firms do not need to go to the capital markets to fund their research; they typically fund new research projects out of profits on existing products**

RESEARCH TOOLS IN MOLECULAR BIOLOGY

- **For these firms, intellectual property is not a means of raising capital, but simply a means of ensuring an effective commercial monopoly for their products. A monopoly position in a new drug will help them recoup what might amount to hundreds of millions of dollars required for FDA-mandated clinical testing before they can bring that drug to market. For this purpose, they seek patent rights that cover the downstream products that they sell to consumers, not the upstream discoveries that they may use along the road to product development**

PATENTS ON RESEARCH TOOLS

- **"Research tools" is not a term of art in patent law. No legal consequences flow from designating a particular discovery as a research tool**

PATENTS ON RESEARCH TOOLS

- **Research tools are not categorically excluded from patent protection (except insofar as they lack patentable utility), nor is the use of patented inventions in research categorically exempted from infringement liability**

PATENTS ON RESEARCH TOOLS

- **There are reasons to be wary of patents on research tools**
- **Although the ultimate social value of research tools is often difficult to measure in advance, it is likely to be greatest when they are widely available to all researchers who can use them.**

PATENTS ON RESEARCH TOOLS

- **For years, we have sustained a flourishing biomedical research enterprise in which investigators have drawn heavily upon discoveries that their predecessors left in the public domain**

PATENTS ON RESEARCH TOOLS

- The nature of patents is that they restrict access to inventions to increase profits to patent holders. An important research project might call for access to many research tools, and the costs and administrative burden could mount quickly if it were necessary for researchers to obtain separate licenses for each of these tools

PATENTS ON RESEARCH TOOLS

- The effects of patenting research tools will vary. For example, patents are unlikely to interfere substantially with access to such research tools as chemical reagents that are readily available on the market at reasonable prices from patent holders or licensees

PATENTS ON RESEARCH TOOLS

- Many of the tools of contemporary molecular biology research are available through catalogs under conditions that approach an anonymous market. Some are patented, but the patents are unlikely to interfere with dissemination. Indeed, it might be cheaper and easier for researchers to obtain such a tool from the patent holder or from a licensed source than it is to infringe the patent by making it themselves

PATENTS ON RESEARCH TOOLS

- Some research tools can only be obtained by approaching the patent holder directly and negotiating for licenses; in this context, patents potentially pose a far greater threat to the work of later researchers. Negotiating for access to research tools might present particularly difficult problems for would-be licensees who do not want to disclose the directions of their research in its early stages by requesting licenses

PATENTS ON RESEARCH TOOLS

- Another risk is that the holders of patents on research tools will choose to license them on an exclusive basis rather than on a nonexclusive basis; this could choke off the R&D of other firms before it gets off the ground. Such a licensing strategy might make sense for a startup company that is short on current revenues, even if it does not maximize value in the long run from a broader social perspective

PATENTS ON RESEARCH TOOLS

- Another risk is that patent holders will use a device employed by some biotechnology firms of offering licenses that impose "reach-through" royalties on sales of products that are developed in part through use of licensed research tools, even if the patented inventions are not themselves incorporated into the final products

PATENTS ON RESEARCH TOOLS

- Firms have been willing to accept a reach-through royalty obligation for licenses under the Cohen-Boyer patents on basic recombinant DNA techniques, perhaps because those patents include broad claim language that covers products developed through the use of the patented technology. But reach-through royalties have met greater market resistance for other patents, including the patents on the Harvard onco-mouse and the polymerase chain reaction (PCR)

PATENTS ON RESEARCH TOOLS

- Licenses with reach-through royalty provisions might appear to solve the problem of placing a value on a research tool before the outcome of the research is known. One difficulty in licensing research tools is that the value of the license cannot be known in advance, so it is difficult to figure out mutually agreeable license terms.

PATENTS ON RESEARCH TOOLS

- A reach-through royalty might seem like a solution to this problem, in that it imposes an obligation to share the fruits of successful research without adding to the costs of unsuccessful research. But it takes little imagination to foresee the disincentives to product development that could arise from a proliferation of reach-through royalties. Each reach-through royalty obligation becomes a prospective tax on sales of a new product, and the more research tools are used in developing a product, the higher the tax burden

Economic Costs and Benefits of Patents

- A broad overview of theories about the principal costs and benefits of patents and assumptions about the contexts in which inventions are made or developed
- Patents play different roles in different technologies and sectors

Economic Costs and Benefits of Patents

- Four broad theories about the principal purposes of patents:
- *Invention-inducement Theory*: The anticipation of receiving patents provides motivation for useful invention.
- *Disclosure Theory*: Patents facilitate wide knowledge about and use of inventions by inducing inventors to disclose their inventions when otherwise they would rely on secrecy.
- *Development and Commercialization Theory*: Patents induce the investment needed to develop and commercialize inventions.
- *Prospect Development Theory*: Patents enable the orderly exploration of broad prospects for derivative inventions.

Economic Costs and Benefits of Patents

- The assumptions are made about the following conditions:
- The nature and effectiveness of means other than patents to induce invention and related activities.
- The likelihood of a group of potential inventors to work on diverse and non competing ideas or to be focused on a single alternative or a set of closely connected ones.
- The transaction costs of licensing an invention with and without patents.
- Whether the multiple steps in the invention, development, and commercialization of a new technology tend to proceed within a single organization or several organizations tend to be involved at different stages of the process.
- The topography of technological advance—how inventions are linked to each other both temporally and as systems.

Invention Inducement Theory

- The theory that patents motivate useful invention is the most familiar theory of the benefits of patenting. Indeed, much discussion about the benefits of patents proceeds as though motivating useful invention were the only social purpose served by patents and patents always serve this purpose

Invention Inducement Theory

- All versions of the invention-inducement theory presume either that if there is no patent protection there will be no invention or, more generally, that without a patent system incentives for invention will be too weak to reflect the public interest
- The version of the invention-inducement theory that we have been considering up to now presumes that more inventive effort and more inventors mean more useful inventing

Invention Inducement Theory

- The best empirical evidence suggests that among firms engaged in R&D, patents are an important part of the inducement for invention in only a small number of industries
- There is a proliferation of empirical work on what patents are about, who uses them, and how important they are. This work is motivated entirely by the invention-inducement theory; that is why a lot of what was learned in the work might not be relevant to research tools

Invention Inducement Theory

- The case can certainly be made that for many university inventions that were funded with public money, the policy implication of the invention-inducement theory is that a patent should not be granted if it is not necessary to grant a patent to get an invention. The results of research would be published in any case. In many instances, firms will have ample incentive to work with and develop what comes out of university research. They can usually patent their developments, gain the advantage of a head start in the market, or both

DISCLOSURE THEORY

- The primary issue raised by the disclosure theory is not so much whether strong patents encourage more inventing, but rather how inventors reap the returns from their inventions
- It presumes that secrecy is possible and sufficient to induce invention but that society is better off granting intellectual property rights and getting disclosure in exchange

DISCLOSURE THEORY

- A patented invention would thus be available for uses that the inventor did not know about or was not in a position to implement.
- Under this theory, a patent both advertises the presence of an invention and facilitates licensing. That argument, in effect, turns the invention-inducement theory on its head: patents are not necessary to induce invention, but rather what patents do is encourage disclosure

DISCLOSURE THEORY

- Secrecy would seem more effective for process than for product inventions
- The most relevant domain of the disclosure theory might be process inventions
- In some industries, firms customarily engage in general cross licensing of their process technologies, a sharing of technology that might not occur if patents on processes were not available

"DEVELOP & COMMERCIALIZE" THEORY

- In its simplest version, the theory that patents induce the development and commercialization of inventions seems to be a variant of the invention-inducement theory, but with patenting occurring early in the process of inventing and with much additional work needed before the crude "invention" is ready for actual use

"DEVELOP & COMMERCIALIZE" THEORY

- A patent at an early stage is seen as providing the assurance that if the development is technologically successful, its economic rewards will be capturable, thus inducing a decision to develop it

"DEVELOP & COMMERCIALIZE" THEORY

- The possession of a patent enables the patent holder to go to capital markets for development financing
- That capability might be important for a small firm faced with large development costs before it can get its invention to market

"DEVELOP & COMMERCIALIZE" THEORY

- The original inventor's possession of a patent then facilitates handing off the task to an organization better situated for development and commercialization
- The development and commercialization theory was widely cited in the discussions that led to the Bayh-Dole Act, which gave universities the patent rights on inventions that emanated from their government-funded research projects

PROSPECT DEVELOPMENT THEORY

- It proposes that the utility of a patent comes after an initial invention is made.
- Having a broad patent on an initial invention enabled the patent holder to orchestrate development of a technological prospect in various dimensions, whereas development of an initial invention that was freely available to all would be chaotic, duplicative, and wasteful

PROSPECT DEVELOPMENT THEORY

- The theory that patents enable orderly development of broad technological prospects differs from the development and commercialization theory in suggesting that a wide range of developments or inventions might become possible if the initial invention is available as an input—through either development or modification in different directions. Many university inventions, particularly research tools, are of this sort.

PROSPECT DEVELOPMENT THEORY

- This theory suggests that an important issue defining the benefits and costs of granting patents on broad prospects is what is assumed about the market for patent licenses
- The question of transaction costs is particularly important when technological advances within a prospect are strongly connected

PROSPECT DEVELOPMENT THEORY

- Advances in technology can be connected to each other in two ways
- First, technological advance can be *cumulative*, in that today's advance lays the basis for tomorrow's
- Second, the operative products or processes can form a *system*, in that they incorporate a number of components

PROSPECT DEVELOPMENT THEORY

- Historical records show that granting broad patents in cumulative-system technologies is often counterproductive (for instance, research tools)
- Unless licensed easily and widely, the presence of such patents tends to limit the range of potential users who have access to all components of the technology. In a number of instances, the consequence was to make technological advance difficult and costly

Some Questions

- Does the delay in disclosure that results from patent application inhibit scientific progress?
- Is access to research tools broad enough to facilitate scientific progress?
- Do the benefits of a protected environment for further development outweigh the costs of excluding others from this research tool?

Some Questions

- Is this technology critical to researchers? Are there other ways to do the same thing?
- Is private investment necessary to make the research tool more useful? Is the size of the potential market sufficient to warrant the amount of extra investment?

Some Questions

- Does or might this research technology have alternative uses for which commercial markets exist, and would private investment be necessary to develop those markets?
- Are multiple dissemination strategies feasible (such as different licensing terms and different fees)?

Some Questions

- Where substantial further investment is necessary to develop the technology, will further development yield additional patentable inventions sufficient to motivate investment?
- Is this invention likely to be only one of many pieces to a complex puzzle, each of which could be separately owned?

Some Questions

- In what fields of technology are technical advances so strongly connected to one another, either temporally or in a system of use, that effective inventing today requires access to prior inventions?
- What are the fields of inventing in which progress generally requires the effective interaction of a number of different organizations?

Some Questions

- Do patents in fact contribute to or hinder the access and cooperation needed for technical advance in such contexts?

Any More Questions ?