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BEFORE THE
UNITED STATES PATENT AND TRADEMARK OFFICE

CONCERNING
PATENT PROTECTION
FOR BIOTECHNOLOGICAL INVENTIONS

ON
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Commissioner Lehman, Mr. Van Horn, Mr. Kushan, and the other members of the panel, thank you for the opportunity to appear and give my personal views on these issues. I am a patent lawyer with the firm of Crosby, Heafey, Roach & May in its Oakland, California office.[1] I also teach patent law at Stanford Law School as a part-time Lecturer.

My comments are arranged in the following order:

1. Patent Law Should Be Based On Sound Economic Analysis
2. The Economic Purpose Of Patent Law
3. There Is Not And Should Not Be A Separate Set Of Patent Law Doctrines For Biotechnology
4. Practical Utility For Biotechnological Inventions
5. Proof Of Operability For Human Therapeutic Inventions
6. Standards Used In Measuring Nonobviousness And Enablement Of Biotechnological Inventions
7. Experimental Use Defense To Patent Infringement
8. Implications Of Pending Legislative Reform On PTO Operations And Examination Procedures
9. Other Issues
10. The Most Efficient Use Of The PTO's Resources In The Overall Patent System

These hearings focus on patent law and biotechnology. Patents are important to the biotechnology industry. The advances of the past twenty years have created vast opportunities for future research.[2] However, the policy and legal issues transcend the biotechnology industry. The policy and substance of patent law should apply to all technologies in the same way. Biotechnology inventors should be treated no less and no more favorably than any others.

1. Patent Law Should Be Based On Sound Economic Analysis

I commend you for holding these hearings and for preparing a thoughtful notice to focus the issues.[3] The notice is a model of good sense in one critical respect. The notice focuses on the economics of the patent system. The notice asks for information about the effect of the law on the amount or rate of investment in attempts to create the technological information about new products and processes that patent law calls "inventions." Patent law has not always developed to best serve the United States economy because the people responsible for making and interpreting the law failed to ask that question or to answer it correctly. A classic example is the Supreme Court's decision in Brenner v. Manson. By asking the right question, these hearings have improved the likelihood that patent law will develop to better serve the country. My concern about the economic effects of patent law lead me to write a book to focus attention on this

question and to try to help answer it.[4] Much of what I say here is described in greater detail in that book.

2. The Economic Purpose Of Patent Law

The notice is fundamentally correct when it says the patent system exists to induce investment and risk-taking in research, development and commercialization of biotechnology inventions.[5] The notice is right on target by focusing on increasing incentives to invest in inventing and take the risk of failure. There are other theories of patent law.[6] The notice provides a valuable insight by ignoring them.[7]

For purposes of developing patent law standards, I would define the role of patents only slightly differently. Patent law exists to alter the private incentives for use of resources that the market would otherwise provide. By "resources," I mean anything that is scarce and that, if put to one use, may not also be put to another. A market may misdirect resources, if people do not expect to capture all the benefits their investments provide to other people.[8] In the absence of corrective laws, potential producers of technical information are likely to spend too few resources over a given period attempting to produce technical information. They will do that, because they anticipate being unable to capture all of the value of the information they produce.

I would say the economic goal of patents is to induce investment and risk-taking in producing technological information about new products and processes that, in the absence of patents, the market would be unlikely to produce or produce as quickly. Whether this information-generating activity is called "research" or "development," the goal is to identify and grant rights in those situations where the cost and risk of production would likely have been sufficiently large that potential profit-motivated producers would likely have shunned the effort in the absence of patent rights.[9]

Patent law seeks to assist markets to induce the owners of resources to use more of them in producing new technical information about potential new products and processes. This means patent law also induces the owners of resources to use fewer of them in producing the products and processes available from existing technical information.[10] United States consumers benefit from this better use of the country's scarce resources. The improved supply of technology may permit different or better products to be produced in the future or to be produced more cheaply.

If the level or rate of information production increases due to patents, the level or rate of commercialization of new products and processes will also increase. However, patent law leaves commercial use to the market, not to legal regulation. Like all other property rights systems, the patent system relies on self-interested decisions by producers, consumers and the

market to decide which inventions to try to make, which to develop and use commercially, and how much to pay for that use. Patent rights were historically granted by the government without regard to their potential benefits to consumers or their potential commercial value.[11] The patent system leaves it to producers and consumers to make those judgments, however wise or foolish they might appear to the government. It is entirely likely that a rational patent system may induce many patentable inventions and only a small percentage of them will be used in a commercial product. That fact is and ought to be no cause for concern.

There is one decision by the Supreme Court in 1966, Brenner v. Manson, that can be read to say the patent system exists to induce the development and bringing of new products to the market.[12] If the goal is to induce developing and bringing new products to market, the standards for patent availability would be quite different than they have been for the last 200 years and are today.[13]

3. There Is Not And Should Not Be A Separate Set Of Patent Law Doctrines For Biotechnology

United States consumers benefit from advances in biotechnology and all other technologies. For that reason, patents apply to all areas of technology where there are opportunities for profit-motivated people to conduct research and produce technical information. Because the policy of patent law

applies to all technologies, patent law doctrines must apply across the board to all technologies.

There is not and should not be a special subset of patent law doctrines for biotechnology. One risk is that a separate set of biotechnology standards may develop in a way that makes patents for biotechnology inventions more difficult to obtain or less valuable than patents in other areas. Patent law would be unwise if it created greater relative incentives to invent the 10,000th mouse trap design than the first therapy for a previously untreatable human disease.

In general, I find the notice to be consistent with that view. However, the notice refers to the Court of Appeals for the Federal Circuit "refining" the law of nonobviousness for biotechnological inventions. I do not understand the Court of Appeals for the Federal Circuit to have created a subset of patent law doctrines for biotechnology. While the decisions cited in the notice discuss patent law in the context of biotechnology, the legal standards found in the decisions are the same standards applied to all types of technologies.

In the patent area, people sometimes confuse legal principles with decisions applying legal principles to particular facts. It is important for patent lawyers and the Patent and Trademark Office ("PTO") to understand that a decision by a court to find a particular invention unpatentable or a patent invalid for lack of utility, obviousness, or lack of an enabling disclosure does not establish a new legal principle. For

example, if the PTO issued a patent on an invention based on research that identified a gene that encodes a particular protein (by identifying the protein sequence, creating sets of probes and probing DNA libraries), and a court were to declare that invention obvious and unpatentable, this decision does not change the law of nonobviousness one iota. That decision is and ought to be irrelevant to the obviousness of a different invention based on research that identified a different gene that encodes a different protein (again by identifying the protein sequence, creating sets of probes and probing DNA libraries). The decision declaring the first invention obvious and unpatentable does not and ought not provide a basis for the same decision in a second case that looks superficially similar.

People who work with patent law often try to find certainty in the law where certainty does not exist and to simplify the process of applying the law to the facts, where simplicity is not possible or wise. The easiest way to achieve certainty (and predictability) and to reduce the cost of decision-making is by applying formal or informal (that is secret) rules of thumb across all fact situations that appear at some general level to be similar. Lawyers, patent examiners, courts and others need to resist that impulse. They need to apply the same general legal standards to the particular facts in each particular situation. The notice affirms that is the operating procedure in the PTO. The notice, borrowing a phrase from antitrust law, affirms there are no <u>per se</u> rules. Each application is examined based on

applying general legal principles to the unique facts surrounding the application. That declaration is very important. The challenge is to make this approach effective.

4. Practical Utility for Biotechnological Inventions

The notice asks about the purpose of the utility requirement. That is the right question. Unfortunately, the Supreme Court in Brenner v. Manson gave the wrong answer.[14] The Court said:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point -- where specific benefit exists in currently available form -- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

In my view, the Court was wrong.

In Brenner v. Manson, Justice Fortas, and six other Justices, implied that inventors seeking a patent must first show that the invention had been developed to the point where "specific benefit exists in currently available form." Justice Fortas seemed to believe it undesirable to issue a patent on the process of producing a chemical, if the only known use for the chemical was to conduct further research into uses for it. Justice Fortas also seemed to believe that research is useless and researchers do not count as consumers in need of better products and processes. I find it startling to suggest that all of the instruments and all of the reagents sold by numerous

companies to the biotechnology industry for conducting research are beyond the pale of the patent system, because research is deemed an inherently useless activity. If someone might be willing to pay for a material, whether an isolated strand of DNA, an isolated polypeptide, an isolated protein, or an isolated microorganism, that material has, in my view, sufficient utility to be patentable.

In my view, Brenner v. Manson's language is unclear and, if taken literally, inappropriate for a well-functioning patent system. I have explained why elsewhere.[15] If someone produces information about the general character and features of a new product or process that distinguishes it from earlier products and processes, he or she traditionally has been and should be entitled to a patent even if (1) there may be no perceivable benefits to consumers or others and no commercial potential for that invention, or (2) there is commercial potential, but there are large additional development expenditures necessary to use that invention commercially. In my view, Brenner v. Manson should also be of limited importance. That decision is inconsistent with more recent Supreme Court decisions defining the purpose of patent law. The Brenner v. Manson majority decision is premised on a "quid pro quo" theory that diverts attention from the real issue - incentives to invent. The dissenters, Justices Harlan and Douglas, asked about the effect of that decision on the incentives to do research into new processes, and reached the correct result. I believe the

dissenter's approach is consistent with the theory the Court applied in its later patent decisions in the 1970's and 1980's, such as Chakrabarty, Dawson, Kewanee Oil, and Diehr and that the Federal Circuit often applies.[16]

Rather, the test articulated by Justice Joseph Story (who sensibly defined most fundamental patent law rules in the early part of the last century) made clear that the criteria for issuing patents had nothing whatsoever to do with the anticipated benefits of the invention. Under Justice Story's test, that prevailed until 1966, any invention was patentable if it might be put to a beneficial use rather than only a harmful enterprise such as poisoning people. If the invention might be put to some use that was not "mischievous or immoral", it was patentable even though consumers and the market might attribute to that invention an economic value of zero.[17] Under that standard, one asked only whether the invention might be useful for any lawful purpose. An invention was unpatentable only if it could not possibly be used for any such purpose.

Are there desirable changes to legal standards? If the Brenner v. Manson language is the legal standard, change is plainly desirable. Under a better rule, the whole question ought to be whether an invention may or might be used by anyone for any lawful purpose. Among the lawful purposes for which an invention might be useful is the conduct of additional research.

I should note that many of the points I have made here and elsewhere were articulated by Judge Rich in his dissenting opinion in In Re Kirk, 376 F.2d 936, 946 (CCPA 1967).

5. Proof Of Operability For Human Therapeutic Inventions

The notice characterizes the next substantive issue as the requirement that an invention be "operative." "Operativeness" is a word sometimes used as a synonym for the utility requirement and for the enabling description requirement in Section 112.[18] The notice directs attention to application of these requirements for inventions whose sole use is the treatment of human disorders. While I do not believe that the law in this area is as clear as it might be, I do not propose to discuss it in any detail. I offer these thoughts.

First, I believe much of the confusion in applying the utility requirement to that type of invention derives directly from the misstatement of the utility requirement in Brenner v. Manson. Assume the law is that an invention is not useful, until a "specific benefit exists in currently available form" presumably to consumers. If the regulatory reality of development and introduction of human therapeutic agents requires many years of development before anyone may lawfully make a product available to consumers, this utility rule seems to preclude a patent until all testing is completed.

Because I do not believe that the utility standard should have anything to do with potential commercial significance, it is an error to require that an applicant have in hand all of the information that will be necessary to immediately introduce a commercial therapeutic product. While some decisions expressly renounce tests that would require possession or disclosure of all commercially significant technical information, the language in Brenner creates a danger that the rules will be applied by decision-makers to require such information. The Supreme Court uttered those words in 1966 and it is difficult to put that genie back in the bottle. However, I think it is necessary to utterly ignore Brenner v. Manson for purposes of applying the utility requirement to human therapeutic inventions. That is a proper thing to do because the applicant in Brenner v. Manson did not assert that its process produced a human therapeutic agent.

Second, while patent law, as I understand it, formally rejects application of Food, Drug and Cosmetic Act standards for safety and efficacy as having anything to do with patent standards of utility, the danger is that in practice they will applied. If the law insists that the PTO and the courts make judgments about whether "specific benefit exists in currently available form," it is likely that many decision-makers will be tempted to take that regulatory reality into account in applying and developing patent standards. The law and the PTO would do well, in my view, to repeatedly and emphatically make clear that the requirements for distributing a drug under the Food, Drug and

Cosmetic Act, or under any other regulatory regime, have no applicability at all to patent law.

Patent law seeks to increase the rate of research about potential new products and leaves it to people and market forces to choose the nature, type, timing and commercial use of the results of the research. The Food, Drug and Cosmetic Act seeks to decrease the rate of research about potential new products, and to replace private, market-driven decisions with government decisions. Adopting Food, Drug and Cosmetic Act standards for patent law (whether formally or informally) would be economic folly.

Third, the utility requirement in this area raises an issue that patent law does not address with much specificity. The question is whether the patent law does, or ought to, require some minimum level of certainty that the technical assertions in a patent application are true before a patent should issue. Should the patent law permit inventors to patent their guesses? Should an inventor be permitted to patent the use of a certain agent for treatment of a certain disease because he or she has some theory that, while somewhat plausible, is more likely than not to be untrue? Should Linus Pauling have been able to patent the use of Vitamin C for treatment of the common cold in the early 1970's? In my view, the law does and must insist that the information in a patent meet some minimum level of accuracy and correctness. I would impose that requirement not out of concern that some apparently goofy idea will in fact turn out to be goofy

and an utterly useless patent issue. Rather, I would be concerned that issuing a patent to the first person to take a wild stab, or even an educated guess, at a potential therapeutic invention decreases the incentives of other inventors, who are undertaking the costs and risks of determining whether such a therapeutic invention in fact will work. By "work", I mean have some biological or pharmacological activity in humans that might potentially be useful in treatment of disease.

The difficult question is how certain one must be before an application is filed. I do not have a good answer. For the near term, I can not do much better than suggest a "reasonable degree" of certainty, recogizing that test is not very meaningful. I would be inclined today to ask whether there is sufficient certainty that we would be willing to call-off all research by others on the same invention and rely on the person who developed the basis for that degree of certainty to carry on the work. The more difficult, but necessary, task is for us to decide how and where to draw that line. It is clear to me is that absolute certainty is the wrong standard, and that certainty to the extent required by the Food, Drug and Cosmetic Act is the wrong standard. Again, I understand the law to endorse those two views.

Fourth, if the law imposes a requirement that there be some degree of certainty about the correctness of an assertion of therapeutic utility, what is the standard that should trigger the PTO's ability to ask for proof and what is the proof that an

applicant must provide? Those are difficult questions. I have no clear answer. However, there are two things I would caution against.

The notice asks about "incurable" diseases. This is an area in which it is unwise to attempt to develop a particular legal standard for each type of disease and each type of therapy. I do not believe it is wise to automatically require proof or require more persuasive types of proof for proposed therapies for "incurable" diseases than for any others. The standards for requiring proof and the nature of the proof should be the same regardless of one's judgment of the history of success or failure in the past.[19] With the exception of a person's ability to patent a machine that violates the Second Law of Thermodynamics, I do not believe that patent law has historically applied any different standard in other areas of technology with long histories of failure. Bell, Edison, Marconi and the others faced no special obstacle when they pioneered new fields. I would not treat medicine differently.

It is also important that the law avoid placing patent applicants in this area in a substantive and, perhaps, procedural disadvantage that does not exist in other areas. My concern is with the operation of rules that shift some type of "burden" from the PTO to the applicant. First, if the law says some "burden" has shifted to the applicant, the law may unnecessarily bias the decision-making process against issuing patents in this area. In the close or difficult cases, and there are many, there is a

temptation to say the person with the burden losses. Second, the law may bias the process against issuing patents if the threshold for requiring proof is low and the threshold for satisfying the burden is high. For example, assume the rule (1) requires the PTO to insist on proof if the assertion of utility is not "likely to be true" or if there is a "reasonable" basis for doubt, and (2) requires that the proof must be "convincing," "persuasive" or some other word meaning very highly likely to be true. There is often a reasonable scientific basis for some uncertainty about therapeutic effects. In an area where the legal standard is not easy defined and there is always some inherent uncertainty about the facts, these rules may operate to require proof in all situations and then require very highly probative evidence, such as substantial human clinical trials, before a patent application may be filed or a patent issued. I believe we should be cautious about such a rule.

6. Standards Used In Measuring Nonobvious And Enablement Of Biotechnological Inventions

The law governing the application of the nonobviousness requirement, Section 103, (and its predecessor nonstatutory invention requirement) has been the most difficult patent doctrine to define and apply, in an area of the law with many serious contenders.[20] The enablement requirement has been less difficult in practice, but no less difficult in theory. These rules defy brief explanation. I would offer only these comments.

First, the notice refers to many decisions in this area by the Court of Appeals for the Federal Circuit and the Board of Patent Appeals and Interferences and notes that they provided "much needed guidance" when applying those standards to "biotechnology inventions." That statement prompts me to repeat what I said earlier. There is not as I understand the courts, and should not be, as I understand the purpose of the law, a separate body of biotechnology nonobviousness or enablement law. Nor should the actual decisions in particular factual settings be extrapolated in decision-making into other settings that look superficially similar.

This is not the first technical field in which the urge to develop shorthand formulas for deciding obviousness has been exhibited. The law books are full of cases that tried to articulate rules of thumb for determining obviousness. Perhaps the most famous was the so-called synergism test for determining the obviousness of "combination" inventions.[21] These rules of thumb have been repudiated.[22] We should be careful not to repeat those experiences in this important technical field.

Second, the notice frames the discussion of nonobviousness in terms of one of its elements, namely, determining the level of skill of an ordinary person at the time the invention is made. In my view, the law has not articulated wonderfully clear standards for decision-making about that subpart of the Section 103 analysis. The Court of Appeals for the Federal Circuit has pointed us to six factors to take into account, but it is far

from clear how to do so.[23] On another one occasion, the Court of Appeals for the Federal Circuit announced that a person of ordinary skill is one who "thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, often expensive, systematic research or by extraordinary insight, it makes no difference which."[24] However, that standard does not seem to uniformly run through all that court's decisions.

One of the factors the Court of Appeals for the Federal Circuit has said should be considered in determining the level of ordinary skill is whether the act is "advancing rapidly."[25] It has never been clear to me how to employ that consideration. The fact that technology in a particular area is moving rapidly does not suggest to me that, if patents are eliminated, the same advances will continue at the same rate. The patent system must be applicable to all industries and technologies, whether the pace of technical change appears to be fast, slow or nonexistent. Of course, the pace of technical change does alter the administrative burdens for the PTO in ways that Congress may dimly or slowly perceive in budget considerations. However, it is important that the PTO avoid any effort or tendency to micromanage the rate of technical change. If technical change in a particular technology appears to be slow, that is no reason to try to issue more patents to speed it up. Conversely, if technical change appears to be very fast, that is no reason to issue fewer patents to try to slow the pace.

Third, the notice refers to changes in the state of the art affecting determinations as to the level of skill possessed by individuals working in the field. While it is true that skilled people are deemed to have available to them the state of the art, I would caution against taking that notion very far. The danger is that, because the state of the art may, for example, include many examples of researchers successfully identifying and isolating genes for particular proteins, all similar efforts are deemed to be within the level of ordinary skill and all such activities deemed obvious and unpatentable. That is very unwise economic policy. The fact that many success stories are reported in the scientific and patent literature does not indicate to me that there are not many failures we can not read about or that the successes came easily and with little risk of failure.

My reading of the decisions in this area over the past about 150 years is, stated generally, that the economic purpose of the unobviousness requirement is to identify and eliminate from the realm of patentable inventions, those that involve such little cost and so little risk that it is highly likely, if not certain, that private producers of products (and today those who make a living as researchers) would have produced those inventions and done so at about the same time.[26] In short, the market would yield those inventions without the additional incentives provided by a patent. If that is the general economic purpose, the fact that many people have used generally similar strategies to, for example, identify and clone genes for particular proteins in many

prior situations, tells me little about whether it is economically sensible to grant patents for people investing effort and taking risks in attempting to identify and isolate other genes. If the costs and risks of that activity in a particular situation are significant, any resulting invention should be a serious candidate for a patent. The fact that many other people have followed similar strategies earlier and many had succeeded does not indicate that patents do not have an important role in inducing researchers dependent on the market from continuing to invest effort and take risks in that activity.

Viewed this way, decisions by the PTO and the courts under Section 103 are not merely technical decisions. They are technical and economic decisions of vast importance. If we lose sight of the economic purpose of the rule in the overall system, we may apply the rule in a way that is inconsistent with achieving the goals of the system.

The difficult issue is that the law has not defined with much precision the minimum levels of cost and riskiness that we require before we say that an invention is not obvious. Perhaps, we will do somewhat better in the future. However, the law does not and should not find inventions unpatentable, because a researcher sitting somewhere in an office would probably have recognized that (1) the invention was one of many possible ones to which attention might be given and (2) the most likely way of making it was a strategy sometimes used successfully in the past on similar problems. That those thoughts would have passed

through the mind of an ordinary person should not render the invention unpatentable, if there were significant risks and costs of carrying out the project. The reason is that simply because someone recognizes the possibility of making an invention and a potential way of doing it, does not mean that, in the absence of likely patent protection, researchers operating in the private marketplace, attempting to make money from that endeavor, would in fact have undertaken the program at about the same time.

7. Experimental Use Defense to Patent Infringement

The December 27, 1993 notice about hearings on the experimental use issue asked many important questions about the economic purpose of patent law and an experimental use doctrine. However, it frames analysis in two respects that I find less helpful than the current notice.[27]

In my view, the purpose of the patent system to promote innovation requires that a person who receives the patent for a particular product or process should not be able to preclude others from using that invention (and making embodiments of it) for the sole purpose of making improvement inventions or substitute inventions. The basic reason is that, if we permit an inventor to capture the value of commercial embodiments of the product or process embodying his or her invention (namely, those supplied to consumers or used to make products supplied to consumers) and the value of all subsequent potential inventions

whose development depends on use in research of the patented product or process, we would permit an inventor to acquire a patent whose value exceeds the value of that inventor's particular contribution. Hence, I have always assumed that a patent did not give the owner a right to exclude others from making or using the invention in order to make complimentary or substitute inventions. While I believe there is room for disagreement about my view of the economic consequences, my understanding of the development of patent law over the years by Congress and the courts is that this view is the prevailing one.

Until the early 1980s, I believe there was a doctrine which generally permitted others to use an invention in conducting research.[28] I believe that the reason there was so little litigation to test that proposition and so few cases, as the earlier notice indicated, was that there was universal consensus about that rule. While the words in the cases seemed somewhat narrower, most patent owners either understood (or operated on the implicit assumption) that others could conduct research using their inventions, when that research was designed to make other inventions, whether complementary or substitute, or to do research simply for the sake of doing research, historically the function of our universities. The Federal Circuit's Roche decision in 1984 and Congress' response to it, as well as other cases, have created confusion and uncertainty. The problem with the Congressional response is that it left unclear whether experiments other than those protected by that section are non-

infringing activities under the general experimental use doctrine.

Therefore, while I find nothing implicit in the public disclosure of the invention in the patent on the day it issues or in the quid pro quo theory to lead me to believe that use of an invention for experimental purposes should not be infringement, I believe it generally should not be. There are two situations where experimentation may be infringement. The first is experimentation involving the use (or making) of an embodiment of an invention, that is useful only in research and is incapable of any other use, such as use by ordinary consumers. Hence if someone invents and patents scientific instruments or reagents useful only by researchers, the making and use of such inventions for their intended purposes should be infringement. However, their use (and making) for the purpose of inventing improved or substitute versions of those instruments and reagents should not be infringement. The second is research conducted only for the purpose of developing a commercial product or process that would itself embody the patented invention. In other words, research undertaken solely and, perhaps, principally to implement a business decision to make, use or sell an infringing product may be called infringement. Such research is no different than building a plant to make the infringing product. It is logically infringement, since the principal value of that activity depends upon some subsequent infringing use of the invention in commercially used products or processes. An alternative is to

reach the same result by permitting an owner to bring an action for threatened patent infringement, whenever it appears that someone else has made a definite decision to infringe and has begun to invest in projects or facilities (including research projects) whose only use would be as a step toward the making, use or sale of an infringing product. However, the courts have limited the availability of that action to such an extent that it may be useful to alter infringement doctrines to make clear that the activity is an act of infringement. The hard cases will be where a company undertakes research that might logically be designed (1) to improve an invention or to find a substitute for it or (2) to use the invention commercially.

I do not find it helpful in these contexts to describe one kind of research as commercial or for business reasons, and another kind experimental or for philosophical reasons. Those distinctions seem to me to bias decision-making against private sector research enterprises that may be conducting research primarily for the purpose of developing improvements or substitutes, and yet, by virtue of their very nature, operate with a commercial and business-oriented goal.

I do not have a view at this time about whether this is a problem best taken to Congress, to the courts, or for patent owners and users simply to work out among themselves. My impression is that legislation might be appropriate in this area. If legislation is proposed, I do not believe that the legislation enacted after the Roche decision was necessarily a happy model.

8. Implications Of Pending Legislative Reform On PTO Operations And Examination Procedures

The notice invites comments about potential changes to the patent system, including a 20-year term measured from the United States filing date and automatic publication of application 18 months after the earliest effective filing date. I am not a proponent of these so-called reforms. My view is that, on balance, this 20-year patent term will diminish the expected economic value of a patent and hence the incentives to do research. The effective term of a patent would then depend directly on the length of prosecution. For complex inventions, prosecution is likely to exceed three years, and the value of patents for such inventions would decline. The length of prosecution for all inventions depends in part on the resources available to the PTO. Those resources depend on Congress, and the political process. If the political process allocates too few resources to the PTO, the system will be devalued. I am not aware of sufficient benefits to offset that cost and risk. I would much rather have dealt with the trivial number of so-called "submarine" patent holders by extensions of estoppel and laches defenses to conduct before the PTO. My view is that these changes are unwise and that, if we were the only country in the world, no one would have suggested them. However, we are not and the events of the last ten to twenty years cannot be rewritten.