

*Instead of legislation, Congress should let the courts continue to resolve the patent crisis.*

# Courts and the Patent System

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**T**he patent system is in crisis. The consensus in favor of strong patent protection that has existed since the 1982 creation of the Federal Circuit (the appeals court that hears virtually all patent disputes in the United States) has broken down. Patent owners — and the Federal Circuit itself — are beset on all sides by those complaining about the proliferation of bad patents and the abuse of those patents in court. Critics point to example after example: silly patents granted by the Patent and Trademark Office (PTO), lawsuits filed by people who invented something decades ago against companies who do something very different today, patent claims so confusing that no one can be sure what the patent covers, and so on.

But the patent system described above — the one in crisis — is not the only patent system in the United States. There is another system in which claims are clear, patents are subject to significant scrutiny, and strong protection is necessary to allow companies to recover hundreds of millions of dollars in investment. The prototypical industry that operates in this second patent system is the pharmaceutical industry, but other industries, including medical devices and chemistry, look more like this as well.

Talk to lawyers or businesspeople at technology companies about the patent system and you will quickly get a sense of our two different patent systems. In the pharmaceutical industry, there seems to be a strong consensus (at least among inno-

vative rather than generic pharmaceutical companies) that patents are critical to innovation. Their only complaint is that patents aren't strong enough. They don't last long enough to compensate for delays in the drug approval process, and the uncertain or probabilistic nature of patent scope and validity leaves them with uncertain protection for their enormous investment.

Lawyers and executives in the information technology (IT) industries, by contrast, almost invariably see the patent system as a cost rather than a benefit to innovation. Even IT companies with tens of thousands of patents generally use those patents only "defensively," to minimize the amount they must pay other patent owners to permit them to sell their products. Ask most of those companies, and in their candid moments they will tell you that they would be better off without any patent system, or at least with one that was radically changed and that left them alone to innovate.

## INNOVATION DIFFERENCES

Any doubts that the patent system is perceived by different industries in fundamentally different ways were dispelled during the past five years of congressional debate over patent reform. Different industries calling for reform couldn't agree on a single principle of reform. The pharmaceutical and biotech industries wanted harmonization on first-to-file, the elimination of the best-mode requirement, and the weakening of rules against inequitable conduct, but those changes were opposed by the IT industry. The IT industry wanted reforms to limit damages and injunctive relief in patent holdup settings and an effective administrative process to oppose patents, but those reforms were opposed by the biomedical industries.

In the last 20 years, legal and economic scholarship has pro-

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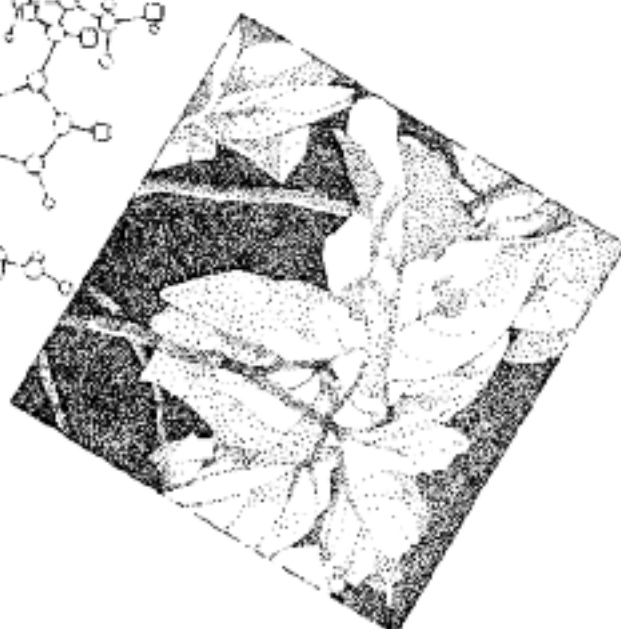
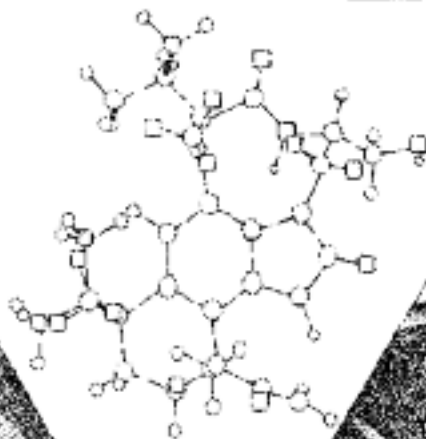
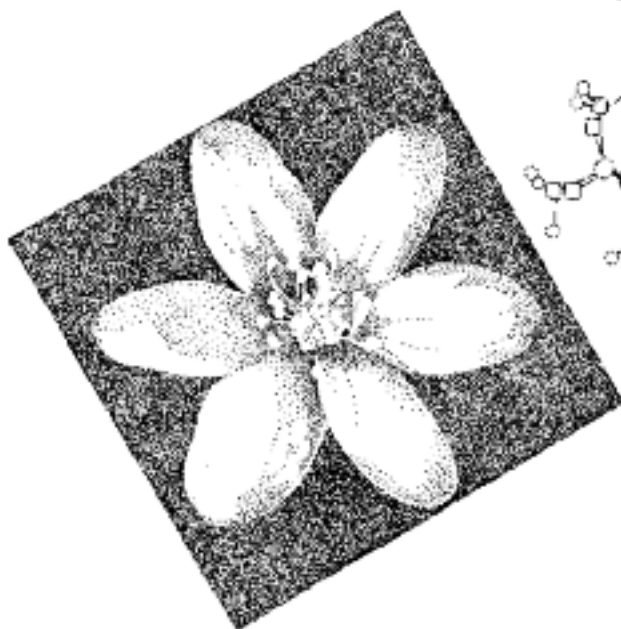
vided valuable evidence about the complex process of innovation and how the patent system affects innovation. Rather than resolve the debate over how well the patent system works, however, this evidence has painted a more complex picture. Different industries vary greatly in how they approach innovation, the cost of innovation, and the importance of innovation to continued growth. One size definitely does not fit all. This observation is graphically illustrated by examples from several industries, whose characteristics we sketch here.

First, the cost of research and development varies widely from industry to industry and from innovation to innovation. In the pharmaceutical industry, for example, the research and development, drug design, and testing of a new drug can take a decade or more and cost, on average, hundreds of millions of dollars. Some — probably most — of this cost is a result of the labyrinthine regulatory process and the detailed study that is required to determine that a drug is safe and effective for humans so the Food and Drug Administration will approve it. A major additional part of the cost stems from the uncertainty of the research and development efforts.

Pharmaceutical companies may try hundreds of compounds before identifying a possible drug, and they may not know for years whether they have chosen the right one for testing. Drug companies need some way to get a return on that significant investment.

Another example of an industry where invention requires significant investment is semiconductors. As microprocessors have gotten smaller, their design as well as the facilities and processes used to create them have grown exponentially more complex. Building a new microprocessor requires not only painstaking work on circuit design — work that can cost tens of millions of dollars — but also the design and construction of an entirely new fabrication process in a new facility. The need for both highly skilled labor and a dedicated physical plant makes microprocessor development highly resource-intensive. Ultimately, the design of a new generation of microprocessors takes years of planning and construction and can cost more than \$4 billion.

By contrast, other industries require significantly less investment in research and development. In the software industry,



for example, it has long been possible for two programmers working in a garage to develop a commercial software program. The cost of writing code has gone up in recent years, particularly for operating systems. Operating systems tend to be more complex than applications programs because operating systems must be written to run a variety of computer programs and control various hardware devices. But it is still possible in many cases to hire a team of programmers to write a new applications program for less than \$1 million. Although debugging a new program is still a significant undertaking, writing such a program takes considerably less time than developing a new drug or producing a microprocessor.

Further, in software and many other industries, particularly biotechnology and the manufacture of machines and consumer products, much of the innovation process has been automated in the last 15 years. Although computer-assisted design and manufacturing tools do not replace the need for innovative ideas, they make the process of prototyping and testing those ideas much easier and faster. Similarly, powerful bioinformatics databases and the development of mass-production techniques like polymerase chain reaction have revolutionized the biotechnology industry, making the identification of gene sequences and the development of related therapies much cheaper and quicker than they were in preceding decades. The use of automated tools that actually generate sections of code to help design simple programs such as websites has made computer programming simpler. The result of this automation is that industries in which traditional innovation was largely an iterative process of optimizing prototypes today require less research and development expenditure than those that require either live testing or a new manufacturing process.

Economic evidence has also shown industry-specific variation in the corporate nature of innovation. The prototypical innovation contemplated by the patent law is made by an individual inventor working in his garage after hours. But innovation in most industries today is generally collaborative and much of it requires large laboratories. The overwhelming majority of patents today are granted to large corporations, and even those granted to individuals and small corporations are often incubated in large research universities. The role of individual inventors is much greater in some industries, such as mechanics and software, than in others, such as biotechnology and semiconductors. And not surprisingly, corporate innovation tends to cost more than innovation by individuals.

### **DIFFERENCES IN PATENTING PRACTICE**

The systematic variation in research and development expenditures across industries naturally affects the need for patent protection. Industries that must spend more time and money in research and development generally have a greater need for patent protection in order to recoup that investment. That doesn't mean that the patent system has no place for cheaper inventions; patents may still facilitate market transactions in new innovations. But certain industries have a stronger claim than others to need the incentives patents provide.

The effective scope of patents that do issue also varies

tremendously by industry. This variance results from the relationship between a patent and a product. Much conventional wisdom in the patent system is built on the unstated assumption of a one-to-one correspondence in which a single patent covers a single product. For example, we speak of patents covering products: in common parlance, Eli Whitney patented the cotton gin, Thomas Edison patented the light bulb, Alexander Graham Bell patented the telephone, and the Wright brothers patented the airplane. Modern patent law also assumes such a one-for-one correspondence in its decision to measure damages by the profits lost in the sale of infringing products.

However, such a correspondence is the exception rather than the rule in the modern economy. Machines of even moderate complexity are composed of many different pieces, and each of those components can itself be the subject of one or more patents. No inventor could patent a modern car, for instance. Rather, he would be required to patent a particular invention — say, intermittent windshield wipers — that is only one small piece of a much larger product. This correspondence may have been overstated even in the classic inventions mentioned in the last paragraph: the Wright brothers did not in fact patent an aircraft; their patent actually covered the use of a vertical rudder and a fixed wing (the “aeroplane”). Edison's patent was an improvement on an existing light bulb that claimed a particular class of incandescent filaments. Still, the traditional mechanical nature of invention was more susceptible to the one patent–one product correspondence than the more complex modern environment.

The strength of this correspondence varies by industry. In some industries such as chemistry and pharmaceuticals, a single patent normally covers a single product — a new chemical or a new use for that chemical. In industries such as semiconductors, by contrast, new products are so complex that they can incorporate hundreds and even thousands of different inventions — inventions frequently patented by different companies. A patent covering one of those hundreds of components will not effectively protect the product; it is useful, if at all, only as a licensing tool. Further, this difference means that we cannot simply apply the remedy rules from one industry to patents in another; if damages are calculated correctly, patents in the semiconductor industry will tend to generate much lower royalty rates than in the single-patent product industries. Mark Lemley and Carl Shapiro, in a 2007 *Texas Law Review* paper, offer evidence that courts do not fully take these differences into account, but they still find industry-specific variation in royalty rates. Still other industries fall somewhere in between. Products in biotechnology or software may require the integration of several different patents, but not hundreds of them. The correspondence between patents and products obviously affects the significance of patents in protecting research and development.

Industries differ in the importance of continued innovation. Innovation is, in general, socially valuable. In many industries, especially young ones, innovation is critical to welfare. But innovation works very differently in different industries. In some industries, notably pharmaceuticals, inno-

vation tends to be a stand-alone process generating a single finished product. Once a drug is developed and tested, it tends not to be improved. At most, pharmaceutical companies will improve the delivery system or patent obvious chemical variants such as metabolites. By contrast, in computer software, cumulative innovation is extraordinarily important. It is received wisdom among software consumers that you shouldn't buy version 1.0 of any program. The expectation is that the programs will be incrementally improved over time. These differences in innovation have great significance for patent policy because they bear on the importance we should attach to pioneer innovation in various sectors as opposed to continuing improvement.

The relationship between patents and innovation is at least as complex as the profile of technological and economic factors that determine innovation. There is no simple or universal correlation between the availability of patents and the incentive to innovate. Indeed, as the American Enterprise Institute's Bob Hahn has put it, "the most general lesson to be gleaned from the patent literature is that there are few general lessons." This is due in part to the fact that the patent system interacts with industries at several different points in the innovation process. Recent evidence has demonstrated that this complex relationship is industry-specific at each stage of the patent process: deciding to seek protection, obtaining a patent, setting the scope of a patent, deciding to enforce a patent, and determining litigation outcomes.

Rewriting the patent law for each industry would involve substantial administrative costs and uncertainty. Congress would have to write new statutes not just for biotechnology and software, but for numerous different industries with special characteristics. Semiconductors, pharmaceuticals, chemicals, nanotechnology, telecommunications, and other industries would all need separate statutes. Past experience with such specialized statutes is also not encouraging. The history of industry-specific statutes suggests that many fail because they are drafted with then-current technology in mind and are not sufficiently general to accommodate the inevitable changes in technology.

### **PATENT POLICY LEVERS**

The need for industry-specific statutory tailoring implicates the broader question of legal generalization versus particularization, of which the issue of rule-based or standards-based decision making is, perhaps paradoxically, a particular instance. Law necessarily contains general prescriptions for governing behavior, prescriptions that may fit particular instances well or poorly. Where the fit is poor, it may be sensible to equip decision makers with discretion to tailor the general prescription. The patent statute equips courts with precisely such discretion via a series of doctrinal "policy levers" that allow patents to be calibrated to the needs of particular industries.

For example, a number of factual questions in patent law are answered from the perspective of the "person having ordinary skill in the art" (PHOSITA). Much of the case law concerning the PHOSITA arises out of the consideration of the

obviousness standard found in § 103 of the patent statute. Although originally developed as a common law doctrine, the non-obviousness criterion was codified in the 1952 Patent Act as a requirement that the claimed invention taken as a whole not be obvious to one of ordinary skill in the art at the time the invention was made. The PHOSITA is equally central to calibrating the legal standard for patent disclosure. In return for a period of exclusive rights over an invention, the inventor must fully disclose the invention to the public. The first paragraph of § 112 requires that this disclosure enable "any person skilled in the art" to make and use the claimed invention. This same standard controls several other disclosure doctrines as well. First, the definition of enablement affects the patentability requirement of specific utility, as the invention must actually work as described in the specification if the inventor is to enable one of ordinary skill to use it.

As the name suggests, PHOSITA-based analysis is specific to the particular art in which the invention is made. Courts measure most significant patent law doctrines against a benchmark that varies by industry, and within industry by technology. If the court concludes that an art is uncertain and its practitioners are not particularly skilled, it will be inclined to find even relatively modest improvements non-obvious to the PHOSITA. At the same time, the court will be inclined to require greater disclosure to satisfy the requirements of § 112, and correspondingly to narrow the scope of claims permissible from any given disclosure. If the art is predictable and the PHOSITA quite skilled, the reverse is also true. The result is to make the PHOSITA a potentially significant macro policy lever, awarding many narrow patents to some industries and a few broader patents to other industries.

There is overwhelming evidence that the application of the PHOSITA standard varies by industry, leading for example to fewer but broader valid software patents, and more but narrower biotechnology patents. It is less clear that the court is in fact using the PHOSITA explicitly as a policy lever, responding to the characteristics of particular industries, rather than merely trying to predict what those of skill in the art would think.

In 2007, the Supreme Court changed the standard of obviousness in the *KSR* case. Rather than focus on the existence of a written suggestion in the prior art, the Court said, the test for obviousness must focus on the knowledge and abilities of the PHOSITA, including whatever creative or innovative tendencies the ordinary scientist in the field possessed. In one fell swoop, the Court turned obviousness from a search for written suggestions in the prior art, regardless of industry, to a question of what the PHOSITA in a particular field would know or could figure out. In so doing, *KSR* gave courts the power to use obviousness doctrine as a whole as a case-by-case policy lever, one that will lead to more valid patents in industries in which the PHOSITA knows little or is uncreative, and more invalid patents in industries with more sophisticated players.

### **EMERGING POLICY LEVERS**

Patent rights are exclusive rights that fit the classic formulation of a "property rule." Indeed, the patent right to exclude

was regarded by the Federal Circuit as a nearly absolute property rule, and the assumption that a finding of patent infringement will be accompanied by an injunction was almost universal from the mid-1980s until 2006. In fact, however, the patent statute provides only that courts may grant injunctive relief, not that they must.

The legal standard for *preliminary* injunctive relief has vacillated over time. Preliminary injunctions were virtually impossible to obtain before the creation of the Federal Circuit. The Federal Circuit substantially liberalized the standard for granting such injunctions in the 1980s, but then tightened it considerably in the 1990s, to the point where today preliminary injunctions are quite rare. The court has the discretion under the statute to do something similar with permanent injunctive relief. In copyright cases, as opposed to patent cases, the Supreme Court has on several recent occasions encouraged the lower courts not to grant injunctive relief as a matter of course.

On rare occasions before 2006, courts in patent cases refused to grant permanent injunctive relief, for example in cases where courts found a strong public policy interest in continued access to the invention. This suggests that injunctive relief can serve as a policy lever by industry or on a case-by-case basis. Courts could deny injunctive relief in some industries altogether. Some consumer advocates suggest that life-saving drugs ought to fit into this category, for example. Alternatively, courts could deny injunctive relief on a case-by-case basis depending on other characteristics that differ by industry, such as whether the plaintiff actually practices the invention.

We recently witnessed the creation of a policy lever in real time. In its 2006 decision in *eBay v. MercExchange*, the Supreme Court rejected the longstanding rule that patentees who won their cases were automatically entitled to an injunction shutting down the infringing product. Relying on the statutory language and common-law principles of equity from outside patent law, the Court held that the decision whether to enjoin a defendant's product must be made on a case-by-case basis after considering four (really three) factors:

- Will the plaintiff suffer irreparable injury without an injunction, or is there an adequate remedy at law?
- Will the hardship to the defendant from granting an injunction outweigh the hardship to the plaintiff from denying the injunction?
- Where does the public interest lie?

The Court emphasized that those determinations should be on the basis of individual facts, not rigid rules or tests.

Dozens of district courts have applied those standards in the past two years. Despite the case-by-case nature of the inquiry, the district court opinions have established some general rules. Patentees who compete in the market essentially always get injunctions under the four-factor test, because it is extremely difficult to determine what would have happened in a counterfactual world in which the patentee actually had market exclusivity. Hence, damages are unlikely to be adequate as a remedy for the lost market share that infringe-

ment causes. In contrast, patentees that do not participate in the market, but merely seek to license their patent to those who do, can almost never satisfy the four-factor test because by definition what they want is money damages in the form of a reasonable royalty. Further, almost all of the non-practicing entity cases arise in complex technology industries in which the patent covers only a small component of the larger product. In those cases, the balance of the hardships strongly favors the defendant because an injunction will shut down not merely the infringing technology, but a much larger set of non-infringing technologies attached to it. There is only one exception so far to this general rule that practicing entities get injunctions and non-practicing entities don't: an aberrational Texas district court opinion that held that special rules should apply to nonprofit entities.

This developing distinction operates as a policy lever. While practicing and non-practicing entities exist in every industry, the reality is that in some industries such as pharmaceuticals, the patentees are almost all practicing entities, while in the IT industries a high percentage of patent plaintiffs are non-practicing entities, sometimes called "trolls" for the practice of hiding under a bridge and popping up to demand a toll from surprised passersby. A rule that practicing entities generally get injunctions while non-practicing entities generally do not has dramatically different effects in the pharmaceutical and IT industries. Coupled with apportionment of patent damages, a rule that limits injunctions to plaintiffs that really need them has the potential to help solve the problems with abuse of the patent system while preserving a strong property rule entitlement for those who really need it.

### INSTITUTIONAL ROLES

The fact that courts proved capable of solving many of the problems on which new legislation has repeatedly foundered suggests that policy levers, not industry-specific legislation, may be the most effective way of dealing with problems in the patent system. Sen. Patrick Leahy (D-Vt.), discussing the most recent efforts at patent law reform, recently remarked that Congress cannot leave reform to the courts because "Congress writes our laws." But even though Congress undoubtedly makes the laws, frequently the best way to make those laws work is to write them so that the details of their application are delegated to the courts.

Skeptics of the judicial approach might rightly observe that litigation is not cost-free, that judicial expertise is bounded, and that appellate courts in particular are not entirely immune from problems of public choice. However, all advantages are comparative and the question is not whether courts are the perfect statutory tailors, but whether we are better off with no tailoring at all. If we're not, then given the risks of industry-specific statutes described above, we must ask if the courts are better situated to engage in tailoring than are legislatures. The likelihood that a unitary, unvarying, and monolithic statute could supply the correct level of incentive to so many diverse industries with divergent incentives is essentially nil. The prospect of the legislature continually revisiting the

circumstances of each industry and passing appropriate new legislation for each situation is equally bleak. In democratically elected legislatures, an enormous commitment of political capital is typically required to draft, promulgate, and reach consensus on new intellectual property legislation, especially if the legislation is to be supported by credible fact-finding and reliable expertise. We can anticipate serious legislative investigation of, and response to, specialized industry needs to be relatively rare and potentially counterproductive when it does occur.

This is not to say that there cannot be a carefully modulated adjunct role for an agency — in this case, the Patent and Trademark Office — to play in statutory upkeep. But the PTO by design sees only one piece of the patent puzzle: the question of whether a patent should issue in the first place. It never sees infringement disputes, or licenses, or has to allocate remedies. As a result, even if we thought the PTO were best suited to setting industry-specific standards for determining patent validity, there is no reason to believe the PTO staff has any comparative advantage in deciding many of the most important questions of patent law. The PTO may be best suited to creating rules that govern practice before the office itself, such as the information applicants must submit or the ability of applicants to use continuation applications. Most particularly, there may be such a role if the agency can be held to what it does best, which is fact-finding, without becoming involved in setting legal standards, which is the strong suit of the courts. But it is a far cry from application of the PTO's fact-finding expertise to the sort of dynamic interpretation of legal rules with which courts have experience, and which we suggest the patent system needs.

“Wait a minute!” some readers might object. “Aren't you arguing for judicial activism?” Not so. If “judicial activism”

means anything beyond a conclusory label suggesting that the speaker disagrees with the court decision, it refers to courts usurping the role of Congress, generally by invoking the Constitution to strike down congressional statutes. We are suggesting something different. Within the framework created by Congress, there remain a large number of issues to be determined, and it is the proper job of the courts to resolve those disputes. That much has been uncontroversial since *Marbury v. Madison* was decided in 1803. The question is how courts are to resolve those issues in the absence of congressional guidance and subject to legislative veto. We think it makes sense for courts in that position to take account of the realities of the modern patent system. And foremost among those realities is that our unitary patent law confronts an amazing diversity of industry needs and experience. For courts to ignore that diversity in setting the rules it necessarily must set strikes us as foolish.

## CONCLUSION

Both innovation and patent law unquestionably work differently in different industries. The law can either take account of those differences or seek to ignore them. Ignoring them would require major changes in existing law. It would also leave the law ill-equipped to deal with the fundamentally different ways in which innovation works in different industries. Indeed, given the crisis of confidence the system currently faces, it is not much of an exaggeration to say that the patent system must bend or break: a patent system that is not flexible enough to account for these industry differences is unlikely to survive, let alone accomplish its stated goals. We believe the system has the flexibility to do both, but this will require the courts to recognize and use the policy levers they have been given. **R**

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