

Just say no to a broad research use exemption in the US

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Innovation depends on patents. Patents advance both industrial application and scientific research by getting technologies to be used broadly and rapidly. As a result, arguments to weaken or eliminate the enforceability of patents in research areas such as biotechnology or nanotechnology are seriously misguided.

Some commentators urge an expanded research use exemption (RUE) to address the supposed problem of patents blocking scientific research. This is a solution in search of a problem. Theory predicts and data confirms that patents don't block research; they advance it. For this reason, the US patent system has been wise in long resisting a broad RUE that would allow particular users to infringe the patent rights of others. Furthermore, a broad RUE would actually frustrate science. A broad RUE, for example, would kill the golden goose that has made the US basic biotechnology sector the world's leader. It would undermine the complex commercialisation process that depends on patent enforcement.

Simply put, patents help, not hurt.

Patents get technologies put to use

Despite the brevity of the US Constitution, its framers thought patents so important that they included in it an express grant of power to Congress for passing patent laws. Congress exercised its power early and President George Washington signed America's first patent statute into law on 10th April 1790. The US patent system was overhauled a few times and the version we use today is essentially the 1952 Act.

The 1952 Act was built on the premise that patents drive the commercialisation of technologies. The central benefit of patent protection in all fields of science, whether

basic or applied, is that inventions get put to use broadly and rapidly. Bringing an invention to market requires coordination among its many complementary users, including developers, managers, labourers, other technologists, financiers, manufacturers, marketers and distributors. And this coordination depends in at least two fundamental ways on the expectation that patents will be enforced:

- The credible threat of the right to exclude that is associated with a published patent acts like a torch in the dark, drawing to itself all those interested in the patented subject matter. This beacon effect gets these diverse actors to interact with each other and with the patentee, starting conversations among the relevant parties.
- Widespread expectation that the patent can be enforced motivates each of these parties to reach agreement with each other over the use and deployment of the technology. This bargaining effect falls apart if the parties are unsure the patent will be enforced because, in that case, there is no need to reach agreement. The fear of weak enforcement creates a disincentive for the necessary parties to work together at the outset.

The profit potential associated with an enforceable patent incentivises everyone in the commercialisation process. Not least of all, the promise of financial pay-offs brings the capital investments essential to start and sustain businesses. And the certainty of enforcement is what convinces the diverse members of an early venture to commit their unique skills to monetise assets to their joint enterprise.

The example of US biotechnology

Patents have been and remain integral to ensuring that the US is the world's biotechnology leader. Although some claim

that adding patents to an industry undercuts competition, the natural experiment history has provided in biotechnology shows the opposite result. As the leading jurist Judge Jerome Frank stated decades ago, when David battles Goliath, vibrant competition is dependent upon investment in David. This needed investment will not occur unless David is armed with the patent slingshot.

The landmark *Chakrabarty* decision by the Supreme Court in 1980 resolved what some thought was an open question and confirmed the availability of patents in basic biotechnology. The rest of the world made the opposite decision and still has various rules that block effective patent protection for biotechnology.

The US, Europe and Japan each had large biotechnology companies, often collectively called Big Pharma, before 1980, and each has continued to have them since 1980. Companies in all three regions have had access to technological and capital resources, but only the US added the ability to obtain a wide range of patents to the mix. And only in the US, and only since 1980, has the biotechnology industry also included a pool of roughly 1,400 small- and medium-sized companies that is consistently turning over.

The unique growth and competition in the US biotechnology industry has directly benefited both the basic biological research community by providing expanded resources such as funding and the general public by providing better goods and services in important industries such as healthcare. In addition, many of the small- and medium-sized biotechnology companies provide the cutting-edge, patented reagents and equipment that other scientists need to conduct research.

A decade after *Chakrabarty*, the US continued to make the largest commitment to basic research in biological sciences worldwide. By 1990, private industry, not the federal government, was the single largest source of funding for biotechnology research and development. According to a recent collection of studies by the National Research Council (NRC), the singular growth of biotechnology in the US is due largely to the link between industry and academic science facilitated by the availability of biotechnology patents. The NRC also credits biotechnology patentability with allowing the US to make better use of biotechnology as a research tool. According to Dr William Raub, formerly of the National Institutes of Health: "Many biological scientists, perhaps most, regard the patent process as a means of institutionalised secrecy, whereas it is in fact

a time-tested way to assure broad and ready access to proprietary information."

Patents keep the US's biotechnology industry vibrant and competitive. Undercutting this success and retarding the US biotechnology sector could well be the consequence of adding an expanded RUE.

The specific question of research tools

Scientists want to spend their time and effort doing their own scientific work, not making the tools necessary to do that work. Patents make it easier for scientists to get access to these needed resources in two key ways: first, patents are at the heart of the business models used to develop the reagents, equipment and other inputs that scientists need; and second, patents allow businesses to fashion delivery channels for these inputs that are easy for end-user scientists.

Countless new technologies in basic biology that have substantially improved how scientists do research owe their success to the protection of patents. For example, the invention of recombinant DNA enabled the entire field of modern molecular biology, which relies on DNA being easy to cut and reconnect. Similarly, the invention of monoclonal antibodies allowed binding reactions to be highly specific and reproducible. The patents on both of these enabling technologies were licensed broadly to universities.

Patents also have allowed businesses to deliver powerful tools for improving basic research. For example, the owner of the patents on the polymerase chain reaction (PCR) created a range of successful business lines for providing all of the materials and equipment needed to conduct this Nobel Prize-winning procedure for amplifying minute quantities of DNA on almost any laboratory bench-top at low price, with consistent supply and for ready delivery. Likewise, Symyx, the owner of patents on path-breaking technologies for high throughput automated research, has enabled chemical companies such as Dow and Exxon Mobil to develop new compounds that already account for hundreds of millions of dollars a year in sales.

Furthermore, the essential new tools that patents bring to science are easy for scientists to use precisely because of the business models patents enable. For a scientist to gain access to a patented technology such as a basic reagent, she does not have to spend time and money to hire a team of expensive lawyers. One illustrative example of the ease with which patented tools are made available to a basic scientist

The benefits of the freezer programme model

In the freezer programme model, the patent is assigned or licensed to a business that arranges for the patented biological material regularly to be brought fresh and frozen to the scientist's university department or lab. The business then charges the scientist's research account only for the quantities actually used.

From the scientist's perspective, the entire process is as easy as getting a can of soda from a soda machine: the cold drink is reliably supplied and paid for each time without the help of a single lawyer or accountant. Further, the patent-based freezer programmes save the scientist from having to spend the time and other resources needed to obtain the material herself, freeing her up to do science. In addition, these businesses help the scientific community at large by providing a uniform source of research tools, equipment and other inputs that decreases variability across scientific experiments, and thereby increases the reproducibility that lies at the heart of the scientific method.

Patents empower junior academic scientists

Competition is not limited to the economic marketplace; and not all scientists interact with others in ways that promote science. In academia, motivations often revolve around markets for more emotional and personal assets such as fame, peer recognition and other kudos. Sociologists of science recognise that as basic science has grown more expensive and complex, the scientific community has become increasingly stratified and power to distribute kudos has been concentrated in a small number of individuals and organisations.

Consider the case of a junior scientist denied permission to use a new technology by a more senior academic wed to an existing paradigm that the junior's research might challenge. Even if the senior academic's technology does not have patent protection, the senior academic may still exert influence over grant-making committees, promotion boards and editorial boards of major publications in ways that can frustrate, if not block, the junior scientist's research. Patent protection responds to the problem facing the junior scientist by providing her with the option of raising financial and other support outside of the academic community, such as from the financial institutions on Wall Street or the venture capitalists in Silicon Valley.

Patents promote competition by empowering academic Davids to challenge established dogma and shift paradigms by freeing them from the gate-keeping of academic Goliaths. For these reasons, the view that patents frustrate scientific development by undercutting norms such as communism and academic freedom gets it exactly backwards. The empowerment that patents bring Davids hinges on the certainty that patents will be enforced, including in areas of research.

Similarly, although the so-called open source communities in the computer software sector, which avoid patents, are touted as offering open participation, empirical studies of different open source software projects show that they are in fact closed in important respects. A small number of individual cohesive groups exercise exclusive control over changes to the actual projects in these cases. Just as in academic science, patents in software help Davids enter the market without having to pay homage to such powerful gatekeepers. Remember, the software industry of the 1970s and 1980s was devoid of meaningful patent protection and yet infamously associated with a single large player, Microsoft.

is the widespread freezer programme business model (see box on page 10).

The longstanding RUE is deliberately limited

Under longstanding interpretation of the US patent system, there are two bodies of law that people point to as creating RUEs. The first comes from old language that appears in some cases and so exists only as a matter of common law. The second comes from a relatively new statute designed to help generic pharmaceutical companies compete against branded drugs.

The common law RUE has long been understood, and was recently reaffirmed in *Madey v Duke*, to be extremely narrow, exempting only those uses that are "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry". For academic researchers, who do much, if not all, of their work to further philosophical inquiry, the RUE allows a very limited amount of research to be conducted on patented technologies to determine whether they work as described in the patent. It does not allow the user of a patented technology to be legally exempt from infringing simply because the use has to do with research or is for research

purposes. The distinction here is between researching with and researching on; between a business purpose that would not be exempt and a purely philosophical interest that could be.

Expanding the exemption in the hope of benefiting every party performing research would do violence to the entire patent system by undercutting incentives for all patents, including incentives to develop enterprises that deliver technologies helpful to those doing research.

The limited nature of the common law exemption from infringement does not mean that most researchers end up being liable for infringement or otherwise frustrated in doing research. Far from it. The empirical data shows that vast numbers of researchers either easily buy licensed research tools through channels such as the freezer programmes or are given licences from patentees for free. No special legal exemption is needed.

Although the statutory RUE is more complex to understand, and broader in its reach in some respects, it is still narrowly targeted to a specific regulatory issue. A review of the drug industry's regulatory system helps illuminate how the statutory exemption operates.

Often, generic drugs are kept from competing with branded drugs by two basic factors: Food and Drug Administration (FDA) regulatory approval; and patents. Obtaining FDA approval requires the generic to generate and then submit for regulatory review a host of data about how its version of an existing branded drug operates. This is time consuming.

Patentees often deny patent permission for generics to conduct the experiments needed to get FDA approval. And the common law RUE does not protect the generics since their research is not merely to test whether the patented technology works, but rather to use their own version of it for commercial advantage.

The combined effect is to keep generics from beginning the lengthy FDA process until the underlying patents have expired. This interplay between the patent and FDA systems could keep generic versions off the market beyond the expiration of the branded drug patents.

In 1984, Congress passed the Hatch-Waxman Act to respond to this interplay by doing a few things, including allowing the FDA approval process for generics to begin before the branded drug patent term expired. The Hatch-Waxman Act was designed to

provide a specific limited exemption from patent infringement for only those uses of patented drugs that generic companies needed to show the FDA that their version of the drug was about as safe and effective as an already approved branded drug. This is a narrowly targeted RUE that in all other respects acknowledges the importance of patents and their enforcement. Expanding the reach of the Hatch-Waxman Act to exempt more research uses would frustrate the important role that patents play in advancing research and commercialisation.

Despite the clear legislative intent to limit the Hatch-Waxman Act's exemption for infringement, the Supreme Court in the recent *Merck* case treated the exemption so broadly that the court gave a free pass from infringement for work relating to preclinical studies of a new drug seeking FDA approval.

A careful reading of the *Merck* decision would not extend its impact beyond the narrow facts of the case. Any other view would be an overly strained reading of the opinion and would undercut the important policies of the patent system. The *Merck* decision must not unduly expand the purposefully narrow Hatch-Waxman exemption Congress enacted.

Arguments for an expanded RUE make no sense

Proponents of an expanded RUE make two central arguments. Both are wrong. Importantly, this is not a case of no harm, no foul. Expanding the RUE would seriously undermine patents' vital role in advancing science.

The first argument is that the patent system needs to be updated to deal with the new technologies of today and tomorrow. Patent critics conjure up the image of America's Founding Fathers, dressed in 18th century fashions, who surely could not have anticipated that the patent system they provided for in the Constitution would be applied to modern marvels such as molecular biology or nanotechnology. But the charge that the law must be updated to deal with new technologies is illogical when it comes to patents.

The entire patent system, with its core patentability requirements of novelty and non-obviousness, was designed to embrace unforeseen technologies. As Chief Justice Warren Burger pointed out in the *Chakrabarty* case: "A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability."

It makes no sense to argue that changes

are needed to update our patent system in recognition of technologies that are new. The patent system more than recognises the possibility of the unforeseen – the unforeseen is what's patentable.

The second argument is premised on the belief that patents block downstream research. This argument is misled by some academic work on the theoretical problem called the anti-commons. There is no anti-commons problem with patents.

The original academic work on the anti-commons problem sought to explain why so many storefronts in the post-socialist economies were left unused. The work found that a large number of bureaucrats were able to deny permission for the space to be used and called the resulting underuse an anti-commons.

The more recent work claiming an anti-commons problem for patents mistakenly stresses this fragmentation of interest – ie, how many different people have a say over an asset's use – as the key to the anti-commons effect. But more important than the number of people who have a say is the type of people with a say and the type of say they have. By focusing on the number of patent permissions needed to use a technology, patent critics have ginned up arguments that the patent system could create an anti-commons.

The US patent system is fundamentally different from the unused storefronts of the post-socialist economy. Where the permission of post-socialist bureaucrats was required, open efforts by the bureaucrats to trade their permission for personal gain were likely to trigger various forms of legal liability for graft, bribery, public corruption and the like. Patent rights are different, because a US patent owner has incentives to engage in, not avoid, open transactions. Transactions over patents are not only allowable, they are important to monetising the value of the patent. Patentees have a strong incentive to encourage use, not to block it. Transactions over patents are also different from transactions with post-socialist bureaucrats in the way the law enforces patent-related transactions. Unlike the bureaucratic permissions of the post-socialist state over which transactions so often failed, patents are clear, certain, owned by a person who is easily findable for free on the web at www.uspto.gov and who is allowed openly to sell licences or assignments; and the resulting contracts are openly enforced by courts.

One could imagine that the number of patent permissions needed to get business done could lead to high prices and difficulties

Don't blame the patent owner

Even when there are occasional breakdowns in negotiations over patents, why let patent critics blame the patentee? Patents are wasting assets, with at most a 20-year term, and their enforcement is vulnerable to defences of laches and estoppel. Further, the value of patents depends on the use of the patented technology. Thus, patentees are incentivised to see their technologies put to use on acceptable terms. Nothing stops a potential user of the technology from making a favourable offer to the patentee. And it would be odd to blame the patentee for refusing to license on unfavourable terms simply because another wants to use the technology. Imagine a rule that allowed a stranger, anytime he sees that you are not putting your car to a use he likes, to take your car and later pay some price a court ordered if you elected to sue all the way to final judgment.

Refusing to enforce patents when there is a breakdown in negotiations triggers a fundamental circularity by creating perverse and harmful incentives. If the ability to avoid the injunction resulting from an infringement action hinged upon the failure to reach a licensing deal, then there would be a strong incentive for those wanting to use the patented technology to resist striking an arm's length deal with the patentee and instead to ask the courts for better terms. A legal test that rewards a failure to cooperate would lead to a decrease in cooperation, not an increase.

In short, the fact that parties do not reach a mutually beneficial licensing arrangement is not a basis on which to cram down a licence on the patentee. To force on a property owner, including a patentee, an unfavourable transaction undercuts the basic purpose of property rights generally and the patent system specifically.

structuring the needed transactions. But even a quick scan of the internet shows that this problem is not real. The typical laptop computer represents a bundle of thousands of patent and other intellectual property permissions, yet the negotiation to buy one takes only a few clicks of a mouse and costs as little as US\$1,000. Patent rights do get licensed and bundled, resulting in goods and services offered in every sector of the economy for the widespread benefit of us all.

The proof is not just on the internet or anecdotal. Several rigorous surveys have been conducted of basic scientists to determine as a matter of fact whether patents are interfering with their work. The answer is a resounding no.

Despite there being many patents in basic science, having many diverse owners, there is no evidence that a significant number of scientists get held up by the need for patent permissions. Many are given express permission for free and many others are in effect given free permission because the patents are not enforced against them. On other occasions, licensing arrangements are successfully negotiated. As canvassed in a 2006 review article by Cauffman *et al* in the journal *Nature Biotechnology*, the empirical data is in and shows that patents don't block science. There is no anti-commons problem with patents. Fears about a patent anti-commons provide no grounds for an expanded RUE.

We must implement the right reforms

At least two types of RUE-related reforms are likely to be considered for the patent system in the near term. Reforms to expand the common law RUE statutorily should be rejected, while reforms to limit or reverse *Merck* statutorily should be implemented.

Allowing an expanded RUE would seriously undermine the industries that advance science. Enterprises in these industries rely on patent protection for their business models, which allow them to provide reagents and equipment to researchers in a standardised fashion with such affordable prices and convenience that it frees up scientists to do science.

Much is made about the problems of so-called upstream patents and the benefits of so-called downstream patents. Upstream patents are said to be bad because they block downstream use. Downstream patents are said to be good because they help important industries.

A fundamental problem with this rhetorical dichotomy between upstream and downstream is that it is false and narcissistic. Terms such

as upstream and downstream are so relative that they are simply synonyms for things to be bought and things to be sold by any individual, who will of course want everything he buys to be free and everything he sells to be protected with property rights. This is neither a principled nor an effective basis upon which to design a patent system that helps anyone other than those regularly able to maintain sufficient political influence to ensure that they are always seen by regulators and courts as sufficiently downstream of their rivals.

In the near term, the best way for Congress to advance science and benefit society through improvements to the patent system is to reassert its original intent for the Hatch-Waxman Act. Specifically, Congress should clarify that the Act exempts from infringement only those uses of a patented drug that are needed to obtain so-called me too approval for a drug by a party lacking patent permission from a patentee who already is on the market with that drug. Efforts to add any RUE must be rejected.

The proposals for an expanded RUE are responding to an imagined and unreal problem. It would be tragic for science and society to give parties what amounts to a right to infringe, when the heart of their concerns, if any, is a mere disagreement over licensing terms. An expanded RUE would force patentees to give a free licence and do violence to the entire purpose of patents.

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