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PATENTS

Research tool patents and the experimental use exemption—a no-win situation?

Because their very purpose is experimentation, applying the experimental use exemption to research tool patents requires a close analysis.

Philippe Ducor

The experimental use exemption to patent infringement has long been considered a benign issue, used mostly to exempt academic scientists from the hurdles of the patent system. More recently, the exemption has surfaced in relation to experimental activities of generic drug manufacturers eager to enter the market soon after the expiration of lucrative drug patents. The increasing number of research tool patents in biotechnology will undoubtedly fuel the debate, further challenging traditional views on the experimental use exemption. Some have asserted that research tool patents are potentially damaging, restricting entire fields of basic research, and have offered the expansion of the experimental use exemption as a possible remedy¹. However, because their very purpose is experimentation, applying the experimental use exemption to research tools is especially confusing. This article aims to clarify the exemption in the context of research tools, while keeping in mind the economic policy considerations underlying the patent system.

Economics of exemption

Courts have long recognized the necessity for some experimental use exemption to patent infringement, as it is believed to serve the ultimate goal of the patent system, which is the promotion of innovation. This innovation-promoting policy of patents has two competing aspects, both deserving of protection: (1) In order to promote innovation, the patent system gives initial inventors an incentive to innovate by providing them a monopoly on their technical advances. Innovation stems from the reward afforded to inventors. (2) In order to *further* promote innovation, the patent system has to limit the monopoly of patent owners so as not to hinder subsequent research and improvements on existing technology. Innovation stems from the free availability of existing technologies, including patented ones.

The grant of privative patent rights directly supports the first aspect of the policy,

while the experimental use exemption serves the second. Both are necessary for the proper implementation of the innovation-promoting policy of the patent system.

As can be expected, the problem with this rule resides in the definition of what exactly can be considered an “exempted experimental purpose.” For a long time—and still today, to a lesser extent—the main criterion when deciding whether the experimental use exemption applies has been to examine the commercial versus the noncommercial motivation of the experimenter. Commercial research essentially meant applied research in industry, while noncommercial research meant basic research in academic settings.

Only a clear, policy-minded definition of the exemption can ensure that all groups involved in scientific research—academic scientists, industry players, and policymakers—speak the same language.

From its inception, the commercial/non-commercial criterion has been daunting to apply, as it tends to systematically exclude from exemption all experimentation occurring in commercial settings. However, valuable follow-on research can and does occur in such contexts, and there is no policy justification for not exempting them. This criterion is even less justified today. On one hand, academic institutions are increasingly marketing their research, with undeniable commercial purposes. The biotechnology industry, meanwhile, is performing more basic research than ever, although such activities ultimately have a commercial purpose. Indeed, the line traditionally separating basic and applied research has all but disappeared.

Distinguishing among experimental purposes

A more sensible approach consists of distinguishing between experimental and commercial use. Adopting the principle laid out

in the Community Patent Convention², several European jurisdictions exempt from infringement “acts done for experimental purposes relating to the subject matter of the patented invention.” These are experiments aiming to understand and/or improve the technology embodied in the invention, or experiments *on* the invention. In other words, experimenting *on* patented inventions is exempted because it relates to the subject matter of the patented invention, while experimenting *with* patented inventions infringes because it does not relate to the subject matter of the patented invention. The US Congress itself used the distinction in its failed attempt to codify the law on the experimental use exemption³.

Experimenting *on* a patented invention amounts to research in the technical field to which the invention pertains, and can lead to further innovation in the field. In this situation, the invention is used for a different purpose from that for which it was originally designed. Such use represents only a minimal loss of revenue for the patentee, as his or her main market resides in other, nonexperimental uses. Accordingly, exempting these activities from patent infringement is consistent with the innovation-promoting goal of patents, as it fairly balances the two competing aspects. That such exempted activities may ultimately lead to improvements or new competing products, patentable or not, does not change the analysis.

In contrast, experimenting *with* a patented invention amounts to using it according to the purpose for which it was first designed, and for which the patentee was granted a monopoly. These activities do not “relate to the subject matter of the patented invention” and do not contribute to innovation in the pertaining field as they leave the invention essentially unchanged. Accordingly, there is no policy reason to exempt such activities from patent infringement. Doing otherwise would deprive the patentee from his or her main market and deny any value to his or her patent. The first aspect of the innovation-promoting policy of patents would be completely sacrificed for the second. Once again, that such activities might lead to innovation in fields other than that of the patented invention, patentable or not, does not change the analysis.

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RESOURCES

The distinction can be clearly seen in a hypothetical example using a patented scale. If an experimenter is interested in weighing technology and performs experiments on the patented scale, his or her activities are covered under the experimental use because they potentially contribute to innovation in the field of weighing technology. These activities do not significantly encroach on the market of the patentee, as they do not use the scale according to the purpose for which it was designed (weighing things), but for advancing knowledge on weighing technology. Should such research lead to a competing product—for example, a new, improved scale—the outcome depends on whether or not the new product falls in the scope of the original patent. If so, the experimenter has to obtain a license from the initial patent owner before commercializing the new scale, and the patent owner ultimately profits from third-party improvements on his or her technology that might not even have occurred except for the experimental use exemption. If the new scale does not fall within the scope of the original patent, the experimenter deserves the full revenue of his or her innovation.

However, an experimenter who makes the patented scale and uses it in the lab to weigh ingredients for chemical research, infringes the patent on the scale. He does not contribute to innovation in weighing technology, ultimately leaves the scale untouched, and merely uses it as a tool. By using the scale according to its primary purpose, the experimenter deprives the original patent owner from revenue that is due to him by virtue of his or her patent monopoly. The fact that he might contribute to advances in the field of chemistry, patentable or not, does not excuse him from infringing the patent on the scale.

Research tools—so special?

Research tool patents concern products and processes whose main purpose is to be used in experimental research. Typical examples of research tool patents in biotechnology include the basic Cohen–Boyer patents on recombinant technology, polymerase chain reaction (PCR), expressed sequence tags, drug discovery assays, sequencers, etc.

As mentioned, applying the doctrine of experimental use exemption in the context of research tools seems especially confusing and appears at first sight to be a no-win situation. Preserving the interests of the patentee by denying any experimental use exemption goes against the free-access aspect of the patent policy, which aims to promote follow-on research. Because research tool patents typically have broad claims, the potential damage to subsequent research is significant.

However, ensuring the free availability of

research tools by admitting a broad and undiscerning experimental use exemption goes against the incentive-by-reward aspect of patents, which motivates initial inventors to innovate. Indeed, because the very market of research tool patents is experimental research, exempting all experimental activities from infringement amounts to denying any value to research tool patents, causing irreparable harm to the patentee's interests.

But applying the experimental use exemption to research tool patents is neither impossible nor unfair, provided one keeps in mind the policy goals underlying the patent system and makes the right distinction between research *on* an invention and research *with* an invention. Using a research tool for its very purpose—that is, performing experiments of the type for which the research tool was first designed—is not exempted under the experimental use exemption, as such activities constitute the main market for the patentee and do not relate to the subject matter of the patented invention. Conversely, experiments studying and advancing the field to which the research tool pertains are covered under the experimental use exemption. Research tools are not so special after all.

The distinction between experimentation on and with a patented research tool can also be applied in the ongoing patent battle between Roche (Basel, Switzerland) and Promega (Madison, WI) over the patented PCR technology currently owned by Roche⁴. In the course of an ongoing legal battle over *Taq* polymerase that started in 1992, Roche named scores of academic scientists as infringers for using unlicensed *Taq* polymerase produced by Promega⁵. If, however, some of these scientists had been interested in improving PCR technology, and performed experiments on it or its components, such as *Taq*, their activities are covered under the experimental use exemption because they potentially contribute to innovation in the field of PCR technology and do not significantly encroach on Roche's market, as they do not use PCR according to the purpose for which it was designed (DNA amplification).

Should such research lead to a competing product—an improved, nonnative *Taq* polymerase, for example—the outcome depends on whether or not the new product is covered by the original patent. If so, the experimenter has to obtain a license from Roche before commercializing the new *Taq*, and Roche ultimately profits from improvements on its technology that might not even have occurred save for the experimental use exemption. If the new *Taq* does not fall under the original patent, the experimenter can exploit it freely.

Other scientists who make or buy unlicensed *Taq* only to amplify DNA in the lab,

do not contribute to innovation in PCR technology, and actually deprive Roche from due patent revenues. The experimental use exemption does not apply, and the experimenter is an infringer. That he might contribute to advances in the field of life sciences through the use of PCR does not change the outcome, hence Roche's stance toward academic scientists using Promega's *Taq*. Roche sued Promega in 1992 for infringement of its *Taq* patent and other contractual issues. Promega responded by arguing that the patent is unenforceable because of Roche's inequitable conduct during prosecution, among other grounds. A California court is to decide on this issue shortly.

The scope of the exemption for research tools may appear restrictive to advocates of an expanded experimental use exemption. However, experience has shown that no paralysis of research has occurred with existing research tools, and that a radical expansion of the experimental use exemption is not warranted. Basic recombinant technology and PCR are widely used around the world, and have contributed to countless advances in life sciences as well as fostering important follow-on innovations despite strong patent protection, uncertainty regarding the experimental use exemption, and sometimes—as in the case of PCR—a restrictive licensing policy.

What is needed, however, is a common understanding of the ideas underlying the debate. All too often, discussions on patent issues are undermined because of different interpretations of the same term. Experimental use is no exception. That research tools are by nature used in experimental settings is no indication that all uses must fall under the exemption. The purpose of the invention must be taken into account, as well as the purpose of the experimenter. Only a clear, policy-minded definition of the exemption can ensure that all groups involved in scientific research—academic scientists, industry players, and policymakers—speak the same language.

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1. Barton, J. *Int. Rev. of Ind. Prop. And Copy. Law* **26**, 605, 614 (1995).
2. Art. 27(b), Convention for the European Patent for the Common Market (CPC). Although it never came into force, the CPC inspired several European national law-making bodies.
3. H.R. 4970, 100th Cong., 2nd Sess. Chapter 9, Report 100-888, 51 (1988).
4. Lehrman, S. *Nature* **397**, 460 (1999).
5. Lehrman S. & Dickson, D. *Nature* **375**, 348 (1995).