Are Patents and Research Compatible?

DUCOR, Philippe


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Are patents and research compatible?

At a time when the number of biotechnology-based patent applications is soaring, it is essential that the law allows a significant 'experimental-use' exemption. The United States urgently needs to modify its legislation in this area.

Philippe Ducor

The patent system is generally agreed to promote innovation, by rewarding inventors with a limited exclusivity on their discoveries. But this goal is attained at the expense of subsequent innovators, who must first obtain a licence to use the patented technology before bringing it to the next step.

To avoid a chilling effect on subsequent innovation and to preserve the original purpose of patents, most countries' legal systems allow some degree of 'experimental use' on a patented invention without considering the patent to be infringed. In fields such as biotechnology, where the number of patent applications is soaring but where subsequent research is usually required before society can benefit from specific patented inventions, it is essential to have a significant experimental-use exemption enshrined in law. Although most European countries and Japan have included this principle in their patent statutes, the US Patent Act has not, the system relying on outdated case law. Considering its position as a world leader in biotechnology, the United States should urgently reconsider its policy.

Broadening uses of patents

Until recently, most patented innovations were incorporated in finished goods or other products and processes reasonably close to the market, as only then were they considered to be worth the cost involved in a patent application. Such inventions typically resulted from corporate scientists or engineers doing product-oriented, 'applied' research, for example the instant camera and the diesel engine. Academics were considered to be doing 'basic' research, motivated by more ethereal goals generally unrelated to financial profit: developing the theory of relativity or discovering the double-helical structure of DNA, to take two famous examples. These worlds remained essentially apart, and patents belonged almost exclusively to the business world.

Patent infringement cases involving experimental use were typically between commercial competitors over marketed or near-market products, and were usually decided against the defendant as the analysis focused primarily on the commercial versus non-commercial intent of the alleged infringer. The law, aiming to protect patent owners who would by definition lose no income from a non-commercial venture, seemed adequate at a time when basic research was hardly ever concerned with patents. Accordingly, experimental-use exemption has long been a relatively uncontroversial issue, confined to judicial dicta and isolated cases.

The advent of biotechnology has radically changed the picture, by virtually eliminating the traditional distinction between 'basic' and 'applied' research. Nowadays, fairly basic scientific information previously considered as strictly academic in nature can have a significant economic value in addition to scientific or academic prestige. As a result, both the biotechnology industry and non-profit research institutions have become interested in the same type of information, and are often equally aggressive in patenting their discoveries. Research collaborations between industry and academic institutions are now widespread, and many biotechnology companies have their origins in university-based research. In this context, the traditional test distinguishing the commercial from the non-commercial purpose of experiments has become essentially inoperative.

On the one hand, the non-profit nature of many university research activities is increasingly questionable. On the other, there is no policy justification to prohibit follow-on research occurring in commercial settings while allowing it in non-profit institutions, as the ultimate benefit to society does not depend on where the research is done.

Patents controlling research

The interest of corporations in basic research and of the academic community in patents has affected not only the number of biotechnology patents issued, but also their nature. A growing number of patents is issued on basic technology, where most of the value lies in the research potential leading to subsequent innovations. As a result, entire areas of research are now controlled by patents.

The Cohen–Boyer patent on basic DNA recombinant technology provides an early example. Thanks to the wise licensing policy of non-exclusivity and modest pricing adopted by the owner (Stanford University), the technology was widely distributed and contributed enormously to the subsequent development of commercial biotechnology. However, the outcome would have been radically different if Stanford had chosen instead a restrictive licensing strategy (exclusive basis, high prices), or granted no licences.

More recently, the Agracetus (now Monsanto) patent covering all genetically altered cotton stirred controversy, as the licence fee for using the technology was fixed at $1 million. This kind of amount is no obstacle for big companies, but it can force smaller ones out of business. Indeed, Mycogen, a company based in San Diego, temporarily abandoned its cotton research programme for this very reason. Out of concern that the Agracetus patent might seriously hamper cotton research, the US Department of Agriculture and another party petitioned the US
Patent and Trademark Office for re-examination. The issue is still unresolved, pending appeal.

In the Cohen–Boyer and Agracetus examples, one or a few broad patents control an entire research area. In other instances, many narrower patents have the same effect. To take HIV research, for example, patents have been issued on most aspects of the virus, resulting in a dense network of proprietary rights. Wild-type HIV strains, envelope proteins, regulatory genes, fused proteins and defective viruses have been patented in addition to innumerable other HIV-related inventions. This has prompted the US patent office to create a dedicated database, containing thousands of entries, available on the Internet at http://www.uspto.gov. Apart from a genuine ‘experimental-use’ exemption, scientists intending to use any of the patented technologies for their research have to depend on sensible licensing and enforcement policies from the respective patent holders. This amounts to leaving the implementation of a policy matter — promoting follow-on innovation — to private interests.

This problem could be tackled by questioning the wisdom of granting patents on exceedingly broad or basic technology — the US Department of Agriculture’s strategy in the cotton patent case — because this practice potentially dwarfs the innovation-promoting goal of the patent system. Prohibiting patents on such inventions would by the same token virtually resolve the problem of experimental-use exemption, as broad and basic inventions are the most likely to lead to further experimentation.

Unfortunately, existing patent laws are ill-suited for distinguishing between technologies that are too broad or too basic to justify patent protection, and others. They rely for this purpose on the fuzzy notions of ‘utility’ (equivalent to ‘industrial application’ in Europe) and ‘enablement’, which are often dauntingly difficult to apply in biotechnology. Besides these legal difficulties, there is no policy rationale to reward only inventors whose applications are close to the market, and not the discoverers of more basic innovations which often bring greater overall benefits to humanity. Accordingly, all inventions meeting the patentability requirements of patent law — utility, novelty, non-obviousness and enablement — probably deserve protection, notwithstanding their sometimes very broad or basic nature.

**Nuanced solution**

Instead of prohibiting certain patents, a true, policy-oriented experimental-use exemption offers a nuanced solution, allowing subsequent research to occur while preserving the interests of initial inventors. Experimental activity intended to bring the technology to the next step is freely allowed, whether in commercial or non-commercial settings. But as no patents need to be prohibited, initial inventors are allowed to reap part of the profits generated by follow-on research once a product (hence actual income) results.

The legal treatment of the experimental-use exemption currently varies from country to country. In most European countries and Japan, the principle has long been accepted and codified in patent statutes. The idea is to grant immunity for research relating to the patented subject matter, the aim being to bring the technology to the next step. Although the provisions existing in European and Japanese laws need to be constantly reinterpreted as new situations and technologies emerge — not every experimentation can be exempted from infringement — they are firmly grounded in their respective legal cultures and generally provide some room for experimental-use exemption in commercial settings.

Nothing similar exists in US law. Most of the experimental-use exemption doctrine is based on isolated dicta in two 1813 Massachusetts cases, focusing almost exclusively on the commercial versus ‘philosophical’ intent of the defendant. Accordingly, some level of experimental exemption seems to exist in US law, limited to non-profit research and subject to the uncertainties of uncodified jurisprudence. Amounting to a no-cost compulsory licence, the principle of experimental exemption has never been popular in US legal culture, traditionally averse to all forms of expropriation. Indeed, a codification attempt by Congress, the Patent Competitiveness and Technological Innovation Act of 1990, failed miserably.

In its 1984 decision Roche v. Bolar, the Court of Appeals for the Federal Circuit cast doubts on the existence of any experimental exemption in commercial settings. The defendant had conducted regulatory testing with the plaintiff’s patented drug Dalmane before the expiration of the patent, to obtain approval for the generic version of the drug as soon as possible after expiry. The court, while correctly deciding that such business testing was not exempted from infringement, insisted in an unnecessary dictum that the experimental-use exemption was “truly narrow”, and that “Bolar’s intended ‘experimental’ use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”. Although the main holding in Roche v. Bolar was legislatively overruled by Congress shortly thereafter (in the Drug Price Competition and Patent Term Restoration Act), the dictum leaves virtually no room for a commercially significant experimental exemption. This was tacitly confirmed in Scripps v. Genentech, decided three years later. In this case, Scripps was the owner of a patent covering the human blood-clotting agent factor VIII:C, as well as a purification method to obtain it. Genentech had used the purified factor to retrieve the human gene encoding it, which at the time was certainly not a routine procedure. Genentech subsequently succeeded in producing recombinant factor VIII:C by cloning the gene, and was about to commercialize it when Scripps sued for patent infringement.

Understandably, most of the attention in the case was drawn to the alleged infringement by Genentech in making recombinant factor VIII:C. However, the issue of experimental use was also very relevant. The district court judge decided without much explanation that the use by Genentech of the patented purified factor VIII:C as a starting point towards the corresponding gene infringed Scripps’ patent. Genentech itself did not invoke the experimental-use exemption, and the issue was not raised by either of the two courts that subsequently reviewed the case.

However, what Genentech did at the time with purified factor VIII:C was precisely the type of activity that should fall under an experimental exemption: using existing technology to bring it to the next step. Purified factor VIII:C was not only an end-product with a significant market; it was also a research tool indispensable to the next technological step. Although Genentech’s production of recombinant factor VIII:C was arguably infringing Scripps’ patent — commercialization of research results must be distinguished from research itself — the initial experimental use of the purified factor VIII:C should have been exempted from infringement. It is revealing that neither the successive courts in charge of the case nor the defendant itself made the distinction.

Many patents in biotechnology today are research tools (invitations to take the next technological step) rather than traditional end-products. In this context a true, policy-oriented experimental-use exemption is essential if the ultimate goal of the patent system is to be preserved. Failing to adapt to new research patterns, current US patent law threatens this goal by allowing research pertaining to specific fields to be confined to the relevant patent owners, and so solutions beyond the owners’ competence or imagination can be overlooked forever. That was not the intent of those who drafted the Patent Act.

Philippe Ducor is at Stanford Law School, Stanford, California 94305-8610, USA. Correspondence address: 18 chemin Pré Cartier, 1202 Geneva, Switzerland.

*e-mail: philduke@elandal.stanford.edu*