

Scientific Research and Intellectual Property in the Public Interest :

“Status of the Research Use Exemption”

— A contributed article from AAAS

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Intellectual property is important because it contributes to science and technology utilization, which in turn encourages economic growth. Policymakers should set out the proper scope of intellectual property protection so that scientific research progresses, leading to technological innovation.

According to Article 1 of Japan's Patent Law, intellectual property protection should “encourage inventions by promoting their protection and utilization so as to contribute to the development of industry.” In this sense, the Patent Law rewards inventors and provides incentive for new inventions by granting exclusive license to inventors or their successors for 20 years after patent application to compensate them for their disclosure of patented inventions and their contribution to technological progress^[1]. If patent protection is excessively narrow, researchers will lose their incentive to invent as well as their motivation to seek legal protection as compensation for their patent application or information disclosure. On the other hand, patent protection that is too extensive will prevent researchers from creating new inventions and commercially feasible products based on modifying other researchers' inventions. Thus, it is necessary to protect intellectual property rights at the proper level.

Exploring the proper patent protection level, the American Association for the Advancement of Science (AAAS) in the US launched a project to examine the relationship between science and intellectual property from a public interest perspective (SIPPI: Science and Intellectual Property in the Public Interest) in 2002. This project examines proper intellectual property protection in the science field, guaranteeing equity in access to the benefits of science and encouraging debate on intellectual property-related public policy^[3]. At its annual meeting in February 2004, AAAS held a symposium entitled, “Intellectual Property and the Research Exemption: Its Impact on Science” to discuss this topic^[4,5].

On the other hand, Japanese policymakers recognize the urgent necessity of clarifying interpretation of Article 69, Paragraph 1 of Japan's Patent Law, which stipulates that “the effects of patent right shall not extend to the working of patent right for the purposes of experiment or research.” There are a number of arguments that favor this patent exemption. Influential scholars argue that such exemption should apply to “activities that aim at technological progress,”^[2] but the Japanese courts have not yet clearly expressed a ruling in this regard.

With rapid technological innovation and deeper collaboration among universities, industries and government, it is increasingly necessary to clarify experiments and research activities beyond patent right protection. The “Intellectual Property Promotion Plan 2004” (dated May 27, 2004) states that the government will provide a clear guideline in FY2004. The Intellectual Property Policy Headquarters has been studying this issue.

Dr. Audrey R. Chapman, co-director of the above-mentioned AAAS project, kindly sent us her paper on the “Status of the Research Use Exemption” as a contributed article for the Journal of Science and Technology Trends.

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[A contributed article from AAAS]

Status of the Research Use Exemption

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Science and Intellectual Property in the Public Interest / AAAS

1 | Background

Because science is one of the most international of all activities, advances in science require the freedom of inquiry, the full and open availability of scientific data on an international basis, and the open publication of results. Growing tendencies to seek copyright and patent protections for scientific data, research tools, and materials, as well as for discoveries, are therefore imposing new costs and problems for scientific research.

Until recently, most developed countries provided extensive public funding for basic scientific research to assure widespread availability of and access to the findings.¹ Large government investments in basic research and development made it possible to argue that the conduct of scientific research, including the maintenance and distribution of scientific data, was a public good. Traditionally, research scientists actively pursued the dissemination of research results through the sharing of data and publication and were disinclined to patent their discoveries.²

However, the landscape, which encouraged the open availability and sharing of scientific discoveries has changed in major ways. Government policies, beginning in 1980 with the adoption of the Bayh-Dole Act in the United States, have encouraged the commercial development of publicly funded research. Universities, particularly in the United States and to a lesser extent elsewhere, now regularly patent the results of government-sponsored research and consider their research work to be an important intellectual property asset. Increasingly, basic as well as applied research is being funded by the

private sector. In turn, these developments have affected science's tradition of open publication. In many scientific fields, particularly the life sciences, scientists are delaying publication and withholding data so as to secure their intellectual property rights. A 1997 survey indicated, for example, that a substantial portion of researchers in the life sciences in the United States had delayed publication or withheld results and materials from colleagues to protect their intellectual property.³

Researchers and universities are now seeking intellectual property protection for research tools and other "upstream" research discoveries, especially in the area of genomic research, which would have been considered too far removed from the commercial marketplace to qualify for patent protection a generation ago. As universities have become increasingly aggressive patent owners, this has imposed restrictions on the transfer of research tools, materials, and reagents.

Within many sectors of science, the ownership of intellectual property rights is becoming fragmented across institutions in both the public and private sectors and, in the view of many, is becoming an "anticommons."⁴ This fragmentation or "patent thicket" often requires that researchers spend a significant amount of time locating a multitude of patent rights to pursue a project. This results in increased legal costs and financial burdens as scientists bundle licenses together licenses in order to conduct research or develop new products. Efforts to develop vitamin A enriched "golden rice," by an international team of researchers for example, required more than 40 separate licensing agreements.⁵

2 Existing Research Use Exemption Provisions

The general rule is that there is an infringement of a patent when an unauthorized use of the claimed invention takes place in the jurisdiction covered by the patent during the period of its life. However, this rule is subject to exceptions, one of which is an experimental use exemption. Several countries have statutes that in some circumstances provide exemptions for research carried out in private for non-commercial purposes and acts done for experimental purposes. Many European Union countries as well as Japan recognize a limited experimental use exemption, but the scope of the exemption is often quite narrow and in some instances unclear. In some jurisdictions, including the United States, Canada, Australia, and New Zealand, limited experimental use defenses are recognized in case law, although there remains a dispute over the scope.

There is significant variation in the scope and nature of the experimental use exemption. One key consideration is the difference between a right of experimentation on a patented invention and experimentation using a patented invention for broader research purposes. The patent laws of the United Kingdom and many other countries in the European Union explicitly limit the research exemption to the subject matter of the patented invention for purposes of research that “builds upon the knowledge provided by the patent, and aims to discover something unknown about the subject matter of the patent or to test a hypothesis about it.”⁶ Similarly, Japanese patent law states that “the effects of the patent right shall not extend to the working of the patent right for the purposes of the experiment or research.”⁷ This definition generally excludes the permissible application of the invention for broader researcher purposes, such as the development of new products. Another important distinction in national laws concerns the extent to which the applicability of the research exemption depends on whether there is some commercial motivation involved.

The U.S. Patent Act has no statutory

exemptions for noncommercial or research uses of an invention with the exception of legislative provision for clinical testing related to the development and submission of information for regulatory approval of generic pharmaceutical products.⁸ Nonetheless, many U.S. scientists had assumed that it was permissible for them to use patented information and resources without seeking explicit permission to do so if they did not intend to commercialize the products. A 2002 decision by the U.S. Court of Appeals for the Federal Circuit, however, rejected an “experimental use defense” in a patent infringement lawsuit against Duke University. The Court of Appeals ruled that neither U.S. law nor judicial precedent provided for such a research exemption. The Court also held that the non-profit or educational status of Duke University did not determine the availability of the experimental use defense because research projects with arguably no commercial application unmistakably further the institution’s legitimate business objectives.⁹ In June 2003, the Supreme Court denied a petition for review of the case¹⁰.

The decision in this case is likely to have major implications for the research community in the United States. Faced with this situation, many researchers and firms may choose to invest resources in less promising projects with fewer licensing obstacles and lower initial start-up costs. In addition, some researchers and developers, especially in universities, may be ill equipped to handle the multiple transactions necessary for acquiring the rights to research tools. It may also encourage academic research to be diverted to foreign institutions in countries with broader experimental use exceptions or the absence of patent coverage.

3 Reform Options

Given the situation noted above, instead of spurring investment and product development, more intellectual property rights may lead to fewer useful products for improving human welfare. At the least there is a need to clarify the scope of the experimental use exception in many jurisdictions so as to eliminate uncertainty. There would also be many advantages in

establishing more uniform provisions across countries consistent with the requirements of the TRIPS Agreement. It is the view of this author that the provisions of a statutory research use exemption should also be broadened to cover research using a patented invention. Options for reform of experimental use defenses are under consideration in several jurisdictions. The American Association for the Advancement of Science has recently initiated a project to evaluate these proposals so as to ascertain which would be the most conducive to encouraging scientific research and innovation.

Notes

- *1 Committee on Issues in the Transborder Flow of Scientific Data of the National Research Council, *Bits of Power: Issues in Global Access to Scientific Data*, (Washington, D.C.: National Academy Press, 1997), pp. 17, 133.
- *2 Amy E. Carroll, "A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Comment: Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law," *The American University Law Review* 44 (Summer, 1995): n.24.
- *3 Eliot Marshall, "Secretiveness Found Widespread in Life Sciences," *Science* 276 (25 April 1997), p.525
- *4 Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280 (1 May 1998), pp. 698-701.
- *5 Travis J. Lybbert, "Technology Transfer for Humanitarian Use: Economic Issues and Market Segmentation Approaches," *IP Strategy Today* 5 (2002): 18.
- *6 Quoted in Australian Law Reform Commission, *Gene Patenting and Human Health*, Discussion Paper 68 (February 2004), p. 388, 14.43.
- *7 Patent Law No. 121 of April 13, 1959, as amended by Law No. 220 of December 22, 1999, cited in Nuffield Council on Bioethics, *The ethics of patenting DNA: a discussion paper* (London, 2002), p. 61.
- *8 35 U.S.C. 271(e) (1).

- *9 *Madey Duke* 307 F 3rd 1351 (2002).
- *10 *Duke University v Madey* No. 02-1007 (Supreme Court of the United States 2003).

(End of Dr. Chapman's paper)

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- [3] AAAS, *Science and Intellectual Property in Public Interest (SIPPI)*: <http://sippi.aaas.org/about/>
- [4] "Impacts from Narrower Scope of Experiment/Research Use Exemption from Intellectual Property Right Claims in the US: How We Should Reconcile Intellectual Right Protection with Smooth Research Activities?" *Science & Technology Trends*, March 2004 Issue (in Japanese) :
- [5] AAAS Annual Meeting: <http://www.aaas.org/meetings/>
- [6] Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science*, Vol.280 pp.698-701 (1998)
- [7] Japanese script of Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" translated by Masako Wakui, *Journal of JIPA*, Vol.51, No.10 (2001)
- [8] *Bio Venture*. Vol.2, No.2 (2002)
- [9] The 6th and 7th document materials circulated at Patent Strategy Planning-related Issues Working Group, Patent System Subcommittee, Task Force on Intellectual Property Policy, Industrial Structure

Council, METI (January 20, 2004) 8 (in Japanese)

Explanation

- *(The tragedy of) The anticommons*

“The tragedy of the anticommons” means that excessive private property right protection of research outcomes will fragment intellectual property rights and prevent their effective utilization because there will no right holders who are able to utilize them effectively^[6,7].

- *Bayh-Dole Act*

The “Bayh-Dole Act” is officially the “Patent and Trademark Act Amendments of 1980” proposed by US senators Birch Bayh and Robert Dole. This legislation allows university, NPO and small- and medium-sized enterprises to entitle their federal-government-funded inventions. In addition, if they obtain a patent and license their invention to a third party, they are required to spend their royalty income on scientific R&D activities for inventors. Because of the Bayh-Dole Act, many universities started to establish Technology Licensing Organizations (TLO) inside or outside universities. This legislation has also paved the way for universities to obtain patents for government-funded research outcomes and also to transfer their technologies based on license agreements with private corporations^[8].

- *International comparison of legal frameworks in terms of “research activities exempted from patent right protection”*

Patent rights usually have certain limitations and are not applicable to research activities from the viewpoint of the patent’s characteristics and of public interest^[1]. Major nations have the following legal patent limitations.

i) The United States

In the United States, “experimental use exemption” originates not from statute law but from case law. “Experimental use exemption” is not applicable if the use of the patented invention is “in furtherance of

the alleged infringer’s legitimate business” and is not “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”^[9]

ii) The United Kingdom

Section 60(5) of the UK Patents Act states that “An act which...would constitute an infringement of a patent for an invention shall not do so if (a) it is done privately and for purposes which are not commercial; or (b) it is done for experimental purposes relating to the subject-matter of the invention...”

iii) Germany

Article 11 of German Patents Act stipulates that “The effects of a patent right shall not extend to (a) acts done privately and for non-commercial purposes; or (b) acts done for experimental purposes relating to the subject-matter of the patented invention...”

iv) France

Article 613, Paragraph 5 of France’s Intellectual Property Act sets out that “The effects of a patent right shall not extend to (a) acts done privately and for non-commercial purposes; or (b) acts done for experimental purposes relating to the subject-matter of the patented invention...”

v) Japan

Patent rights are only applicable for using patentable inventions for “business purposes.” This concept refers to the use of patentable inventions that do not fall under the “use of patentable inventions that is unrelated to industry, in other words, for personal use or family use.”

Article 69, Paragraph 1 of Japan’s Patent Law states that “the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.” While the Japanese courts have not yet clearly expressed an interpretation in this regard, influential scholars argue that experimental use exemption should apply only to “activities that aim for technical progress,” such as patentability investigation, the investigation of functions and experiments for improvement/development

purposes^[9].

• *Madey v. Duke University*

In this court trial, the US Supreme Court expressed its judgment on “experimental use exemption.” The plaintiff filed for an injunction on the grounds that Duke University’s experiments and research activities would infringe another person’s rights.

Professor Madey at Duke University installed some equipment in his laboratory. Several pieces of equipment in Madey’s laboratory were covered by patents owned by Madey. Duke continued to use the laboratory’s equipment even after his resignation. Based on this unauthorized use of his patents, Madey sued Duke for patent infringement. However, Duke argued that the university is a non-profit organization that provides education and that its continued use of the equipment falls under “experimental use exemption.”

The district court judged that Duke’s use of the equipment fell under “experimental use exemption,” but at appeal court level, the Federal Circuit Court denied Duke’s logic. In short, making clear its intent to limit the “experimental use exemption” strictly to activities that are “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry,” the court noted that, regardless of whether a particular institution

or entity is engaged in endeavors for commercial gain, as long as the act furthers “the alleged infringer’s legitimate business,” the act does not qualify as the very narrow and strictly limited “experimental use exemption.” (See *Madey v. Duke University*, 307 F.3d 1351 (Fed.Cir2002).)

In response to this ruling, Duke University filed a final appeal to the US Supreme Court, but the Supreme Court refused to grant a review in June 2003. (See *Duke University v. Madey* No. 02-1007 (Supreme Court of the United States 2003).)^[9]

• *The TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights)*

The TRIPS Agreement, which became effective on January 1, 1995, sets out the minimum requirements for WTO member nations in terms of patents and other intellectual property protection.

In terms of experiment/research exemptions, Article 30 stipulates that there are “Exceptions to Rights Conferred,” stating, “members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

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