

**Guidelines for Facilitating the Use of
Research Tool Patents in the Life Sciences**

March 1, 2007

Council for Science and Technology Policy

1. Introduction

- (1) In the domains of medicine and biotechnology, a single basic patent often enables the patentee to exclusively manufacture more than one product or use more than one method. Furthermore, a considerable amount of time and huge high-risk investments are required throughout the process from making an invention to putting it into commercial use. In this context, patents play an important role in promoting R&D and product development activities as well as creating innovation from achievements stemming from such activities.
- (2) In particular, most patents for research tools¹, such as genetically engineered animals and plants and screening methods, are applicable to various purposes and are helpful in promoting research. However, at the same time, they are often less substitutable. If research tool patents are not easily available for research, the R&D process becomes stalled. In fact, negotiations between patentees and users often proceed with difficulty due to differences in desired licensing terms, some of which have been brought to court for patent enforcement seeking injunction against research activities².
- (3) In order to address these problems, which take place not only in Japan but also in other developed countries, the OECD has established the Guidelines for the Licensing of Genetic Inventions (February 2006), providing policy for the broad licensing of genetic inventions for research purposes³.
- (4) In the United States, the National Institutes of Health (NIH) has also issued guidelines for disseminating research tools arising from government-funded R&D, and has disclosed information on the research tools retained by NIH and other governmental institutes, with the aim of promoting the use thereof⁴.

- (5) In Japan, among universities, etc.⁵ and private businesses with research tool patents, consensus has not yet been reached as to how best facilitate the use of these patents for research purposes. Nor has any information on such research tool patents or licensing terms therefore been made readily available to researchers.
- (6) Facilitating the use of research tool patents is an important challenge in the promotion of R&D activities in the life sciences and the creation of innovation from achievements in such activities, as well as the enhancement of the international competitiveness of Japanese industry. It is necessary to share this understanding among all relevant parties nationwide, including universities, etc. and private businesses.

2. Purpose of the Guidelines

- (1) In light of the circumstances described above and based on the understanding that balance should be achieved in practical operation between patent protection for research tools and promotion of their use, the guidelines aim to facilitate the use of research tool patents in the life sciences by expressing basic ideas in regard to cases where universities, etc. and private businesses use such patents in research.
- (2) Universities, etc. and private businesses are expected to endeavor to establish practical operations in line with the guidelines and avoid disputes involving research tool patents, thereby facilitating the mutual use of research tool patents in research.
- (3) In order to ensure practical operation in line with the guidelines, it should be noted that the guidelines present basic ideas for licensing in accordance with the Patent Act of Japan⁶ and they are applicable to research activities conducted in Japan, for which Japanese patents are effective.

3. Basic Ideas

Upon licensing, universities, etc. and private businesses that own or use research tool patents shall act in line with the basic ideas outlined below⁷. However, this shall not apply to research tool patents relating to products or methods that have already been commercialized and made available to the public in the market.

The guidelines shall also apply to inventions relating to research tools for which patent applications are currently pending.

(1) Provision of licenses

The holder of a research tool patent shall, when requested to provide a license for using said patent in the research phase⁸, provide a nonexclusive license as requested, unless doing so would affect their business strategy⁹, while giving due consideration to facilitating the use of research tool patents¹⁰.

(2) License royalties and licensing terms

Royalties for nonexclusive licenses for research tool patents shall be assessed as to their reasonable value by taking into consideration the nature of the research in which the patent is to be used and whether or not the patent in question has arisen from a government-funded R&D project¹¹; Upon making this assessment, due consideration is required to avoid any disturbance to the use of said research tool patent.

In particular, from the perspective of encouraging academic activities at universities, etc., it is desirable that licensing between universities, etc. be conducted for no charge (only requiring the cost of the tangible materials supplied)¹². This does not preclude any reasonable

licensing terms other than royalties¹³.

(3) Simple and speedy procedure

Parties to a licensing agreement on a research tool patent shall endeavor to ensure a simple and speedy licensing procedure. In this case, it is recommended that licensing documents be prepared using simple templates.

(4) Supply of tangible materials

When using research tool patents in research, users require, in addition to a patent license, the tangible materials needed when using said patents. Therefore, owners of such tangible materials shall endeavor to supply them under reasonable terms and through simple and speedy procedures.

4. Information Disclosure on Integrated Database

In order to promote the use of research tool patents, it is necessary to disclose and disseminate information on research tool patents owned by universities, etc. and private businesses (including patent-pending inventions in this chapter) and licensing terms therefor.

(1) Compilation of an integrated database

The ministries concerned shall compile an integrated database so as to disclose information on licensable research tool patents owned by universities, etc. and private businesses as well as tangible materials relating to such patents, e.g. the type of research tool, patent number, terms of use, license period, license royalties (actual royalty rates applied in the past), terms of payment, and contacts for negotiation. The database

shall be designed so as to enable bulk searches of such information as is necessary for promoting the use of research tool patents.

(2) Provision of information by universities, etc. and private businesses

Universities, etc. and private businesses shall endeavor to manage their research tool patents, and disclose information on licensable patents on the integrated database (e.g. licensing terms) if such disclosure is acceptable to them. With regard to research tool patents arising from government-funded R&D projects, they shall, in principle, provide information on such patents for disclosure on the integrated database.

(3) Disclosure of information on tangible materials

Universities, etc. and private businesses shall endeavor, to the greatest possible extent, to provide information on tangible materials relating to research tool patents and other tangible materials for the disclosure thereof on the integrated database if such disclosure is acceptable to them.

5. Dissemination of the Guidelines

(1) Publication of the Guidelines

The ministries concerned shall endeavor to publicize and disseminate the Guidelines among universities, etc. and private businesses, so as to ensure their appropriate practical operation in research. They shall also prepare and release simple licensing document templates for universities, etc. and private businesses.

(2) Development of licensing policies, etc.

Universities, etc. shall endeavor to publicize the Guidelines among

researchers and impart them with understanding thereof, and shall also endeavor to develop and release licensing policies and regulations as well as templates for licensing documents wherever necessary. Private businesses shall also endeavor, to the greatest possible extent, to develop licensing policies in line with the Guidelines and disseminate them.

(3) Public offering of R&D grants

The ministries concerned shall make clear in their outlines of publicly offered R&D grants in the life sciences that grant recipients will be required to comply with the Guidelines.

(4) Support for handling the royalty issue

The ministries concerned shall develop, with the cooperation of the universities, etc. and private businesses, example cases for setting royalty rates for research tool patents, and publicize such cases.

(5) Establishment of necessary infrastructure at universities, etc.

In order to promote practical operation in line with the Guidelines at universities, etc., the ministries concerned shall encourage them to establish the necessary infrastructure, including relevant regulations and intellectual property departments, and also provide them with support as necessary.

(6) Follow-up surveys

The ministries concerned shall conduct follow-up surveys on the status of research tool patent licensing and the disclosure of relevant information according to the progress in initiatives taken at universities, etc. and private businesses, and report the findings of such surveys to the Council for Science and Technology Policy.

¹ In the guidelines, the term “research tool patents (patents for research tools)” refers to Japanese patents granted with respect to products or methods to be used as tools for conducting research in life sciences, e.g. patents for test animals and plants, cell lines, monoclonal antibody, and screening methods.

² For example, a dispute over a research tool patent was determined in a judgment by the Tokyo District Court as of October 10, 2002 (Case No. 2004 (ne) 675). In this case, the US biotechnology venture holding a Japanese patent for mouse models of cancer metastasis sought an injunction to stop Hamamatsu University School of Medicine, etc. from using test mice in its research. The court determined that the defendant’s test mice did not infringe the patent.

³ The guidelines present basic ideas for facilitating the use of research tool patents in Japan, while respecting the intent of the OECD Guidelines.

⁴ The NIH discloses on its website information on research tools developed by researchers at US government institutes (NIH and FDA) such as the type of relevant tangible materials, existence/absence of patent, terms of use, period of license, actual royalty rates, and terms of payment. Many universities in the United States also disclose their research tools on websites.

⁵ In the guidelines, the term “universities, etc.” shall include universities, inter-university research institutes, colleges of technology, national institutes engaged in R&D, public test and research institutes, and special corporations and incorporated administrative agencies engaged in R&D.

⁶ Article 69(1) of the Patent Act provides that “a patent right shall not be effective against the working of a patented invention for experimental or research purposes.” “Experimental or research purposes” as set forth in this provision are construed to be limited to experiments for improving or upgrading the patented inventions themselves (See the report by the Working Group on Patent Strategic Plan Issues under the Patent System Subcommittee, Intellectual Property Policy Committee, Industrial Structure Council, entitled “Issues on Facilitating of the Use of Patented Inventions” (November 2004)). No court decision has been made on this provision.

⁷ When arranging licensing agreements, parties are expected to comply with the basic ideas of the guidelines; however, they may finalize agreements at their discretion while taking into consideration the circumstances of individual cases.

⁸ In the guidelines, the term “research phase” shall be understood as meaning the phase wherein universities, etc. or private businesses conduct basic research or preliminary research for commercialization. For instance, in the case of medicine, the phase prior to clinical trial is regarded as a research phase.

⁹ Business strategies would be affected in cases where: the patentee’s business plan includes the sale of said patented research tool as a commercial product; the patentee needs to use the research tool patent for carrying out R&D; in the research area to which the research tool patent pertains, it would be difficult to achieve commercialization due to competition with others without retaining the right to exclusively use said patent. This situation would also arise when universities, etc. attempt commercialization through joint research or university start-ups.

¹⁰ Holders of research tool patents shall, even when providing an exclusive license for research tool patents due to the need thereof for their business strategy, endeavor to take flexible measures, such as retaining the right to provide a nonexclusive license to

a third party in other research area.

¹¹ In the guidelines, the term “government-funded R&D projects” shall be understood as meaning R&D projects in which direct expenses are covered by government funds. Such funds include contract project expenses to be provided indirectly via the New Energy and Industrial Technology Development Organization (NEDO), the Japan Science and Technology Agency (JST), etc.

¹² Special consideration is required in the case of licensing of patents owned jointly by universities, etc. and private businesses, or licensing to universities, etc. engaged in research projects sponsored or jointly conducted by private businesses.

¹³ Possible licensing terms may include restrictions on sublicensing to third parties, prohibition of the use of the licensed patents for purposes other than their intended purposes, and protection of know-how relating to the licensed patents. Consideration should be given to ensure that licensing terms do not unduly restrict the freedom of presenting academic papers, and to avoid imposing such terms that might contravene the Anti-Monopoly Act, such as requiring that said licensee “grant back” the R&D achievements made by the licensed research tool patent to the exclusive domain of the licensor (grant-back clause).

Project Team on
Protection and Utilization of Intellectual Property in the Life Sciences
Expert Panel on Management of Intellectual Properties

(Chairperson)	Masuo AIZAWA	CSTP member
	Tasuku HONJO	CSTP member
	Mutsumi SANO	Officer/ Director of Intellectual Property Department, Takara Bio Inc.
	Sumio SUGANO	Professor, Graduate School of Frontier Science, University of Tokyo
	Koichi SUMIKURA	Associate Professor, National Graduate Institute for Policy Studies
	Megumi TAKATA	Technology Transfer Group Leader, Intellectual Property Management Center of Kyushu University
		Associate Professor, Graduate School of Economics, Kyushu University
	Masau TAKAYANAGI	Executive for Intellectual Property, Mitsubishi Pharma Corp.
(Chief)	Sadao NAGAOKA	Professor, President, Institute of Innovation Research, Hitotsubashi University
	Akimitsu HIRAI	Attorney at law/patent attorney, Lexwell Partners
		Guest Professor, Tokyo Medical and Dental University
	Keiko HONDA	Director, Toudai TLO, Ltd.
		Doctor of Medical Science
	Yoshinobu MUROFUSHI	Director, Intellectual Property Department, Pfizer Japan Inc.
	Patent attorney	
	Ryuichi MORISHITA	Professor, Graduate School of Medicine, Osaka University
		Director, AnGes MG, Inc.