

Draft Interim Report Summary for FY2007
Compiled by the Legislation Committee of the Subdivision on Copyrights within the
Council for Cultural Affairs

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The Legislation Committee
The Subdivision on Copyrights
The Council for Cultural Affairs
JAPAN

Section 3. Review of Limitations on Copyright

1. Pharmaceutical administration-related issues

Regarding limitation of copyright for making a reproduction of academic and research papers and/or other relevant documents for examination and distributing/providing it to healthcare professionals by a manufacturer and marketer of a drug or related product for the purpose of providing information required for the proper use of pharmaceutical products

(1) Defining the problems

The Pharmaceutical Affairs Law (Law No. 145 of 1960) obliges manufacturers and marketers of a drug or related product to make every effort to collect, examine, and provide information required for the proper use of pharmaceutical products to healthcare professionals (Article 77-3 of the Pharmaceutical Affairs Law).

In the provision of information by pharmaceutical companies in accordance with this stipulation, the reproduction and distribution of relevant literature may incur a need of handling copyright issues, for which there have been requests for limitations on copyright based on medical demands for the prompt provision of information and the present situation surrounding copyright management procedures.

For this issue, it was decided in the FY 2006 final report by the Legislation Committee of the Subdivision on Copyrights within the Council for Cultural Affairs that “For the time being, whether the developed systems will effectively work, in terms of collecting usage fees, should be closely followed using the utmost efforts. At the same time, continued consideration should be given to appropriate actions, duly based on the current status of reproduction for the purpose of providing information required for proper use of pharmaceutical products.”

According to the results of the FY 2007 survey on photocopy usage by the Federation of Japan Pharmaceutical Wholesalers Association, of all copyrighted works that need to be photocopied in order for individual information provision to healthcare professionals, approximately 70 per cent overall, including both domestic and foreign copyrighted works, are under the management of two copyright clearance bodies, or the Japan Academic Association for Copyright Clearance, Inc., or the JAACC (including those by the Copyright Clearance Center, Inc., or CCC) and the Japan Copyright Licensing System Co., Ltd., or JCLS (see Reference 1).

According to the Federation, pharmaceutical companies typically have a comprehensive licensing agreement with the JAACC for management of such copyright, while a copyright license agreement with the JCLS has yet to be established. (Notes by JCLS : JCLS has, however, already signed agreements with all of major document suppliers who supply photocopies to pharmaceutical companies which in turn supply them to healthcare professions.) JCLS is now in the process of preparing to start a discretionary management service (Notes by JCLS : For blanket arrangement for internal uses.) in accordance with the Law on Management Business of Copyrights and Neighboring Rights. Both parties are in talks about topics such as the details of license fee regulations, with the aim for concluding a comprehensive agreement for such service.

[Reference 1: State of management of literature in relation to information provision in accordance with Article 77-3 of the Pharmaceutical Affairs Law]

- Of the total number of copies of literature provided in accordance with Article 77-3 of the Pharmaceutical Affairs Law, 43.7% were based on requests from medical institutions and healthcare professionals, while the remaining was attributed to information provided voluntarily by companies.
- Of copyrighted works that need to be photocopied for the purpose of information provision, slightly below 70% were those for which licensing procedures are commissioned to one of the copyright clearance organizations (about 50% for domestic works).

<Management of literature>

Results of the FY2007 survey on photocopy use by the Federation of Japan Pharmaceutical Wholesalers Association (for external use)

Ratio by clearance organization (Domestic and Foreign copyrighted works combined)

Domestic / JAACC 9.00%

Domestic / JCLS 24.8%

CCC 35.7%

Not mandated 30.0%

Results of the FY2007 survey on photocopy use by the Federation of Japan Pharmaceutical

Wholesalers Association (for external use)

Ratio by clearance organization (Domestic copyrighted works)

Domestic / JAACC 14.0%

Domestic / JCLS 38.5%

Not mandated 47.5%

JAACC: Japan Academic Association for Copyright Clearance

JCLS: Japan Copyright Licensing System Co., Ltd.

CCC: Copyright Clearance Center

(Source: Federation of Japan Pharmaceutical Wholesalers Association)

(2) Results of discussions

1) Basic concept

In this discussion, usages for which limitations on copyright are requested are cases of information provision by pharmaceutical companies to healthcare professionals, excluding those of voluntary provision by pharmaceutical companies. In other words, they are considered to be cases in which provision of information is requested by healthcare professionals for the purpose of handling individual patients.

Such information provision is in accordance with the effort obligation as stipulated by the Pharmaceutical Affairs Law. They are related to the lives and bodies of patients, and thus considered to require in many cases a prompt response, for which it may also be inappropriate to take time in individual licensing for the reproduction of literature.

Given such circumstances, pharmaceutical companies and relevant organizations have been making efforts to establish a comprehensive agreement as discussed above. In fact, of all literature that requires information provision, approximately 70 per cent is under the management of relevant clearance organizations, including those under negotiation, while the remaining 30 per cent is not handled by a clearance organization and may face difficulty in promptly obtaining advance authorization.

Therefore, the majority of opinions supported that it would be appropriate to take some measure by means of limitations on copyright.

2) Directions in taking measures through limitations on copyright

In imposing limitations on copyright based on the discussion 1) above, it may be appropriate to take the following stance:

- a. Subjects of limitations on copyright, in line with the purpose of limitations on copyright which

regards it as inappropriate to take time in advance authorization in the cases that involve the lives and bodies of patients for which prompt measure is required, should be limited to cases of provision of information in accordance with Article 77-3 of the Pharmaceutical Affairs Law, i.e. made upon request from a medical professional for a pharmaceutical product that is manufactured by the pharmaceutical company for the purpose of providing information required for the proper use of the drug.

In other words, it should be ensured so that it excludes voluntary provision of information by manufacturing companies made unrelated to requests from medical professionals, and cases of providing literature that are not related to the drug that is offered by the pharmaceutical company, even if made in response to a request from medical professionals.

- b. In imposing limitations on copyright, it may be appropriate to oblige payment of compensation equivalent to the regular usage fee by the party to photocopy the literature to the copyright holder.

This is based on the concept that, given the presumption that literature as the potential subject of limitations on copyright may often be medical literature and is likely to be read by those who work in medical settings, provision of literature by pharmaceutical companies may potentially conflict with the interests of the right holder of the literature, hence imposing limitations on copyright without compensation may unfairly impair the economic interests of the right holders.

Concerning compensation schemes, some opinions suggested that payment should be secured for literature whose copyrights are not managed by clearance organizations, by means of pooling compensations, and it may thus be that those who make photocopies should notify the copyright holder of the fact or take other measures to ensure the compensations be effective.

3) Points of consideration

In designing systems in the stance discussed 2) above, it may also be necessary to note the following issues:

- a. In implementing a compensation scheme, it is necessary to have common understanding between the right holder and user concerning the amount of compensation. From this standpoint, the present situation in which efforts to establish a comprehensive agreement between pharmaceutical companies and the JCLS have yet to establish a consensus on usage conditions is of concern when assessing whether the compensation scheme will work in effect. It is thus first necessary for a consensus to be established between the concerned parties.
- b. In order to ensure that the regulations on limitations on copyright are securely implemented without the scope of regulations expanded for no practical reasons, it may be appropriate that pharmaceutical companies and other relevant parties take adequate measures such as developing

guidelines, so that whether the provision of literature by pharmaceutical companies is within the scope of scheme as specified in the 2) a. paragraph may be determined as objectively as possible.

- c. Considering that the purpose of limitations on copyright is based on the necessity of prompt measures in the cases that involve patient lives and bodies, it may be necessary to first discuss what type of scheme may allow healthcare professionals to obtain required information without waiting for literatures to be provided by pharmaceutical companies. In fact, considering that such a scheme of information acquisition by healthcare professionals has been developed in overseas countries before implementing limitations on copyright with regard to reproduction, it may be appropriate that, even if such limitations on copyright are realized, concerned authorities should continue discussion on these issues and to discuss as needed whether this scheme should be maintained.

4) Summary

As has been discussed above, it may be appropriate that provision of literature to healthcare professionals by manufacturers and marketers of a drug or related product should be subject to discussion of limitations on copyright under certain conditions, with the presumption that an adequate environment is to be developed for the effective implementation of the scheme, in terms of the status of agreements between pharmaceutical companies and copyright clearance organizations or initiatives to aim for proper implementation of the scheme, and that discussions as to whether the scheme should be maintained are to be made as necessary.