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Via e-mail: ch-houki@bunka.go.jp

Legislation Department Copyright Division Director-General's Secretariat Agency for Cultural Affairs 2-5-1 Marunouchi Chiyoda-ku, Tokyo 100-8959 Japan

Subject: Opinions to Draft Interim Report Summary by Legislation Committee

- 1. Classification: Group
- 2. Name of group: International Association of Scientific, Technical & Medical Publishers
- 3. Address: 2nd Floor, Prama House, 267 Bandbury Road, Oxford, OX2 7HAT, UK
- 4. Contact details: Michael Mabe, Chief Executive Officer; Phone: +44 1865 339321, Fax: +44 1865 339325, E-mail: mabe@stm-assoc.org, Web: www.stm-assoc.org
- 5. Page/title of item(s) at issue: Page 27-30 or Section 3, Paragraph 1 of the Interim Report Summary by Legislation Committee
- 6. Opinion

Dear Sirs,

The International Association of Scientific, Technical & Medical Publishers (STM) appreciates the opportunity to comment on the Interim Report Summary for FY2007 of October 4, 2007.

STM represents approximately 90 member publishers that are collectively responsible for more than 60% of the global annual output of research articles and publications of tens of thousands of print and electronic books, references works and databases. The works of STM publishers are sold and licensed electronically widely to academic and corporate libraries (e.g. pharmaceutical companies and medical professionals), educational institutions. The electronic, physical or other delivery of individual copies

of articles and books is an important source of revenue for scholarly publishers. Thus, selling and licensing is and continues to be one of the major markets for STM publishers.

It is our understanding that your department is considering a new limitation in Japanese copyright law that would permit pharmaceutical companies the reproduction of STM material, as indicated in section 3, paragraph 1, of the Interim Report Summary for FY2007 of October 4, 2007. In particular, it appears that, under paragraph 1 (2) 2) a of the above mentioned section 3, the limitation would allow the provision of photocopies of medical articles or other STM material by pharmaceutical companies, upon request from a medical professional, in order to provide information necessary for the adequate use of a drug of that pharmaceutical company, at no, or limited, compensation. This paragraph generally assumes that the provision of such photocopies was necessary because those cases involved the lives and bodies of patients, and therefore required prompt measures. Allegedly, the prior seeking of licenses would not be possible without putting the lives and bodies of patients at risk. In addition, it is suggested that the limitation should be in accordance with the obligation of pharmaceutical companies under Article 77-3 of the Pharmaceutical Affaires Law. That obligation, in other words, would be transformed into a copyright limitation.

We would like to stress that we have serious concerns with the introduction of such a copyright limitation, for a number of reasons, as follows.

I. Japan is, of course, a member of the major international treaties dealing with the protection and enforcement of intellectual property rights, including the Berne Convention for the protection of literary and artistic works (1971). An integral aspect of the Berne Convention is that only those exceptions to copyright are allowed that meet the "3-step" test, set out in Article 9(2). The "3-step" test, also embodied in Article 13 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement, 1994) reads: "Members shall confine limitations and exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the rights holder."

In our view, the limitation as suggested above would not meet the requirements of this test. It clearly conflicts with the normal exploitation of material published by STM publishers. In particular, it conflicts with STM publishers' reprint business, but also with the sale of single electronic articles of STM journals, as well as in general with the subscription business of STM journals. These three businesses are the core journal businesses of STM publishers, especially in the medical field.

Reprint Business

The reprint business has been developed by STM publishers since several decades of years. In the medical field, it has been developed to serve the interests of pharmaceutical companies. It is to be considered as the normal exploitation of articles of STM journals. Reprints are multiple paper copies of a single article of a journal. They are ordered by pharmaceutical companies to be then distributed to

medical professionals as a marketing exercise for the drugs analyzed in the respective articles. This reprint business is particularly concerned by the considered limitation. Instead of ordering reprints from STM publishers, the limitation would allow pharmaceutical companies to reproduce and distribute single articles themselves or to let them produce by document delivery services. According to the figures referred to by the Committee, the limitation would have the potential to eliminate 43.7 % of the reprint business. This, obviously, would put the entire reprint business at risk. The Committee refers in section 3, paragraph 1 (1), to the figures provided in the FY 2007 survey on photocopy use by the Federation of Japan Pharmaceutical Wholesalers Association, and suggests that the limitation should "only" include the provision of information supplied upon request of a medical professional. If the figures of the Association are correct, however, an impressive amount of 43.7 % of the information provided by pharmaceutical companies were provided upon a specific request of a medical professional. The considered limitation, therefore, would obviously conflict with the normal exploitation of articles published by STM publishers, and hence violate Japan's obligation under the Berne Convention. The estimate of Japanese publishing companies that some 30 million pages are copied upon request of medical professionals every year, confirms the massive potential damage for publishers.

Sales of Single Articles in Electronic Form/Subscription Business

The limitation clearly also has the potential to put STM publishers' sale of single articles in electronic form at risk. This business has been developed by STM publishers in 1997, and is the normal exploitation of single articles since several years. This service individually offers the articles of STM journals online, to be downloaded and printed, at a publisher set price. The suggested limitation could again have a massive impact on this business. Once more, the amount of 43.7 % of the provided information may serve as a point of reference. Instead of buying those articles from STM publishers in electronic form, pharmaceutical companies would be allowed to provide or let provide articles under the considered limitation. This exception appears to cover not only the provision of articles in printed/photocopied form, but also in electronic form. Pharmaceutical companies might thus be encouraged to stop buying articles from STM publishers, or even to cancel their subscriptions of STM journals. Medical professionals may commence to rely on the provision of information covered by the considered limitation, and might likewise start to reconsider their subscriptions. This demonstrates that the suggested limitation also conflicts with the single article sale and the subscription business. Both are substantial parts of the normal exploitation of works published by STM publishers.

Compensation Scheme

The Committee also raises the issue of a compensation scheme. In our view, there is no room for such a discussion. As set out above, the normal exploitation of works is at the discretion of authors and right holders. This includes the setting of the price of reprints, or the licensing the above mentioned businesses to customers of STM publishers under market driven conditions.

- It is our understanding that the Committee considers, in section 3, paragraph 1 (2) 2) a of the Interim Report Summary, that the suggested limitation be comparable with other copyright limitations that address certain urgent cases where prompt measures are required and where, therefore, prior authorization from the copyright holder can not be sought. However, in the suggested limitation such a condition of urgency is not included. The Committee only indicates that the suggested limitation should be restricted to cases in accordance with Article 77-3 of the Pharmaceutical Affaires Law. Otherwise, the only condition is the request of a medical professional. The urgency of the request, in other words, is not set out as a condition of the suggested limitation. Under Article 77-3 of the Pharmaceutical Affaires Law, there are multiple reasons which may be the basis of a particular request, only few of which would be urgent. We believe that, since urgency for lives and bodies of patients appears to be the key issue to consider such a limitation, that element of urgency would need to be explicitly defined in such a limitation. Otherwise, the suggested limitation once more would not be in compliance with Japan's obligation under to Article 9 (2) of the Berne Convention and Article 13 of the TRIPs Agreement.
- III. In our view, it can not be assumed that medical professional, e.g. individual health practitioners, hospitals etc., generally rely on an ad-hoc provision of copyright protected content by pharmaceutical companies to adequately use the drugs, especially not in urgent cases. To the contrary, it is our experience that medical professionals seek a permanent flow of information by subscribing to relevant medical journals. The information provided by pharmaceutical companies, therefore, in general only is an additional source of information concerning the application of a drug.
- IV. The Committee raises the issue how medical professionals could be provided with information from pharmaceutical companies or other suppliers upon a specific request in cases that require prompt measures. We believe that the licensing and distribution scheme provided by STM publishers already allow the prompt supply of their content, as follows.

As explained earlier, there is the reprint business of STM publishers in place. Pharmaceutical companies can – and do - order relevant articles as reprints in advance in order to distribute them immediately when a request is made. Pharmaceutical Companies are able to identify the articles that analyze their drugs, and to order them in advance. Reprints are also available in electronic form from STM publishers. This saves the time of printing/photocopying the requested articles and delivering them by mail to pharmaceutical companies and medical professionals. Since several years, individual articles of journals, as well as books of STM publishers, are available online. Medical professionals and/or pharmaceutical companies can easily and immediately acquire the requested article or books online, and use the content in compliance with the respective license agreement.

V. The Committee indicates that another option for pharmaceutical companies would be to clear the rights with a copyright clearance organization in Japan. This might be an option, however, as set out under I. above, only if the organization

obtained a respective license from the right holders. The matter of urgency discussed above is not problematic in such a scenario since copyright clearance organizations in Japan do not require "pre-use licensing". The use could, therefore, be cleared afterwards in such cases of urgency.

- VI. According to the figures of the FY 2007 survey on photocopy use by the Federation of Japan Pharmaceutical Wholesalers Association, pharmaceutical companies voluntarily provide some 56,3% of information (including medical articles) to medical professionals, in addition to the obligatory provision upon request. This demonstrates the pharmaceutical industries' massive interest in providing information on their respective medical products to medical professionals. It should, therefore, be carefully weighed if an obligation that clearly serves the interests of pharmaceutical companies should be translated into a new limitation to publishers' copyright.
- VII. STM and their members recognize that there are legitimate exceptions and limitations to copyright. We accept and understand that, for instance, customers who have purchased or licensed our material have legitimate needs to use such material for their research purposes within their own institution. Our view, however, is that the proposed exception for the pharmaceutical industry is unnecessary and overly broad, impinges on a well-established business model involving copyright works, goes well beyond internal research needs, and would place Japan at risk with respect to its international treaty obligations.

We will continue to monitor the developments in Japan and would welcome the opportunity for further discussion on this important point.

Yours sincerely,

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Michael Mabe

Chief Executive Officer International Association of STM Publishers 2nd Floor, Prama House 267 Bandbury Road Oxford, OX2 7HAT, UK

Phone: +44 1865 339321 Fax: +44 1865 339325 E-mail: mabe@stm-assoc.org Web: www.stm-assoc.org