The updated Pharmaceutical Model Licence for E-journals: a continuing collaboration between publishers and the pharmaceutical industry

Seven years have passed since the International Association of Scientific, Technical and Medical Publishers (STM) and the Pharma Documentation Ring (P-D-R) first agreed on a Draft Model Licence. The original not only became the foundation of licensing e-journals within the pharmaceutical industry, it also created a better, mutual understanding between publishers and pharmaceutical companies. The P-D-R and publisher copyright taskforce have updated the original licence, which now better reflects advances in technology and business practices. This article discusses the development of the new licence, the rationale behind the changes, and the benefits to the pharmaceutical industry.

PHILIP J DITCHFIELD
Manager, Contracts and Licensing
GlaxoSmithKline Research & Development Limited

HENNING P NIELSEN
Manager
Novo Nordisk Library
Novo Nordisk A/S

Background

In 1998 a joint Pharma Documentation Ring (P-D-R) and STM Publishers' group was set up to address the unique licensing requirements of pharmaceutical companies. Until that time, publishers' licences were very much orientated towards academic institutions, and the needs of pharmaceutical companies were little understood. Publishers had limited experience of dealing with the nuances of pharmaceutical companies' business practices, such as regulatory obligations, patent and medical information requirements, inter alia. This often meant negotiations between the two parties were difficult and protracted. Since then, in part due to the success of the standard licence the P-D-R group developed, the publishing world is much more familiar with the unique needs of pharmaceutical organizations.

The first model licence was published in 2000 and has since formed the basis of licence discussions; many publishers have adopted it with limited modification, others have taken clauses from the licence and incorporated them directly into their own corporate licences. Most publishers have since embraced the original P-D-R Licence and understand its purpose.

Benefits of the Model Licence

There are numerous benefits of the P-D-R Model Licence. Firstly, it significantly reduces the amount of time required to negotiate licences. For smaller publishers, who may not have the luxury of a legal department, the fact that the licence has been adopted by many larger publishers and, indeed, that these publishers were actively involved in its writing, gives them the confidence to accept the terms of the licence without the need for legal

counsel. At the same time, due to its universal acceptance, smaller pharmas and biotechs were able to take advantage of the licence during their own licensing negotiations, confident that their needs were also addressed.

Changing environment

The original model licence was produced seven years ago and much has happened since then: publishers' platforms offer more features, information departments provide more sophisticated services, and end-users have become more demanding. Electronic journals are ubiquitous, print is disappearing and many of the old concerns, such as speed of access and reliability of electronic content, are less of an issue. Virtual libraries are global, companies are building research laboratories without physical libraries and print subscriptions are reducing rapidly; indeed print holdings have zero significance today in determining pricing.

Pharmaceutical companies are under greater budgetary pressure and their libraries need to maximize the benefit of information resources. It is no longer acceptable simply to provide first class electronic journals, databases and e-books – users also expect ever more powerful interfaces, federated searching and linking at all levels; and business chiefs expect the best return on investment over shorter periods of time. Information sources have to satisfy business priorities. Although corporations welcome new services offered by publishers, our primary concern is that after investing in information, we have the appropriate access rights and the authority to manipulate the data in ways that meet our business needs. Without these extended business rights, companies will not be able to get full benefit from their information investments, and renewing expensive content will be difficult to justify.

At the same time, the pharmaceutical industry has to appreciate publishers' concerns – such as protecting intellectual property and avoiding loss of revenue due to global licensing and reduced reprint sales. It is therefore in both parties' interest that licences clearly define usage rights and what is unacceptable commercial use. The 'copyright taskforce' meetings have helped publishers understand that pharmaceutical companies are also built on intellectual property and that licence compliance is a key concern to both sides. Advances in technology and changes to digital rights make it very confusing for end-users and, as licensees have an obligation to communicate usage rights to their end-user populations, licences need to clearly define rights and be updated regularly.

The copyright taskforce

Most P-D-R members have robust licences with larger publishers. However, there are many smaller publishers who either do not have a corporate licence or, if they do, have not updated it since the original P-D-R Licence was published seven years ago. It was therefore agreed within the P-D-R, together with a number of publishers, to set up a taskforce to address this. The goal of this taskforce was to produce a new standard licence fit for 2007 and beyond. The committee was to be represented by pharmaceutical information managers and STM publishers, and in January 2006 the new taskforce was set up, comprising:

Publishers:
Janet O'Flaherty, BMJ Publishing
David Hoole, Nature Publishing Group
Fiona Bennett, Oxford University Press

P-D-R Representatives:
Michael Archer, AstraZeneca
Philip J Ditchfield, GlaxoSmithKline
Henning P Nielsen, NovoNordisk
Daniel Doran, Roche.

This article reports on the workings of the taskforce, highlights some of the changes to the new model licence, and the reasons behind those changes.

The taskforce met numerous times during 2006 and 2007 both in London and Copenhagen. The starting point was a detailed review of the original licence, together with a close examination of present-day business processes and how electronic content is used. Clauses were reviewed in detail. Pharma representatives argued why clauses were required and publishers raised any concerns. Some clauses required a number of edits, others were much easier to agree, with minor changes. After several months of discussion and analysis, the members' legal departments were consulted and their comments were incorporated.

The conclusions were then presented to members of ALPSP (Association of Learned and Professional Society Publishers). This led to further dialogue and their feedback was then studied before consulting with the individual P-D-R organizations. At the end of this lengthy process, the final 2007 Model Licence was drafted.

Key changes

Below is an overview of some of the areas examined and some of the key modifications as expressed in the annotation to the new licence. (The full text of the licence can be seen on <http://www.pdr.com/Licence/STM_PDR/stm_pdr.html>).

Authorised Users (§1.1)
This clause was simplified. The two requirements are that users are employed or contracted by the Licensee and have access to the Licensee's secure network. This provides a robust system of authorization since Publishers need only know the Licensee's IP addresses and the Licensee need only control access to their secure network.

Affiliates (§1.4)
The essential requirement for a business entity to be an Affiliate of the Licensee is that the Licensee has control over the entity; this is normally demonstrated by the Licensee having more than 50% control of the entity.

Licensed Materials (§3.1)
The actual details of the Licensed Materials are left to Schedule 1. Besides the electronic content defined within the Schedule, the Licensee would want to have the ability to define the Permitted Uses (§3) of the Publisher's Licensed Materials obtained by other legal means, such as from document delivery companies, when this material is not available from the Publisher's site.

Internal redistribution (§3.1.3)
The Licensee needs to be able to use parts of the Licensed Materials for various activities where it would be more efficient for a single Authorised User to make multiple copies for a group rather than individual Authorised Users doing it themselves. There was one minor modification of this clause compared to the 2000 Sample Licence, which was the removal of the permission to copy 'all' the Licensed Materials.

Project storage (§3.2.5)
Researchers work on projects, defined as a deadline directed activity by a limited number of people for a limited time period, in groups which need to share information during the time of that project. Clause 3.2.5 allows the electronic sharing of parts of Licensed Materials by Authorised Users during a project's lifetime.

Regulatory submission (§3.3.1)
As part of their normal business, Pharmaceutical (Pharma) companies are legally obliged to register their products with regulatory authorities, such as the Food and Drug Administration (FDA) and European Medicines Agency (EMEA). These authorities require that copies of the supporting publications be submitted to them. Paper copies of articles are now no longer acceptable as the entire regulatory application is electronic. In order for a Pharma company to interact with the authorities they must be working on the same electronic documents and hence parts of the Licensed Materials must be stored with the electronic in-house copy of the regulatory application. The storage of documents used for regulatory submission does not impact upon the actual usage of Publisher's content, as these documents are not accessed by end-users.

Regulatory submission usage is distinct from legal usage (§3.3.2).

Medical information (§3.3.3)
Pharma companies are required by law to support health care professionals in the use of their products. Although the majority of inquiries are handled by phone or e-mail, occasionally, when an article exactly addresses an issue posed by a health care professional, a copy of that article may be sent to the health care professional. These are sent on a reactive basis only and have no impact on ordering reprints, which are used for proactive marketing purposes.

Supply of contractors (§3.3.4)
As noted above, Authorised Users already include contractors working for the Licensee (§1.1). However there are situations where contractors do not have access to the secure network, although they would normally be permitted to do so. This clause allows the Licensee to supply copies of parts

of the Licensed Materials to such contractors for use during the duration of the Licensee's contractual arrangement with them, and under the conditions of this it would be required that the supplied Licensed Materials be destroyed at the end of that contractual arrangement.

Limited corporate copies (§3.3.5)
There are occasions (e.g., executive board, stakeholder, or scientific advisory board meetings) when there is a business need to proactively distribute limited numbers of parts of the Licensed Materials to scientific advisors who are not Authorised Users. This clause would permit this practice. In no case does this clause allow use of these articles for marketing purposes.

Professional courtesy copies (§3.3.6)
This clause makes it explicit that Authorised Users in Licensee's organization have the same right to share scholarly articles as their colleagues in academia for the purposes of their own personal research or private study. In no case does this clause allow use of articles for marketing purposes.

Corporate e-prints (§3.3.7)
The reprint business is becoming electronic. Both Publishers and Pharmaceutical companies would like to find ways to move easily from paper reprints to electronic e-prints. To expedite the use of e-prints, this optional clause would allow the Licensee to have predefined usage and costs terms specified in the attached schedule.

Perpetual access / post-cancellation access (§8.3.2)
This clause concerns the content that remains accessible to the Licensee after cancellation. For comparison, this is similar to the perpetual access issues that are of concern to the academic community and, while the need for an e-archiving solution like Portico is not great within the Pharmaceutical world, this is an important area and both Licensee and Licensor need to clarify this in their licence agreements.

Positive response

The group is now delighted to make available the new standard licence to any pharmaceutical, biotech and publishing company. The licence better reflects the needs of Pharmaceutical companies in today's global electronic environment; it is more suited to digital publishing and meets present-day requirements for disseminating information. Both publishers and corporations have welcomed the new licence and it has received very positive feedback from all sides. This can be attributed to the fact that publishers and pharmaceuticals were represented during every discussion, giving both parties the opportunity to understand and address the needs and concerns of the other. The P-D-R has been able to allay publishers' fears and publishers have been able to voice their concerns; working closely together has strengthened the relationship between industry and supplier and resulted in a new robust licence.

The rationale behind the new licence was presented to other publishers during an ALPSP meeting, and this has led to a better understanding of the complex and regulated environment in which pharmaceutical companies work. The final version was also presented at the ALPSP/STM Copyright Committee, where all three parties agreed to publish it on their website. The new licence has gained wide acceptance from publishers large and small. The joint publishing of the licence not only provides the closest we can get to an endorsement of the new licence, it is also a place where publishers and pharmaceutical companies can download the licence itself.

Beyond licences: reprint and e-print services

As a result of the discussions and the mutual understanding of needs and concerns of the two industries, a paper was also drafted by the group focusing on the requirements of e-prints, aimed at bridging the gap between licences and bulk reprint services.

Pharmaceutical companies are the principal users of large quantities of journal articles from peer-reviewed journals for marketing purposes. However, reprint services are still based on historical bulk sales of paper reprints. These may work well for planned events, where large quantities of reprints are required as physical handouts, however it does not work for global sales organizations when an urgent delivery of smaller numbers of reprints is required for tomorrow's meeting. The e-print business is still in its infancy and remains a matter for negotiations with

individual publishers. The pharmaceutical industry would like to make individual electronic articles available to its customers via newer technologies such direct e-mailing, web postings, memory sticks, CD-ROMs, i-Pods, etcetera.

The lack of systems and services to facilitate these needs affects potential revenue streams. It hinders the free exchange of information, and it may encourage non-compliant use of copyrighted material by employees, who have access to the information as authorized users, but do not have immediate access to a fast, simple and flexible ordering system for reprint material.

Publishers are willing to sell reprints and e-prints, but wish to monitor and control the distribution to ensure that their intellectual property is protected. A variety of digital rights management (DRM) methods have been used to count and control distribution, however none of these have been well received by licensees or end-users. The process of securing reprints and e-prints can take time, which leads to end-user frustration, and DRM limitations also complicate proceedings.

The P-D-R has published a paper: *Requirements for reprint and e-print services* on the P-D-R website: <http://www.p-d-r.com/Licence/STM_PDR/stm_pdr.html>, and we would welcome suggestions from document suppliers and publishers on how we might work together to develop such systems.

Further reading

Nielsen, H P and Whittall, J, Model Licensing. Key Elements and Specific Needs in Electronic Journal Licensing for the Pharmaceutical Industry, *Serials*, 2000, 13(2),103–109.

Gottwald, M, Nielsen, H P, Brown, R and Renn, O, Proposals for quality standards for electronic STM journals, *Serials*, 2006,19(1), 42–46.

Website links

The Pharma Documentation Ring (P-D-R):
http://www.P-D-R.com

Association of Association of Learned and Professional Society Publishers (ALPSP):
http://www.alpsp.org/ngen_public/

International Association of Scientific, Technical, and Medical Publishers (STM):
http://www.stm-assoc.org/

New Model Licence for Publications in the Pharmaceutical Industry:
http://www.p-d-r.com/Licence/STM_PDR/stm_pdr.html

■ **Philip J Ditchfield**
Manager, Contracts and Licensing
GlaxoSmithKline Research & Development Limited
Greenford Road
Greenford
Middlesex UB6 0HE, UK
Tel: +44 20 8966 3994 | Fax.: +44 20 8966 2608
E-mail: philip.j.ditchfield@gsk.com

■ **Henning P Nielsen**
Manager
Novo Nordisk Library
Novo Nordisk A/S
Krogshøjvej 46
DK-2880 Bagsværd
Denmark
Tel: +45 44 42 20 48 (direct)
E-mail: hepn@novonordisk.com