

MODEL LICENSING. KEY ELEMENTS AND SPECIFIC NEEDS IN ELECTRONIC JOURNAL LICENSING FOR THE PHARMACEUTICAL INDUSTRY

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Electronic licensing is demanding on resources from both licensee and publisher, therefore a need for model licences. The Pharmaceutical Industry has special characteristics and needs as well as characteristics shared with the corporate sector and academia. There has been a need for a model licence in the pharmaceutical sector to make licensing meet their requirements, which are concentrated around globalisation, secure networks, regulatory submissions and product support.

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Why model licences?

The Internet has introduced dramatic changes in the way that we purchase and access information. Ten years ago we subscribed to our journals via agents and accessed electronic information via a limited number of database hosts aimed at the professional user. Now a global, electronic information space has taken over. A very anarchistic Internet world has enriched and multiplied information beyond imagination, but it has also fragmented the information world and left us to bargain for terms and prices with every information producer on the net.

Today, access to electronic information has to be licensed, rather than purchased. Licensees have to negotiate with individual publishers/information owners directly, as the unifying agents or aggregators have yet to fully transform their services into the new environment. Neither party, information vendor nor information purchaser, is used to this new scenario, resulting in frustration and time consuming discussions and negotiations around the terms of electronic content licensing.

Standard licensing was a natural consequence, but publishers' existing licences were designed primarily for the academic market and the large academic consortia and did not take into account the needs of corporate and particularly pharmaceutical organisations. It has therefore been logical to create model licences that meet the needs of specific corporate sectors, with the aim of reducing negotiation time and ensuring that special needs are met.

Existing standard licences

A series of standard licences have been modelled over the past years. Some of the more successful being the ones mentioned

below. These can all be found on the Yale Liblicense web site¹:

- <http://www.library.yale.edu/~llicense/index.shtml>², which is an indispensable source of information on electronic licensing issues:
- <http://www.nesli.ac.uk/nesli8a.html>³: NESLI is the UK National Electronic Site Licence Initiative.
- <http://www.library.yale.edu/~llicense/Pajisc21.html>: from the Publishers Association and the Joint Information Systems Committee.
- <http://www.library.yale.edu/~llicense/covenant.html> between Scientific and Professional Publishers of the Dutch Publishers Association and the co-operative body Innovation Scientific Information Supply
- <http://www.licensingmodels.com>⁴: these four licences, produced for a group of five subscription agencies by consultant John Cox, are intended to be a model for libraries, publishers, and vendors negotiating licences.
- <http://novanet.ns.ca/consort/>: This is a movement of Canadian consortia directors to promote national site licensing initiatives in Canada with several projects under way.
- CLIR/DLF Draft Model Licence. The Council on Library and Information Resources, the Digital Library Federation and Yale University Library sponsors the Liblicense standard licensing agreement.

The PA/JISC draft model licence has been particularly successful in being the model for several of the others including the model for the pharmaceutical industry, which is described in further detail below.

Need for a specific licence for the pharmaceutical industry

The existing standard licences focus on the needs of specific sectors. Most of these attempts to create model licences are aimed at serving the needs of academia, or of academic consortia. The pharmaceutical industry has different specific needs for licensing of electronic full-text content. Many of these needs are shared with other corporate sectors such as the chemical, oil and gas and financial industries. However, the pharmaceutical industry has additional special

needs relating to the pharmaceutical regulatory authorities, prescription drug marketing and medical information needs. Pharma Documentation Ring (PDR), therefore, took an initiative to create a special model licence for this industry. (PDR is described in detail in a separate appendix to this article)

Pharmaceutical industry characteristics

The pharmaceutical industry has many characteristics in common with other corporate sectors. It tends to be international or global in scope. The impact of global organisation has been emphasised in the last 6-8 years by the increased drive for global communications, electronic access to proprietary and external information and increasing staff mobility.

Corporate organisations work in a competitive environment. Access to information that may influence the direction of a research effort and potentially of a patent application is time critical – the sooner the information is available, the sooner it can be used to drive business decisions.

Customers for information services within the corporate world are predominantly internal customers – associates working within the R&D and marketing organisations. These customers work with sophisticated internal information applications and have high expectations of applications delivering external information content. The organisations are predominantly fast moving, adaptive and creative, which adds to the drive to provide fast, high quality, adaptive and creative information solutions.

Access to external information content within the corporate world is determined by corporate objectives, which can change rapidly. Collection management in an electronic environment is, therefore, still an issue. Paper based journal collections are changing content/titles ('churn') by 8% annually in the pharmaceutical environment, compared with 1% in the academic sector⁵. This 'churn' is likely to be higher in the electronic environment, as better understanding of the use of electronic journals is achieved through more accurate usage statistics. This continuous change in the information needed to support objectives has an influence on the types of licence applicable for the corporate world.

The move from paper-based to electronic

access has to be justified on grounds of cost benefit. There tends to be little or no additional funding for purchase of electronic access. The funds that were previously devoted to purchase of paper access are in many corporations being used to fund electronic access.

Secure networks and authorised users

Security of access to the networks and their information is a prime concern in the corporate sector. A significant amount of proprietary data and information is generated within a corporate organisation. Access to this information by competitors and others would have serious adverse effects on the corporation – in terms of access to competitor information and patentability. The security of the communications network within an organisation is therefore a key to the organisation's success.

Identified, authorised users, i.e. employees, affiliates and authorised independent contractors, have access to the secure corporate network for access to proprietary information and for access to externally generated information, including access to electronic full-text. Increasingly mobile corporate employees frequently require access to information from locations other than the site at which they are based. Access to proprietary and external information from home, whilst travelling, from corporate offices on the other side of the world is a requirement in the fast paced corporate world.

Thus, the secure networks and authorised users constitute an ideal basis for defining an organisation and who has rights to access information in an electronic environment. Licences limiting access to electronic full-text from a specific location and those that require additional passwords to authenticate users who already have access to the secure corporate network, do not meet the needs of a corporate organisation.

Pharmaceutical industry licensing requirements

Quality and standards

In many corporate organisations, access to electronic full-text is regarded as business critical. The concept of business criticality is an important one. If an organisation is to change its users'

behaviour from reliance on paper based information to one of embracing the electronic information environment, information must be delivered with consistent quality and standards.

Quality includes guaranteed accessibility in a 24 x 7 timeframe, guaranteed access and response times (such as access to the journal title within x seconds and access to the full-text within y seconds), and guaranteed technical quality of data. Clauses should be included in a corporate licence, which guarantee all three of these factors.

Access to electronic full-text within a corporate environment will not be successfully implemented unless standard formats and software are used. There is little place within a large corporate organisation for support of specialist software, particularly, if it does not deliver enhanced functionality over standard systems.

Quality also applies to content, not only at the intellectual or scientific level, but also the stability of the content in an electronic environment. It must be guaranteed that access to content, at a minimum, includes exactly the same information as in the printed version (as long as there is a parallel printed version). Then there might be add-ons in the form of links, multimedia, and other new technologies that will change future publishing in the electronic environment. We can only guess how these changes will appear, but definitions of content and stability of this content should be covered in licensing.

Service levels

Guaranteed accessibility, access and response times and technical quality of data should be covered in a service level agreement in the licence. In addition, a service level agreement should cover availability of data, schedules for pre-notification of system changes and statistics monitoring, and availability of a Help Desk with guaranteed response times.

Availability of electronic full-text prior to or equivalent to hardcopy is a key advantage in the move from paper to electronic access. Speed of information access is critical to many business decisions. There is reduced value and cost benefit in moving from paper to electronic without the guaranteed speed of availability. Notification of update schedules, i.e. when the next issue of each

title is expected to be available, is also key to building alerting services and customer reliance on electronic full-text. Users of full-text information in paper form are accustomed to regularly receiving new issues of journals on which they rely. They have at least the same, if not greater, expectations of information in electronic form.

Pre-notification of both system changes and scheduled downtime is another important factor in enabling the move from paper to electronic formats. Access to electronic journal information is no different from access to databases of secondary information in this context.

Copyright versus licence

The pharmaceutical industry is founded on intellectual property rights and therefore recognises the need for compliance with copyright and respect for the intellectual rights of the authors and publishers. This compliance must be sought through education and guidance of end-users. Paper copyright is one issue that we have learned to manage over many years. Electronic copyright is new and not very well understood by end-users, especially as the legislation nationally or internationally (EU, WIPO, etc.) is publisher driven and very restrictive compared to the paper copyright.

It is, therefore, important that permitted usage is very well defined in a licence, as this will replace the copyright regulations within the organisation and normally will be more open than the legislation. In this area the secure networks and the definition of authorised users are of utmost importance to gain the mutual understanding between rights holders and users. When these definitions are in place, it should be possible to define corporate usage as comprising everything except altering content or carrying content outside the network or to non- authorised users.

Perpetual access versus access to archival electronic full-text

Within the paper information environment, access to archives of information already purchased is dependent on available space. Licensing electronic content raises the question of

future access rights to purchased content, and who should guarantee this access right and archiving. Licences must address this and some publishers have issued statements guaranteeing perpetual access. The short/medium term problems are probably well solved between publishers and licensee. Long term archiving should be a national task, and long-term access could be tied to this or to commercial initiatives. It is important to get these problems solved. Publishers should be encouraged to include in their licences text which indicates that they will either ensure access to archival information through their own efforts or through those of a third party.

Pharmaceutical industry specific needs

The pharmaceutical industry is a particularly information intensive industry, both in terms of the proprietary information that it generates throughout the drug discovery and development process, and in terms of the external information, which feeds its innovation. Pharmaceutical organisations tend to be multi-site, multi-national with a highly information literate and information demanding, mobile workforce.

Access to electronic full-text is becoming the de facto standard within the pharmaceutical industry for providing external information input to research and development decisions. Research and development is highly project oriented, often on a multi-site basis. The ability to share full-text information in project team databases is an emergent need. The information is being shared within the secure corporate network environment with minimal risk of unauthorised use.

Access to electronic full-text is also required to support regulatory submissions, patent litigation, product marketing and medical information processes. Regulatory submissions are now primarily electronic and submissions include supporting external information from journal information sources. A licence for electronic journal access should explicitly provide permission to include electronic journal material in regulatory submissions. Similarly use of electronic full-text in patent litigation work should be explicitly included.

Pharmaceutical companies support their medicinal products by providing externally

generated information as an integral part of the drug marketing process. Unlike products in other sectors, it is essential that marketing claims be substantiated by published clinical trial information. Pharmaceutical companies also provide information support to health care providers in the countries where their products are marketed. This kind of marketing is also moving into web-based applications and e-commerce, where product support includes published literature in electronic full-text. Electronic full-text licences should, therefore, also include definitions and terms for these specific uses.

In order to attract high calibre staff into the pharmaceutical industry, frequent use is made of corporate web sites to publish corporately authored articles. Permission for this activity should also explicitly be stated in electronic full-text licences.

Linking, linking, linking

The ability and importance of linking electronic full-text in a variety of ways has been recognised by both vendors and users of electronic full-text. Linking within articles, between articles, between journals, to secondary information sources and to corporate and academic library management systems are all aspects, which need to be progressed, if the benefits from electronic information access are to be realised fully. Standards for linking and business relationships between vendors must be progressed to ensure success in this area. Electronic journal full-text licences should include specific text securing the licensee's access rights to licensed information through the rapidly evolving linking technologies.

Future discussions

Academia and the corporate world have been accessing web-based, electronic full-text for 4-5 years. In the paper world it was never possible to provide accurate usage figures for specific journal titles. Electronic access has provided the mechanism for gathering accurate usage statistics, not only at the journal level but also at the article level. This information is potentially invaluable to vendors and purchasers of full-text information.

Usage statistics enable one important new possibility: new pricing models. To date the price of electronic full-text access has been determined primarily on historical subscription levels for particular titles. Future models must be based on usage patterns. Licensees will still have budgetary limitations and publishers will want to maintain some subscription-like commitment. Such requirements are hard to match with usage-based licensing, but it can be done, especially as the licensee will be able to ascertain the value for money of titles purchased. Vendors on their side will in the future be able to identify the types of article that are of most value to any audience. This ability to analyse the market to identify 'value for money' scientific articles will raise discussions about freedom of research and the role of commercial publishers in scholarly publication.

Linking technology is rapidly evolving, and the real impact on searching, navigating, and creating dynamic interactions between data remains to be seen. Searching will not in the future be accepted as a task that requires access to, and separate searching of, many databases. Linking is one of the most pressing issues in full-text licensing debates and it is imperative that the ability to provide links is included in standard electronic full-text licences.

Will linking be free? Will linking become a commercial service or 'free' navigation tool to content? The content is what we want. The content represents the value, for which we want to pay today. But what happens if the content becomes free?

If the pre-print/'free-print' initiatives like Pub Med Central, BioMedCentral, take off and create a scientific publishing environment where primary scientific publications will become freely available, the added value could very well be the linking and interaction. Before that really happens, the peer reviewing processes have to be in place and accepted by the scientific world. Pre-print archives also represent a challenge to indexing and abstracting services. It is important for us to have the information available as soon as possible but is equally important that the information quality is ensured via the peer review process.

We are in the beginning of a phase where scientific publishing could change radically, and where the impact on publishers' roles could

become threatening. Evolving technology finally leads on to the much-discussed topic: "What is a publication?".

References

1. *LIBLICENSE. Licensing Digital Information. A resource for librarians.*
<http://www.library.yale.edu/~llicense/index.shtm>. This is the most comprehensive electronic licence site hosted by Yale University Library. It includes literature, links to the existing model licence initiatives. The Liblicense discussion forum hosts a very lively and informative debate on issues relevant to all with licensing responsibilities.
2. *PA/JISC 'Draft model licence':*
<http://www.library.yale.edu/~llicense/Pajisc21.html> Framework for material supplied in electronic form: from the Publishers Association and the Joint Information Systems Committee.
3. *NESLI Draft Licence:*
<http://www.nesli.ac.uk/nesli8a.html> NESLI is the UK National Electronic Site Licence Initiative. Based on the PA/JISC draft model licence, this is the model used by the NESLI Managing Agent in negotiations with UK publishers for agreements to provide UK universities with access to electronic journals.
4. *Licensingmodels.com*
<http://www.licensingmodels.com/> These four licences, produced for a group of five subscription agencies by consultant John Cox, are intended to be a model for single academic institutions, academic consortia, public libraries, corporate and other special libraries.
5. *'Paper based journal collections are changing content/titles ('churn') by 8% annually in the pharmaceutical environment, compared with 1% in the academic sector'* These figures are personal communications from one of the major subscription agents.

Appendix

Pharma Documentation Ring (PDR) URL:

<http://www.p-d-r.com>

Pharmaceutical industry information management groups have a strong history of working together to positively influence information vendors to meet industry needs. Much of this influence has been achieved

through the work of the Pharma Documentation Ring (PDR) PDR is a group of corporate representatives from 24 of the major pharmaceutical companies. Representatives must belong to the scientific, biomedical or technical information function of a research-based pharmaceutical company and be able to report on non-confidential aspects of the information science activities of the corporate group. The majority of PDR member companies spend over \$1 billion per annum on R&D activities.

The aim of the PDR is to attain improved coverage, better distribution and optimum use of chemical, biomedical and pharmaceutical information. This aim is achieved by promoting exchange of experience and ideas between members in non-confidential areas of work and by jointly studying and assessing existing information products and services for the purpose of improvement.

The PDR also initiates and encourages the development of new information services tailored to the needs of the pharmaceutical industry and provides a forum for the information industry serving the pharmaceutical sector.

It was recognised that existing licences, both the model licences such as Yale and the licences, being offered from major vendors, did not meet pharmaceutical industry needs. As a response to this, the PDR sponsored a meeting on Electronic Journals in spring 1998. The meeting brought together publishers, aggregators and pharmaceutical industry information management groups to participate in debate on the many issues surrounding the move from paper to electronic access to full-text journal information. Subsequently a joint PDR/STM (Science, Technology and Medicine) publishers group was established to progress the development of a model licence for access to electronic journals for the pharmaceutical industry.

Representatives of the PDR and STM publishers worked together for 18 months to produce a model licence for use within the pharmaceutical industry (Reference to URL). The model licence will provide a common starting point for negotiations between publishers and the pharmaceutical industry. The successful

outcome of this initiative has been influenced by a number of factors.

Publishers and other key players were involved from the outset of discussions on the need for a model licence. Both publishers and pharmaceutical industry information managers focused on building understanding of business drivers in their respective industries. Although the working party was large (see Appendix) a small group, two from the STM publishers and two from the pharmaceutical industry, worked together on drafts of the licence in intense but profitable meetings. Both parties were committed to a successful outcome to this initiative.

Membership of the PDR/STM electronic journal licence working group:

PDR representation from

- Astra Zeneca
- Glaxo Wellcome

- Novo Nordisk
- Roche
- Schering
- SmithKline Beecham

STM publisher representation from:

- STM secretariat
 - Association of Learned and Professional Society Publishers
 - Academic
 - American Chemical Society
 - Blackwells
 - British Medical Journal
 - Elsevier
 - New England Journal of Medicine
 - Springer
 - Wiley
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