

Now that the rapid exchange of scientific research and product information across international borders has become commonplace, rights holders and users of published material face an increasingly complex set of issues involving reuse rights, permissions, restrictions and fees.

Copyright laws vary from one country to the next, making the resulting mix of obligations difficult to reconcile and enforce, especially for global, research-driven organisations with employees working in different countries.

Research and information professionals in the pharmaceutical and life sciences industries depend on the ability to disseminate important information quickly for a variety of reasons—to accelerate drug discovery, to keep physicians and patients informed, to communicate with government regulatory authorities and to monitor the safety of drugs in the pipeline and in the marketplace.

The challenge, especially for the medical affairs professional, corporate librarian or pharmacovigilance team, becomes sharing business-critical content in a timely fashion while respecting the rights of the content rights holders.

Copyright awareness in the workplace

Researchers and other knowledge workers tend to forward information to their peers quite often, yet many of them are unaware of their responsibilities when it comes to using copyrighted material.

According to last year's *Information Consumption and Use Survey* by research and advisory firm Outsell (commissioned by US not-for-profit organisation the Copyright Clearance Center, © 2013 Outsell Inc, www.outsellinc.com), 81 percent of knowledge workers at global companies share information with their immediate team members at least once a week and often daily.

But the majority of surveyed workers—65 percent—believed that if they could access content online for free, then they were free to share it without the permission of the copyright holder. Not many knew that there might be terms and conditions related to sharing that online content. For example, while an Open Access title may be free to download and access via the internet, there

COPYRIGHT COMPLIANCE IN THE LIFE SCIENCES INDUSTRY

Many researchers are unaware of the legalities when it comes to sharing and using copyrighted material, but licensing agreements can help, says Kate Alzapiedi of copyright licensing firm RightsDirect.

may be specific terms prohibiting the reuse of the article for commercial purposes.

Some organisations adopt copyright policies to educate and guide their employees on copyright compliance. In those organisations, awareness among employees tended to vary considerably. The same Outsell study revealed that only 44 percent of respondents were even aware of their own organisation's copyright policy. Of the rest, 32 percent were not certain of the details and a further 24 percent were either unaware of a policy or said that such a policy did not exist.

As the evidence suggests, low organisational awareness of copyright issues is the norm and presents several challenges for senior management, compliance officers and information specialists.

Content sharing habits and challenges

In order for pharmaceutical and life sciences workers to perform well, collaboration is vital. Sharing published scientific content from journals, books, newspapers and magazines throughout the organisation and across borders is crucial to the ongoing exchange of ideas.

Email is the preferred tool for employees. In fact, 84 percent of surveyed employees said they forward content to co-workers and others

through email. Nearly half of them reported cutting and pasting the material into an email before sending. Collaboration tools such as Lotus Notes, Microsoft SharePoint and company intranet sites are commonly used by companies to capture, annotate, store and share information in a single location.

But who is most likely to be sharing and storing this content, and for what purposes? The following scenarios are based on interviews conducted by RightsDirect with information specialists at several global pharmaceutical companies, and serve to demonstrate how and why content is shared both internally and externally.

Sharing key research findings with R&D project members

The staff of corporate libraries (also called knowledge centres or scientific information centres) play a key role in the licensing and distribution of scientific content to their R&D colleagues. Fast dissemination of the latest scientific articles enhances productivity and can often speed the pace of drug discovery.

Maintaining pharmacovigilance databases of company products

Drug monitoring helps ensure the safety of drugs in the development pipeline and those already approved for marketing. Storing

published information about the company's products in up-to-date databases allows the pharmacovigilance department to distribute time-sensitive information quickly as an early warning tool for the detection, assessment and prevention of possible adverse effects.

Responding to requests for scientific information from customers

Medical affairs departments are often asked to provide patients, doctors and other healthcare professionals with scientifically-validated information, including full-text articles from peer-reviewed journals. These published works typically come with specific permissions and restrictions guiding how they can be distributed.

Keeping regulatory authorities informed

As the agencies responsible for the scientific evaluation of medicines used in their jurisdictions, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require that any adverse reactions to medicines be promptly reported by the manufacturers and applicants for new drugs. Using copies of previously published material in the process of obtaining regulatory clearance for drugs and medicines is where copyright compliance becomes important.

Displaying information for educational purposes

The sharing of published product information on tablets and smartphones is a vital sales tool, whether for display during an individual sales call or for showcasing at a large medical conference. However, some employees may not be fully aware of the licence limitations that apply to the reuse or redistribution of these materials.

What all these scenarios have in common is the ongoing need to distribute copyrighted materials to perform a required business task. But often copyright is perceived by employees more as an interruption to the exchange of information rather than as a facilitator of it.

Copyright compliance and the socially responsible company

Trust in a company's commitment to the public good often takes decades to build. Yet it can be ruined in minutes through a seemingly minor misstep that results in unwanted scrutiny from regulators, governments, customers and the media.

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These days, consumers are paying closer attention to corporate practices and policies than ever before. According to APCO Worldwide Inc's 2013 *Champion Brand Study* (<http://apcoworldwide.com/champion/#/1>), the majority of the public (71 percent) said they cared more about a company's behaviour today than they did just 10 years ago.

As business activities become increasingly complex, a growing number of companies is voluntarily embracing the value of fostering an enterprise-wide culture of integrity and transparency. This heightened focus on corporate social responsibility is slowly expanding to include a greater awareness of—and respect for—copyrighted material and the IP rights of others.

For years, global organisations have been working to protect their own IP from misuse or misappropriation by others. It makes sense, then, to extend and expand this same respect and protection to include materials produced and distributed by others.

To do this, companies need to have the right policies, training, processes and monitoring tools in place in order to have any chance of succeeding. Naming a point person for copyright issues in the organisation is essential, as is the proper implementation of copyright guidelines.

Making copyright compliance easy

While technology has made it easy to find and use content, obtaining copyright permissions can be difficult, time-consuming and expensive. Subscriptions and access to publisher databases provide basic usage rights, but sharing rights granted by publishers differ. Some publishers do not

offer licences permitting employees to share published content legally at all. And clearing permissions individually, one publisher at a time, can prove to be quite challenging for multinational organisations.

A better and more comprehensive solution is an annual repertory licence that simplifies the licensing of content and helps researchers and other knowledge workers to use copyrighted materials without having to seek multiple individual permissions.

Multinational copyright licences allow cross-border sharing of copyrighted materials throughout the entire organisation. The ideal licence would cover millions of rights from tens of thousands of international publishers, and also cover a broad range of content types and authorised use cases. With an annual, multinational copyright licence in place, medical professionals in pharmaceutical companies and healthcare organisations would be able to lawfully reuse content within their organisation in a variety of ways that typically occur every day.

For example, the Multinational Copyright License developed by RightsDirect allows sharing of digital and print content such as full-text scientific articles within the organisation; enables the sharing of single digital or print copies of an article with healthcare professionals and other customers who request them; allows the storage of articles for records, projects and pharmacovigilance databases; and lets users submit copies of articles to government agencies for regulatory filings.

It is clear that pharmaceutical and life science companies can benefit from a consistent set of permissions across all participating rights holders and reduced time pursuing permissions individually. In doing so, these same companies will be demonstrating their respect for the IP of others as well as their willingness to conduct business in a socially responsible manner. ■

Kate Alzapiedi is RightsDirect's business development director, responsible for copyright licensing solutions across Europe. She has an extensive background in scientific, technical and medical publishing with more than 15 years of experience at Elsevier Publishing and Excerpta Medica Medical Communications.

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