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IPR & Life Science News

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In this March edition of our newsletter, we comment on the most recent decision regarding file sharing from the Danish courts.

Further, our newsletter covers both the use of so-called “linkbuilding” with respect to rules on hidden advertising and the new criteria for use of unpublished data in the Medicines Council’s evaluations and recommendations.

Danish Court changes course and acquits the defendant for illegal downloading and file sharing

The much-debated C&D letters to private individuals have been a hot topic from a legal perspective, whether one considers the letters as being intimidating and disproportionate threats or a necessary battle for copyrights.

The Copenhagen City Court's case law regarding the several hundred cases of illegal download and filesharing have not been clear and cogent, but the majority of the cases were ruled in favour of the plaintiffs and copyright holders.

This course may be changed with the recent decision from the Copenhagen City Court and the pending appeals before the Eastern High Court.

With the many popular options for streaming movies and music, one would believe that the days of PirateBay and illegal downloading were over. That is assumingly also the direction we are moving towards, but that does not stop the copyright holders from taking legal action against internet subscribers who allegedly have been downloading and sharing copyright protected material illegally through their internet and associated IP-addresses.

Numerous individuals have received a C&D letter from one of the active law firms on behalf of one of the entities, who are enforcing the rightsholder's copyrights in many countries, including Denmark. The letters include a proposal to settle the matter upon paying a given amount. One of the involved law firms has previously stated that potentially 150.000 letters have been sent based on the number of IP-addresses and the information that the tele companies have handed over. Same law firm has also stated that about 60 percent of the recipients have settled and paid the imposed amount. The recipients who refuse to pay, as they refuse to have conducted any illegal downloading and file sharing, will be the object of a civil lawsuit.

Rule of Presumption

The copyright holder's claims are based upon data from a computer programme that is able to track illegal downloading and file sharing, time of download and the associated IP-address. When combining the IP-address with the information from the telecommunication companies, it is possible to identify the subscriber of the internet connection.

Based on this information, the right holders claim that in Danish law a strong rule of presumption must apply, after which the violation must be presumed to be committed by the owner of the IP-address, if he or she has an access code on their internet connection.

In absence of any solid evidence of the defendants IP-addresses being hacked, misused or similar, the rule of presumption has been decisive for the numerous rulings from the city courts, especially rulings from the city courts in Eastern Denmark. This means that most of the rulings have been in favour of the plaintiff and the copyright holders.

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Most recent ruling and pending, preliminary appeals

The latest ruling from the Copenhagen City Court changes the course just before the Eastern High Court has decided on the matter. The Copenhagen City Court ruled that, even though there may exist a presumption that the violation was committed by the internet subscriber and that the subscriber therefore is liable for the violation, the defendant was able to prove such specific circumstances, which with a high degree of probability precludes the possibility of the defendant being at home on his address, or through his computer downloading and file sharing the movie while not being at home. Through the defendant's own explanation before the court and submitted bank statements, the defendant was able to render unlikely and thus overcome the presumption that he himself had committed the violation on the specific time the movie was downloaded from his IP-address.

It is essential to note that the defendant could not prove with certainty that he was not at home on the specific time the violation assumingly had taken place, but he could render likely with a high degree of probability that he was not at home, when the movie was downloaded and file shared. The bank statements showed that the defendant had used his payment card about 160 kilometres from his home at 7:59 PM, Thereby, the court rendered that the defendant was not home, when the movie was downloaded from his IP-address at 6:39 PM.

The ruling does not set aside the rule of presumption, known from several similar cases, but it does modify it and show that the rule of presumption can in fact be overcome – even without certain proof. Consequently, this latest case appears to take a more nuanced view on the issue and the burden of proof in such cases.

Presently, the many city court cases have been put on hold while waiting for the rulings of the Eastern High Court. Four judgements that were ruled in favour of the copyright holders have been appealed. The appeals are scheduled in March 2020, but one of them has already been settled, leaving only three preliminary cases to be decided by the Eastern High Court.

Accura's dedicated team of intellectual property lawyers will follow this matter closely and keep us up to date with the three pending preliminary rulings from the Eastern High Court.

Use of "linkbuilding" and rules on hidden advertisement

Hidden advertisement remains one of the Consumer Ombudsman's main areas of interest. More recently, the Consumer Ombudsman has taken on the issue of a newer method for businesses to hide their advertising, that is through "linkbuilding".

The Consumer Ombudsman has informed 19 media agencies and companies behind websites that the rules on hidden advertisement in the Danish Marketing Practices Act also apply to linkbuilding.

Linkbuilding refers to the situation where a company receives payment for linking to another company's website in order for the other website to attract more traffic. This also has the valuable advantage that search engines will rank the website higher and place the website in the top of the search results if a certain website is linked to from reliable medias. However, linkbuilding may be deemed as hidden advertising if the commercial content is not clearly identified. Failing to comply with the hidden advertising rules will entail a significant risk as both the media platform and the company will be liable.

Hiding commercial intent is punishable

According to the Danish Marketing Practices Act, a company must at all times clearly identify the commercial intent of their advertising. The purpose of this provision is to ensure that the consumers are aware of the commercial content and thereby evaluate the content based on the commercial context.

The Consumer Ombudsman finds it highly criticisable that trusted online media such as web-based newspapers have been hiding commercial content in seemingly editorial articles by using linkbuilding. Readers need to know if they are reading an editorial article or text with a commercial intent. In that regard, the Consumer Ombudsman has stressed the importance of maintaining the confidence in the media. Thus, hiding commercial intent is illegal.

Furthermore, it is stipulated in paragraph 11 of Annex 1 to the Danish Marketing Practices Act that it is misleading to use editorial content in the media to promote a product, when a trader or a company has paid for the promotion, without this being evident in the content or in images or sound that can be clearly identified by the consumers.

The Consumer Ombudsman has previously demonstrated that she is serious about her statements regarding the severity of hidden advertising. Not long ago, we were able to inform that the Consumer Ombudsman had reported four influencers to the police for failing to comply with the rules on hidden advertising.

At the moment, no media agency or company has been reported to the police for use of linkbuilding, but it will be considered an aggravating factor, if a media or a company has received an admonition from the Consumer Ombudsman and has chosen not to comply herewith.

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Clear identification of commercial intent

If the purpose of a text, article or similar, is to link to another company's website, the commercial intent must in all aspects be clear to the consumers. This applies to any use of linkbuilding as marketing. The Danish Marketing Practices Act does not further specify the requirement of "clear identification", nor does it provide any directions as to when the requirement is met. However, the Consumer Ombudsman has instructed that a text linking to a company's website must clearly be marked with "advertisement" or with another word that the consumers will understand as a clear sign of advertisement. If the commercial content is obvious from the text, it is not necessary to mark the text with "advertisement". Thus, the Consumer Ombudsman assesses the entire text as well as the context and platform in which it is published, including how it overall appears to the general consumer.

Furthermore, the rules do not only apply to the published text itself. Also, excerpts and abstracts of the text must clearly identify the commercial intent. Examples of excerpts and abstracts of a text may appear on the frontpage of the website or other websites, including in Google searches.

Especially, excerpts appearing in Google searches are interesting for the Consumer Ombudsman, since not marking the text that links to another website with "advertisement", will have a higher chance of affecting Google and their search tools. The Consumer Ombudsman has discussed this issue with Google. Google has explained that texts are automatically copied from the website, including headings and meta descriptions, which are a short and precise summary of the site's content.

The meta descriptions are often what the companies use to generate traffic to their website. The Consumer Ombudsman therefore finds it highly important that the clear identification of commercial content also appears in the excerpts and meta descriptions of a website that links to a text with commercial intent.

Checklist on how to comply

For media agencies and companies using linkbuilding, we recommend following these guidelines:

- Media agencies, companies, web-based news media etc., which are using linkbuilding must in *all aspects* ensure that the commercial intent of the text that links to a website is clearly identified.
- Using abbreviations and slang words such as "ad" and "spons" or wordings as "in collaboration with" is not sufficient to clearly identify the commercial intent. Instead, use "advertisement" or "commercial promotion".
- Both the company that has paid for the text and the linkbuilding as well as the media or company publishing the text with commercial content, must give specific instructions to one another on how to properly mark the texts, excerpts and meta descriptions of the content as advertisement or commercial content.
- The instructions may be given in the written agreement between the parties, but it is vital that these instructions are clear and specific for both parties to comply with the Danish rules about hidden advertisement.
- Media and articles with *editorial and informative content* must particularly ensure that all texts linking to another company's website or similar, are properly marked as advertisement.
- Media and the companies using linkbuilding must on a continuous basis review the texts, excerpts and Google search results to make sure that all parties in fact are complying with the rules and that all the texts and excerpts are marked with commercial content.

Feel free to contact Accura's dedicated team of marketing law specialists if you have any questions or wish to know more about the rules on use of linkbuilding.

Unpublished data and the Danish Medicines Council

The Danish Medicines Council has provided new criteria for determining when unpublished data can be used in the council's evaluations and recommendations.

The Medicines Council and the new criteria

In late 2019, Danish Regions accepted that the Medicines Council is free to use unpublished data in the council's evaluations and recommendations under the condition that the council would establish specific criteria for the determination of when such use would be appropriate. The Medicines Council has now released such criteria, which are available in Danish here.

The Danish Medicines Council is the independent council that provides evaluations, recommendations and guidelines on medicinal products to the five regions of Denmark. These evaluations and recommendations mainly concern whether new medicinal products (or extensions of therapeutic indications) are to be recommended as possible standard treatments at Danish hospitals. The regions further receive joint therapeutic instructions from the Medicines Council.

In December 2019, we wrote about the Medicines Council's new method for assessing new medicinal products (see newsletter here).

Data that will be available

Until now, the Medicines Council has solely relied upon peer-reviewed articles published in scientific journals along with data from the European Medicine Agency (EMA) and the agency's European Public Assessment Report (EPAR).

Going forward, the Medicines Council may always also rely on reports from the US Food and Drug Administration (FDA) and reports from certain internationally recognized Health Technology Assessment (HTA) agencies. Data from these sources will now be considered on equal footing with data from EMA and EPAR.

Data that may be available

According to the new criteria, certain other types of data may under certain circumstances be used and relied on by the Medicines Council in situations where published peer-reviewed articles and reports from acknowledged agencies are deemed insufficient. This presupposes that the Medicines Council finds this to be relevant and professionally justifiable to strengthen the basis of evidence.

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In this regard, the Medicines Council distinguishes between three categories of data which may be used:

- Data from manuscripts related to unpublished articles, if i) the manuscript(s) concerned have been accepted by a peer-reviewed journal and ii) the council is granted access to the manuscript(s) in its entirety and consequently receives knowledge of its design and methodology.
- Data which is published, but has not been peer-reviewed, if the design of the study, its methodology and primary results are published in either i) articles, ii) EPAR, or iii) FDA, and/or reports from internationally recognized HTA-agencies. An example could be results from abstracts with a follow up time exceeding what is published previously.
- Data which is neither published nor peer-reviewed, if the design of the study, its methodology and primary results are published in either i) articles, ii) EPAR, or iii) FDA, and/or reports from internationally recognized HTA-agencies. This could be aggregated data from companies (data on file) or data collected from a clinical practice in Denmark as long as the council is aware of the data collection methodology and analysis.

The Medicines Council must on a case-by-case basis conduct an assessment of the relevance, professional standard and the influence of such data, as well as of the extent to which the data will strengthen the basis of evidence. The council must take biases and plausibility into account and generally analyze the quality of the data.

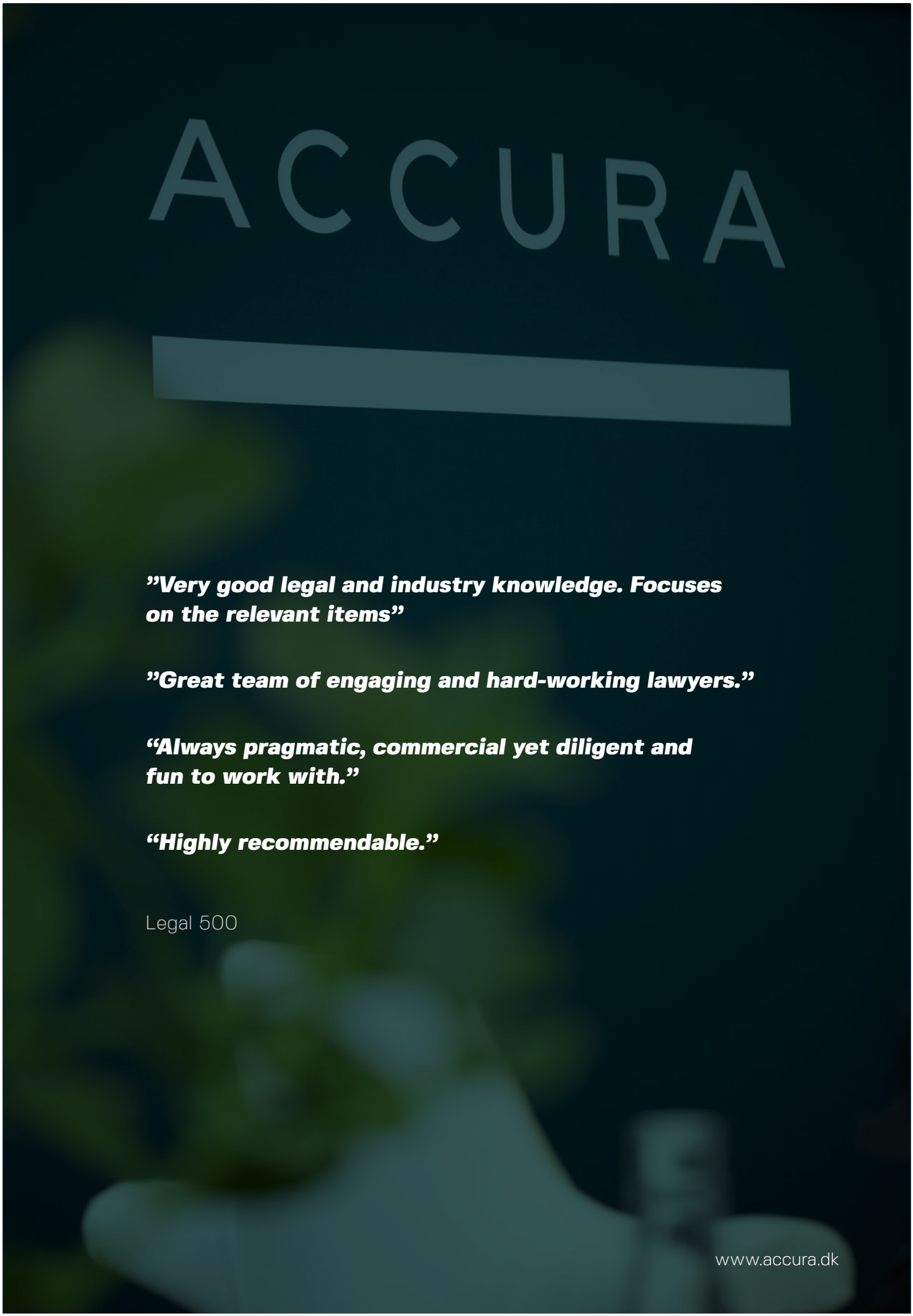
When using the data, it must be clear from the Medicines Council's recommendation and guidance where and how the relevant data has been used, including the type of data and the published main study it is based on.

In any case, it is a requirement for the Medicines Council's use of unpublished data that such data can be published no later than a year following the time of the council's recommendation and guidance.

Accura comments

The introduction of new types of data available for the Medicines Council to rely on is expected to be warmly welcomed by the industry as it provides the Medicines Council with the opportunity to rely on the latest knowledge in the field even though such knowledge has not yet been published.

By allowing the publication of data to be postponed by up to a year, the Medicines Council seems to acknowledge that suppliers of data have a strong interest in being the first to publish data. At the same time, the council recognizes the fine balance that any postponement of the publishing of data beyond reason could collide with the principle of transparency given that both industry and the general public has an interest in the scientific basis of the evaluations and recommendations made by the Medicines Council.



”Very good legal and industry knowledge. Focuses on the relevant items”

”Great team of engaging and hard-working lawyers.”

“Always pragmatic, commercial yet diligent and fun to work with.”

“Highly recommendable.”

Legal 500

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