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IPR & Life Science News

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New important decision from ENLI's Appeals Board

On the ethical rules for the pharmaceutical industry's dialogue and negotiations with decision-makers (the Lobbying Code)

On 16 December 2021, the Appeals Board of the Danish Ethical Committee for the Pharmaceutical Industry (ENLI) issued a decision that may clarify the scope of the prohibition against financial support or sponsorships to decision-makers in Article 13 of the Lobbying Code.

In its decision, the Appeals Board found that a pharmaceutical company's contemplated podcast project with politicians did not go against the Lobbying Code and its overall purpose, and the Appeals Board therefore reversed the Investigator's Panel's (1st instance of ENLI) decision.

The Lobbying Code and the podcast project

According to Article 1 of the Lobbying Code, the Code provides the legal framework for an open, honest, fair and credible dialogue between pharmaceutical companies and politicians and regulatory authorities, while the Code's Article 13 prohibits pharmaceutical companies from providing financial support to decision-makers (being politicians or public officials).

Considering the Lobbying Code and these provisions, a pharmaceutical company requested ENLI's Investigator's Panel's prior approval of a contemplated podcast project.

The project more specifically involved the publication of 7 podcast episodes to be made available at one or more podcast platforms and to be offered to radio stations. In each episode, the chairman of the relevant regional council and the respective chairman's rival political candidate as well as a representative from another political party and a health economist were to debate the future of the Danish healthcare system in year 2041. The participants would not receive any form of payment and would be given equal speaking time during each episode. The pharmaceutical company would pay the podcast production costs, which would appear (both in speak and description) from each podcast episode, and all participants would be informed thereof as well.

The decision of the Investigator's Panel

The Investigator's Panel found that the pharmaceutical company's coverage of expenses related to the production and distribution of the podcast could be characterized as an indirect financial support to the participating politicians and therefore contrary to Article 13 of the Lobbying Code. The Panel attached importance to the fact that the pharmaceutical company was covering expenses that the participating politicians would otherwise have to cover themselves to disseminate their political viewpoints. According to the Investigator's Panel, the participating politicians were thereby granted an economic advantage.

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The decision of the Appeals Board

The Investigator's Panel's dismissal of the podcast project was appealed to ENLI's Appeals Board. The Appeals Board did not agree with the Investigator's Panel's notion that the pharmaceutical company's coverage of expenses was considered an indirect economic advantage within the scope of Article 13 of the Lobbying Code. The Appeals Board found that that the podcast as described would contribute to the general political debate on healthcare and that there was no risk that the podcast would be able to promote certain political opinions.

In its decision, the Appeal Board refers to the main objective of the Lobbying Code; to guarantee an honest and credible dialogue between pharmaceutical companies and decision-makers and to make sure that these parties are financially independent.

In this regard, the Appeal Board emphasizes that the participating politicians would not be remunerated for their participation in the podcast episodes and that each politician would be granted equal speaking time. Further, it would be ensured that the participating politicians represented different political views and values thereby balancing the debate.

In light of the above, the Board found that the podcast did not conflict with the main objective of the Lobbying Code.

Accura comments

The Lobbying Code was last revised in June 2017, and the code is not supplemented by detailed guidance as some of the other ethical rule sets from ENLI. Further, only a handful of published decisions from ENLI have been made within the last 5 years to shed further light on the Lobbying Code. Accordingly, the Appeals Board's decision on the podcast project provides some much-needed guidance on the Lobbying Code's overall purpose and the scope of the prohibition against financial support or sponsorships to decision-makers in Article 13. With the decision, it is established that certain types of support from pharmaceutical companies to projects involving decision-makers such as politicians are not per se incompatible with the objectives pursued by the Lobbying Code.

Feel free to reach out to Accura's team of Life Science specialists, if you have any questions regarding the decision or the Lobbying Code in general.

2022-trends

Digital IP infringements and how to avoid them

While a new year has just commenced, e-commerce continues to be in a rapid development. The COVID-19 pandemic has contributed to be in a speeded growth as an increasing number of consumers are resorting to online marketplaces rather than physical stores.

However, the booming e-commerce has also entailed an undesirable increase in the trade of counterfeit products and introduced new forms of digital IP infringements that are difficult to combat.

In this article, we guide you through some of the latest trends in the digital world that right holders should be alert to in 2022.

Dupe culture

Dupe Culture has gained ground on many of the predominant social media platforms for user-generated content.

Dupe Culture means that platform users are highlighting and sharing where to purchase so called "off-brand alternatives" – these alternatives are often counterfeit products that look almost identical compared to the original.

Posts regarding such counterfeit products are eagerly shared between the platform users by hashtags, links etc. The sharing of such posts makes it possible for counterfeiters to reach a high number of potential buyers at the disadvantage of the right holders. As Dupe Culture contributes to legitimize trade of counterfeit products, it has the potential to cause significant problems for right holders.

Sales on live stream

Many social media platforms provide live stream options. Livestream makes it possible for users to interact with their followers in real-time and therefore constitutes an effective sales tool that can be used by traders, including counterfeiters, to reach consumers.

Livestream sales of counterfeit products may impose a challenge for right holders as content from livestream videos is rarely available for streaming on demand once the livestream session has ended. Also, counterfeiters can easily start a new livestream session should the initial one be shut down by the platform used or by the right holder. These factors are making it particularly difficult for right holders to discover and document potential IP infringements conducted on livestreams.

Re-commerce and second-hand sale

The search for unique or sustainable products at a reasonable price has created a high demand for second-hand products. The number of online marketplaces that facilitate trade in second-hand products is therefore steadily growing.

While second-hand trade contributes to the circular economy, it also entails an increasing trade in counterfeit products with easy access for counterfeiters to create sales profiles on online platforms. Additionally, it will often be difficult for consumers to assess if a second-hand product is original or not – especially when the purchase process takes place online. Though many providers of online platforms are using algorithms designed to detect sales of counterfeit products, many counterfeits stay under the radar.

An increasing number of online platforms

The number of digital platforms suitable for e-commerce is continuously on the rise, providing counterfeiters with many new ways to reach potential buyers of counterfeit products.

As a direct consequence of this development the right holders' task of monitoring potential infringements on online platforms continues to grow and be more demanding. Further, the development makes the enforcement of IP rights more complex and demands enhanced monitoring capacities and e-commerce knowledge from right holders.

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How do you protect your IP rights in the digital world of 2022?

Right holders must (continue to) take diligent action in 2022 to protect their IP rights in the digital world.

Providers of online platforms as well as several public authorities are aware of the many challenges caused by the accelerating e-commerceand are therefore making rights monitoring and enforcement tools available for right holders. By way of example, The European Union Intellectual Property Office (EUIPO) has published an overview of the enforcement tools that are made available by a selection of the major e-commerce platforms.

The awareness of and fight against the digital challenges regarding counterfeit products are also reflected by case-law where many court proceedings have resulted in online platform providers being held responsible for knowingly facilitating the misuse of trademarks.

Get off to a good start in 2022

Proactive and focused enforcement of rights begins with an adequately prepared IP strategy. We recommend starting out 2022 by considering the following:

1. An up-to-date IP strategy

Make sure that the IP strategy is up-to-date and that it provides the necessary protection of the IP rights in all relevant markets.

2. To register or not to register?

Consider which IP rights should be protected by registration and which IP rights can be protected unregistered based on use. Make sure that the necessary measures to document any use of the IP rights have been established.

3. Customized monitoring

An optimal monitoring and watch strategy must be implemented. Among several steps, this strategy must involve the use of monitoring tools supplied by the providers of online platforms and searches for new trademark registrations. Consider which parts of the monitoring strategy are important to minimize major risks based on the specific IP rights and business and which parts may be downgraded for commercial and/or economic purposes.

4. Enforcement

Ensure clear and sufficient procedures and politics for how to handle potential infringing activities. Consider how to immediately secure the necessary documentation of potential infringement, which additional actions are necessary and when external legal counsel shall be engaged.

5. Long-term thinking

Consider the development of relevant IP rights and business in the following 5 years. If expansions into new markets or introduction of new products are on the horizon, a thorough consideration of when to carry out the necessary preparatory steps must be initiated. These acts may involve searching for existing (identical or similar) rights and/or monitoring of new IP applications, registrations of company names, domains etc.

If you have any questions regarding the protection of IP rights in the digital world and the development of a solid enforcement strategy, feel free to reach out to Accura's IPR & Life Science team.

The Danish Medicines Council

Conditional recommendations of medicinal products

As per 1 January 2022, the Medicines Council can issue conditional recommendations of medicinal products for a limited period, while awaiting collection of additional data regarding the respective product's efficacy, safety and cost efficiency.

This type of recommendation may be particularly useful for innovative medicinal products that, on the one hand, may possess added therapeutic value but, on the other hand, may be accompanied by high performance uncertainty. Conditional recommendations can also prove valuable when using the accelerated approval process or for medicinal products that target very small patient groups (such as personalised medicines). In such cases, it can be difficult for the Medicines Council to assess the efficacy, safety and cost efficiency of the medicinal product, and whether the medicinal product should be recommended as a possible standard treatment.

New course of action

Until recently, the Danish Medicines Council only had two possible courses of action when assessing medicinal products with documentation subject to significant uncertainty; The Medicines Council could either refrain from recommending the medicinal product, or demand decreased pricing of the medicinal product. Now and instead of rejecting recommendation, the Medicines Council may choose to issue a conditional time-limited recommendation.

During the conditional time-limited recommendation period, the medicinal product may be used as a possible standard treatment. Meanwhile the pharmaceutical company must collect additional documentation for the efficacy, safety and/or costs of the medicinal product, as relevant.

Criteria for conditional recommendations

If the Medicines Council concludes that the relation between effect and costs cannot be assessed due to material uncertainties, the Council can decide to further investigate whether a conditional recommendation can be issued.

A conditional recommendation is reliant on the following criteria:

1. The Medicines Council will not recommend the medicinal product as a possible standard treatment, because the uncertainty related to efficacy, safety and/or costs, is too high,
2. The medicinal product has the potential to be cost efficient at the offered price,
3. More data would possibly reduce the clinical uncertainties,
4. The price of the medicinal product must reflect that the size of the effect of the product is uncertain; and
5. The pharmaceutical company will finance the data collection.

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Conclusion of the data collection

Once the new data collection has been completed, the Medicines Council will perform a renewed assessment of the given product's effect, safety and/or costs.

The central Danish purchasing body, Amgros, will negotiate the price of the medicinal product based on the assessment of Danish Medicines Council.

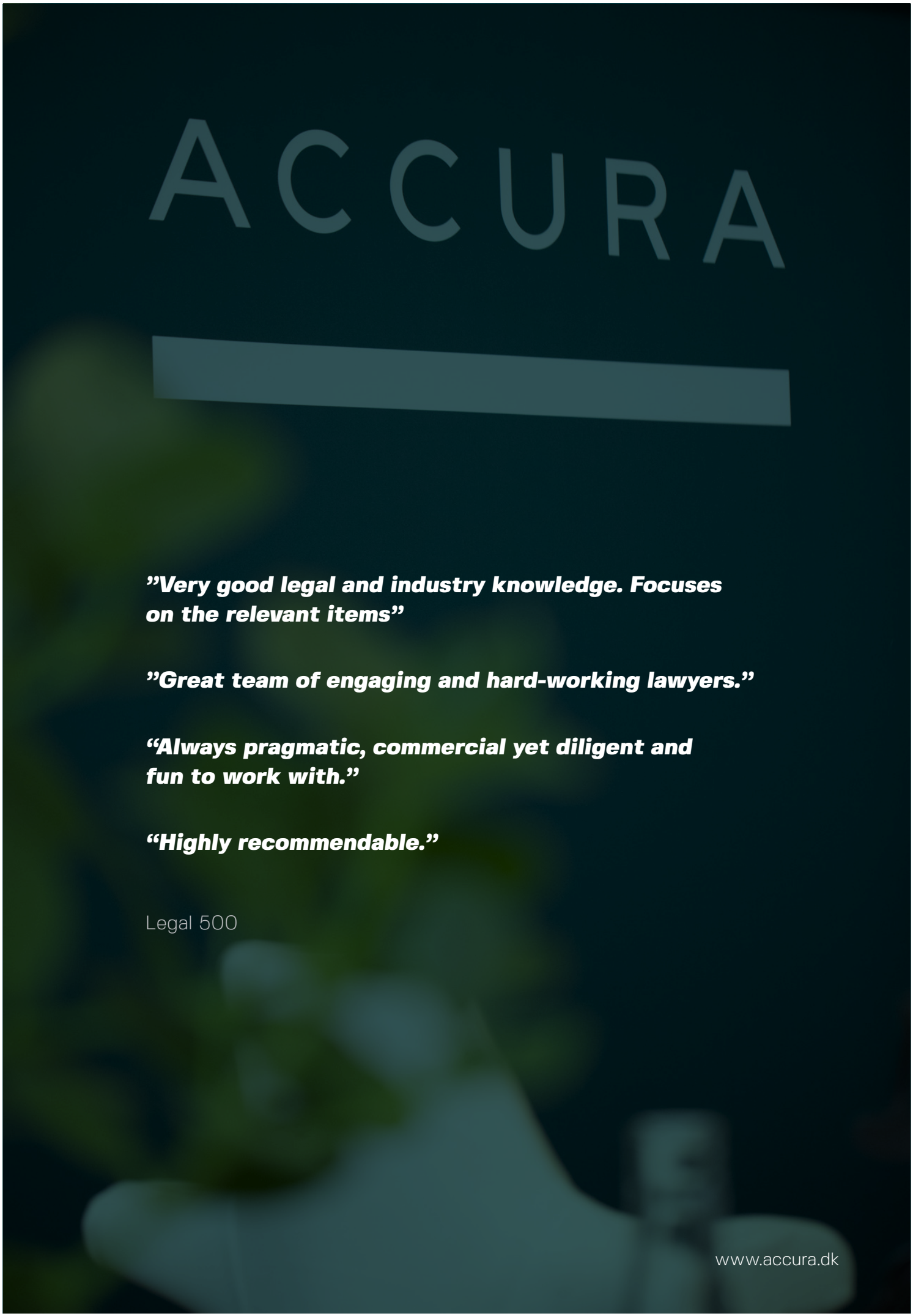
Following the conclusion of the negotiations by Amgros, the Medicines Council will finally assess whether the medicinal product can be recommended as standard treatment – without conditions.

You can read the Danish Regions' memo on the model for using conditional recommendations (PDF document only available in Danish) here.

Accura comments

The possibility for the Medicines Council to issue conditional recommendations will likely prove beneficial for all stakeholders in the life science industry, including pharmaceutical companies and patients, as such recommendations may provide quicker and increased access to new and potentially very beneficial medicinal products at Danish hospitals.

You can read more on pricing of medicinal products in the hospital sector and the use of value-based pricing in our article contribution "Value-Based Pricing Agreements for Hospital Medicines" in the latest issue of the Swiss legal journal Life Science Recht. Do not hesitate to contact Partner and head of team, Morten Bruus, if you are interested in a copy. The article is also available here (payment wall).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