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December 2020

IPR & Life Science News



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Danish court issues important ruling

in pharma press release case between Sanofi and Novo Nordisk

In a groundbreaking case regarding a global press release covering results of a clinical trial, the Maritime and Commercial High Court in Denmark (home of diabetes giant Novo Nordisk) ruled on 1 December 2020 that an international press release issued by Novo Nordisk in Denmark was illegal advertising of a pharmaceutical product and that it was in breach of the Danish Marketing Practices Act.



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Notably, the court found that the contents of the press release were scientifically unfounded and that the press release's communication of results from a major post marketing study comparing basal insulins from the two parties was fit to mislead readers and have a damaging effect on the sales of Sanofi's product and on Sanofi's reputation.

The Maritime and Commercial High Court imposed sanctions of unprecedented nature in such cases by not only fining Novo Nordisk and ordering the Danish pharma company to pay damages to Sanofi but also ordering Novo Nordisk to issue a rectification in English withdrawing the press release through the same international channels as the press release was issued, including media, news subscribers and the company's own .com website.

From a legal point of view, the ruling clarifies that press releases – although generally exempted from the rules of pharmaceutical advertising – can indeed be considered advertising. Furthermore, the court states that the general rules on unfair marketing practices (in Denmark the Marketing Practices Act) apply in parallel with the more specific pharma advertising rules. The general rules on unfair marketing practices allow, to a greater extent than the specific pharma rules, consideration for not only patient interests, but also competitor relations and the commercial interests at stake when communicating about competing products.

Accura represented Sanofi in the case before the Maritime and Commercial High Court in Denmark. The verdict can be found [here](#) (in Danish).

EU directs action plan and strategy to IP and life science

With the recent issuing of an Action Plan on Intellectual Property and a Pharmaceutical Strategy, the European Commission has put the spotlight on the importance of intellectual property and life science as a key driver for economic growth and health in the EU.

Action Plan on Intellectual Property

The Action Plan on Intellectual Property aims at preserving EU's creative and innovative industry as a global leader and supporting the industry's role in securing economic recovery and resilience in the EU.

The Action Plan was commenced following the [New EU Industrial Strategy](#), published earlier this year. The Action Plan emphasises the importance of IP and its cornerstone placement in the European economy. In Europe, IP-intensive industries account for 93% of good exports from the EU and 45% of all GDP. The evident presence of IP is further highlighted by the fact that IP filings are rising both globally and within the EU according to the Action Plan.

The increased awareness of the importance of IP calls for improvement of EU's IP system. Overall, the Action Plan uncovers that the IP framework needs upgrading and new policies to help companies capitalise on their inventions and creations while ensuring that such intangible assets benefit the EU economy and society.

Among the announced measures are ensuring *improvement of the SPC regime* by possibly introducing a unified SPC grant mechanism, *modernising EU design protection* and

registration processes and further *exploring the use of new technologies* such as 3D printing, AI and blockchain to promote the uptake of such IPs and to improve the effectiveness of IP systems. Where registration is needed to protect IP rights, the Action Plan suggests pushing for more *one-stop shop procedures* to reduce complex and costly processes and barriers of protection.

Other key measures in the Action Plan are to *facilitate sharing and access to (critical) IP* and to *boost the uptake of IP by SMEs* by improving information, advice and assistance. The Action Plan further takes steps to *combat counterfeiting and piracy* by establishing an "EU Toolbox" with joint action principles and by clarifying and upgrading responsibilities of digital services, including online platforms.

The measures of the Action Plan on Intellectual Property are expected to be implemented over the next few years. Read the Commission's press release [here](#) and the Action Plan [here](#).





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Pharmaceutical Strategy

The intent of the Commission’s Pharmaceutical Strategy is to strengthen the EU’s pharmaceutical systems by launching several legislative and non-legislative actions.

Primarily, the Strategy seeks to ensure access, availability and affordability of medicines. Other key objectives are to support the EU pharmaceutical industry’s competitiveness, sustainability and innovation and to initiate bilateral cooperation promoting regulatory convergence to improve access to effective and safe medicinal products on a global level.

The Strategy introduces flagship actions such as a general revision of the Medicinal Directive (2001/83/EC) and Regulation (EC 726/2004), a proposal for a Health Emergency Response Authority and a European Health Data Space to support digital infrastructure, and enhanced cooperation between national authorities relating to pricing, payment and procurement policies for the improvement of affordability of medicines.

The Commission emphasises that the actions of the Strategy are partially inspired by the learnings from the initial response to the COVID-19 pandemic, which not only showed effective cooperation and strengths in the EU health care system, but also revealed pitfalls and vulnerabilities relating to, inter alia, data availability and medicinal supply.

The actions of the Pharmaceutical Strategy are expected to be introduced and proposed over the next few years. Read the Commission’s press release [here](#) and the Pharmaceutical Strategy [here](#).

Accura’s dedicated team of IP & Life Science experts will follow the implementation of the initiatives closely.

Higher legal costs awarded in IP litigation in Denmark



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Winning parties of IP court cases in Denmark can look forward to enhanced reimbursement of legal costs spent on future litigation.

With several recent decisions, the Danish Eastern High Court has clarified that legal costs awarded in disputes on intellectual property rights should not be limited to the Courts' usual standard rates but better reflect lawyer's fees in the area of intellectual property together with a significant and appropriate part of the reasonable expenses actually incurred.

Previous practice

Under Danish law, the party winning a litigation is awarded legal costs by the Court to be paid by the losing party. In civil proceedings the amount awarded will be a "reasonable amount" based primarily on the value of the case. The High Courts have prepared a memo with advisory flat rates for cases of various values, including instructive maximum amounts, considered to be such reasonable amounts.

For years, this principle for calculating legal costs has also been applied to disputes concerning intellectual property. As cases concerning intellectual property are often complex and thus expensive, legal costs awarded have rarely been anywhere near to cover the actual costs spent by the winning party on enforcing its rights.

CJEU case C-57/15, United Video Properties Inc.

It follows from the Directive (2004/48/EC) on the enforcement of intellectual property rights that the member states must ensure that reasonable and proportionate legal costs and other expenses incurred by the successful party as a rule must be borne by the unsuccessful party.

In 2016, the CJEU considered whether a Belgian regulation concerning a flat-rate scheme for the reimbursement of costs for the assistance of a lawyer was compatible with the Directive. The CJEU ruled that the requirement under the Directive that the unsuccessful party must bear "reasonable" legal costs cannot justify legislation providing flat rates which do not ensure that, at the very least, a significant and appropriate part of the reasonable costs incurred by the successful party are borne by the unsuccessful party because the maximum amounts of such flat rates are too low.

New practice

Following the above CJEU decision, the Danish Eastern High Court has considered how Danish law on awarding legal costs in intellectual property disputes should be interpreted in accordance with the CJEU decision. Just this year, the Court has in at least five cases concerning patents, trademarks, and copyrights, respectively, expressed almost identical statements in its reasonings that legal costs should be interpreted in accordance with Directive 2004/48/EC and the CJEU case C-57/15. Also, the Eastern High Court has in more cases added in its reasonings that this implies that the winning party shall be entitled to recover legal expenses which reflect partly the rates charged for legal assistance in the field of intellectual property and partly a significant and appropriate part of reasonable expenses actually incurred. Last month, the Supreme Court confirmed this new practice in a case concerning trademarks.

Although legal costs will still not be fully recovered in successful legal proceedings, the new practice established by the Eastern High Court and the prospect of enhanced reimbursement of legal costs makes it more attractive for parties to enforce their intellectual property rights in Denmark.

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”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