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IP & Life Science News

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Can a preliminary injunction be based on a patent pre-grant?

In cases of alleged patent infringement, preliminary injunctions are considered the primary relief for patentees, allowing for provisional and immediate enforcement. But can preliminary injunctions be based solely on a patent application (a patent pre-grant)?

The obvious answer seems to be 'no', as the prospective patentee holds no patent (yet). But does the answer change into a 'yes' if there is a great certainty that the patent will in fact be granted – and likely during the preliminary injunction case?

This question was recently raised in a series of court cases in Europe in which pharma company Novartis has sought preliminary relief against a number of generic competitors based on a patent application.
While the Danish Maritime and Commercial High decided that a preliminary injunction cannot be requested before a "decision to grant", the UK Patents Court ruled that preliminary injunctions in the UK are, in principle, possible pre-grant, however refusing Novartis' request in the specific case.

The facts

During the spring of 2022, Swiss pharma company Novartis filed requests for preliminary injunctive relief in a series of European jurisdictions. The cases were brought against a number of generic competitors to keep their generics off the market for Novartis' prescription-only medicinal product fingolimod ("Gilenya") for the treatment of relapse remitting multiple sclerosis.

Novartis filed a European patent application for a divisional patent (based on an application from 2007) that is currently still pending; In November 2020, the European Patent Office (EPO)'s Examining Division denied grant due to lack of novelty. Novartis appealed to EPO's Technical Boards of Appeal (TBA). In February 2022, TBA remitted the case to the Examining Division with an order to grant the patent. TBA's full written decision and subsequent remission to the Examining Division, entailing setting dates for decision to and mention of grant as well as processes on validity, translations etc., are still en route.

In Germany, Austria, Finland and the Netherlands, Novartis' requests for a preliminary injunction have been denied. In Belgium and Spain, the requests were granted but with reference to rules on fair trading practices (and not based on the patent application). Below in this article, we elaborate on the decisions in the UK and Danish case.

UK case

As the preliminary injunction was requested by a prospective patentee not (yet) holding a patent but only a pending application, the Patents Court (at the High Court of Justice) had to first consider, whether the court, in principle, is competent to grant preliminary injunctions for patents pre-grant. The court affirmed that it holds jurisdiction to do so.

The court stated that its power to grant injunctions is unlimited, subject only to statutory restrictions. Though a patentee may only initiate patent infringement proceedings and claim damages post-grant, the British Patents Act does not impose any statutory bars on granting a preliminary injunction based on a patent pre-grant. The court noted that final remedy in damages is very different from preliminary injunctive relief, which is temporary, provisional and protects the defendant by cross-undertaking in damages.

The court then pointed to the Senior Courts Act section 37 and established case law, stating that accrued cause of action is not a requirement to seek an injunction. In this regard, the court dismissed arguments presented by some of the defendants that the request for injunctive relief pre-grant of the patent was an abuse of process. The parties "all know that a patent will be granted and the scope of that patent" and that administrative procedures applicable to the EPO alone is causing the delayed grant. As Novartis may later claim damages for loss suffered in the period between the introduction of the generic products and the day of grant (once the patent has been granted), it did not constitute an abuse of process to seek preliminary injunctive relief pre-grant.

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As for concerns raised by the defendants that allowing for preliminary relief pre-grant could result in a floodgate of cases, it was simply stressed that the court will be wary of attempts to obtain an injunction pre-grant and that injunctions at this stage are only possible in exceptional cases with regards to the certainty of the patent being granted and its scope.

Preliminary injunction

As for the present case, the court considered, inter alia, whether damages are an adequate remedy for the loss of the claimant if an injunction is not granted.

Novartis argued that the launch of generics would cause a downward price spiral. The court rejected this argument, stating that as fingolimod was prescribed in secondary care only, the price was determined by National Health Service (NHS) tender agreements which would make it easy to calculate Novartis' loss. Thus, damages were an adequate remedy, if Novartis were to ultimately prevail. On the contrary, damages (cross-undertakings) were an inadequate remedy for the generic defendants if the injunction was to be granted and Novartis then failed on its claim at (main) trial.

The court therefore denied Novartis' request for a preliminary injunction. Novartis applied for permission to appeal the decision, which was denied. The main trial (on validity) is set for October 2022. Red the full decision of 26 April 2022 by the Patents Court here.

DK case

In the Danish case, the defendants made an objection of inadmissibility, claiming that Novartis lacked sufficient cause of action as Novartis, at this point, only holds an application for patent and not yet a valid intellectual property right. The Danish Maritime and Commercial High Court listed this specific procedural issue for a separate oral hearing which was held on 2 June 2022.

Novartis, claimed that the final decision from TBA, ordering the Examining Division to grant the patent, is sufficient to establish cause of action. The defendants contested this, stating that a preliminary injunction request cannot be processed without the existence of a valid intellectual property right to be enforced.

The Maritime and Commercial High Court ruled that Novartis' requests for preliminary injunctions were inadmissible. Cause of action, including real and current relevance of the claim, must be present once legal proceedings are commenced (i.e. at the request for preliminary injunction). Though the parties disagreed as to the predictions of when Novartis' patent will be granted, it was undisputed that the patent was in fact not granted at present time and that "decision to grant" had not yet been issued. Additionally, the court touched upon the lack of certainty of the grant of the patent in its current form, noting that there was a risk, albeit small, that the wording of the patent as granted could end up diverging from the wording of the patent application. Novartis therefore lacked cause of action at this point in time and the requests for preliminary injunction were dismissed (with the exception of one claim against one defendant which was also based on a valid patent).

The decision of the Danish Maritime and Commercial High Court, which is still open for appeal, can be found here (only available in Danish).

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Accura comments

The question of basing a preliminary injunction on a patent pre-grant has seemingly not been raised before in Danish or UK case law. To answer the question, one must first ask the difficult question of when is the grant of an intellectual property right so likely or imminent that it may already be enforced? What degree of certainty that the patent will actually be granted is necessary? Must it be 100 % (which does not seem to be an option before the patent is formally granted)?

Procedural law is primarily a matter for national law makers. Consequently, the conditions for claiming a preliminary injunction varies from country to country. However, as this is a matter likely to come up in cross-border patent litigation it is worth considering if any general findings or affirmations can be drawn from the current cases.

Learning from the UK and Danish case, a preliminary injunction based on a patent pre-grant requires "certainty" of the patent actually being granted including a clear determination of its scope. According to the UK case, such certainty seems to exist when the patent authorities have made a final decision to grant the patent, but the execution of such decision is still awaited. Basing a preliminary injunction request on a patent pre-grant is thus only relevant under exceptional circumstances such as in a case where only the formal grant is missing and soon to be expected.

Differently, according to the DK case, the threshold for grant certainty seems to be higher, at least requiring the existence of a "decision to grant". In both jurisdictions, the courts' decisions do however open up for preliminary injunctions prior to the patent actually being granted and validated in the relevant jurisdiction.

While the two cases are playing out in different jurisdictions under different national law, they do provide some useful preliminary guidance and insight at least as to what arguments might or might not be successful.

At the same time, the commencing of the Unified Patent Court (UPC) is getting closer, for which the question of basing a preliminary injunction request on a patent pre-grant will likewise be highly relevant. Under the present framework for UPC (which is still in preparation) in art. 62(2) of the UPC Agreement, the UPC must weigh up the different interests of the parties by taking all relevant factors into account, when assessing a request for a preliminary injunction against an alleged patent infringer. According to UPC's guidelines this balancing of interests includes an assessment of whether the evidence provided by the applicant establishes the existence of the patent "with a sufficient degree of certainty" as well as "details of the patents concerned, including the number", cf. rule 13 of the UPC Rules of Procedure. In conclusion, it seems that the legal framework for UPC has so far (like legislation in Denmark and UK) not explicitly considered the question of basing a preliminary injunction on a patent pre-grant but the requirement of rule 13 clearly speaks in favor of a granted patent being a necessity in preliminary injunctions.

New case law on the importance of registering trademarks

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Recent case law from the Danish Maritime and Commercial High Court underlines the importance of registering trademarks, which provides indisputable evidence of the right's existence, instead of relying on the – potentially uncertain – rights derived from the mere use of a mark. While trademark rights can be obtained based on legitimate use in accordance with the Danish Trademark Act section 3 (1) (iii), this court decision illustrates that registering trademarks provides companies with a more predictable legal position.

The case at hand was brought before the Maritime and Commercial High Court by a Danish provider of advisory services within the energy sector, andelcph, claiming that another trader within the fiber and energy sector, Andel Group's (Andel Holding A/S and Andel A.M.B.A) registration and subsequent use of the trademark ANDEL infringed andelcph's alleged trademark ANDEL. andelcph, who had not registered the mark ANDEL, claimed that it had acquired valid rights hereto by way of legitimate use in Denmark in accordance with the Danish Trademark Act section 3 (1) (iii).

In its judgement, the Court cited the Danish Trademark Act and confirmed case law, stating that a trademark may be acquired by use only for the goods or services it is used for if i) the trademark is sufficiently distinctive and ii) it is widely used both quantitatively and geographically. Within this assessment, the extent of the marketing activities in relation to the relevant customer group must be considered. The court noted, in accordance with the preparatory works, that passive marketing on the company's own website does not suffice as single evidence. The Court further found that the distinctive character of the trademark ANDEL was limited, necessitating a considerable marketing effort to establish the rights to the trademark based on legitimate use.

As andelcph had not presented evidence to support a wider knowledge of the trademark ANDEL among the company's customer group, nor used any notable amount on marketing, andelcph had not acquired trademark rights to ANDEL. Further, andelcph and Andel group did not operate in the same markets and there were no examples of customer confusion. The Court therefore found that there existed no likelihood of confusion.

Accura comments

With the 2019 amendment of the Danish Trademark Act, which clarified what already followed from case law, it was added that the use of a mark in the course of trade must be of more than mere local significance to create a trademark right. It must furthermore be possible to identify both the mark and the individual goods or services for which the mark is used, in order to amount to a qualifying use and protection.

The ruling from the Court confirms more recent discussions before the Danish PTO in connection with the 2019 amendment on the requirements for acquiring use-based trademark rights by underlining that companies must make quite significant efforts before a trademark right is established based on legitimate use – especially when the mark in question is not very distinctive.

Accura therefore recommends that companies always secure their trademarks by way of registration with the Danish PTO or EU IPO. Registration of a trademark will provide clear evidence of the scope of protection for a company, not least vis a vis third parties' later use, and use-requirements will not enter before 5 years after the date of registration.

If you have any questions regarding trademarks or other IP rights, you are welcome to reach out to Accura's IP team.

Revision of ENLI's Codes and Guidelines

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The Danish Ethical Committee for the Pharmaceutical Industry´s (ENLI) has revised four of its sets of ethical codes as well as its Penalties and Fees Regulations by adopting a number of changes and adjustments. Several changes are made as a result of the Danish Medicines Agency's newly published guidelines on the advertising of medicinal products.

The ethical codes (with related guidelines) concerned are the Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals (the **Promotion Code**), the Ethical rules for the pharmaceutical industry's donations and grants (the **Donation Code**), Ethical Rules for Collaboration between Patient Organisations, etc., and the Pharmaceutical Industry (the **Patient Organisation Code**) and the Ethical rules for dialogue and negotiations with decision-makers (the **Lobbying Code**).

The majority of the changes to the four ethical codes and guidelines are either updates in the form of clarifications or structural and linguistic adjustments. One common structural change is that so-called "rule boxes" are introduced and added to each provision in the guidelines to make it possible to read the provision in question together with the relevant guiding comments. A focal point of the changes has been to create more clarity and transparency, and the material changes are summed up below.

So what's new?

With respect to the Promotion Code, it is worth noting that the monetary thresholds for meals (food and beverages) in Denmark during professional events in Article 13(8) have been raised to: DKK 450 for lunch, DKK 850 for dinner and DKK 1,400 covering all meals at all-day meetings/conferences, etc. Also, the language requirement in Article 21(3) on the reporting of printed promotional materials aimed at healthcare professionals (HCPs) have been removed, so that promotional materials in English aimed at Danish HCPs in accordance with current practice are also subject to the reporting requirement. Additionally, the exceptions to what constitutes advertising for medicinal products are now written directly into the code along with definitions of the terms "advertising", "healthcare professionals" and "the public" from the Executive Order on Advertising of Medicinal Products.

In the Lobbying Code, Article 1 on the purpose of the code has been rewritten to make it more similar to the corresponding provision in the Promotion Code. Further, a newer decision from ENLI's Appeals Board from December 2021 is referenced in connection with the code's Article 13 on the prohibition of financial support to decision-makers. The decision is important for understanding the boundaries of the prohibition in Article 13 and what does not constitute prohibited financial support to decision-makers. The decision is explained and examined in more detail in Accura's previous newsletter from January 2022: Read it here.

As for the Donation Code and the Patient Association Code, no substantive changes have been made, and the same rules and practices therefore apply as previously. Both codes have, however, been rewritten and structured more systematically, and new provisions have been inserted while the content of others have been specified and given new paragraph numbers.

Lastly, the content of ENLI's Penalties and Fees Regulations has been clarified by inserting "+ VAT" in the provisions on fines and fees in line with current invoicing practices, and two examples on this issue, both of which are based on cases from the Appeals Board in 2021, have been inserted in Article 6.

The above changes to the ethical codes and pertinent guidelines entered into force on 15 July 2022.

Feel free to reach out to Accura's team of legal life science specialists if you want to discuss ENLI's codes in general or the recent changes thereto.

New partner to strengthen Accura's IP & Life Science team

On 1 July 2022, attorney Søren Chr. Søborg Andersen joins as partner in Accura's IP & Life Science Team.

Søren Chr. Søborg Andersen will focus primarily on Accura's work with complex patent cases and on providing legal services to the pharmaceutical industry.

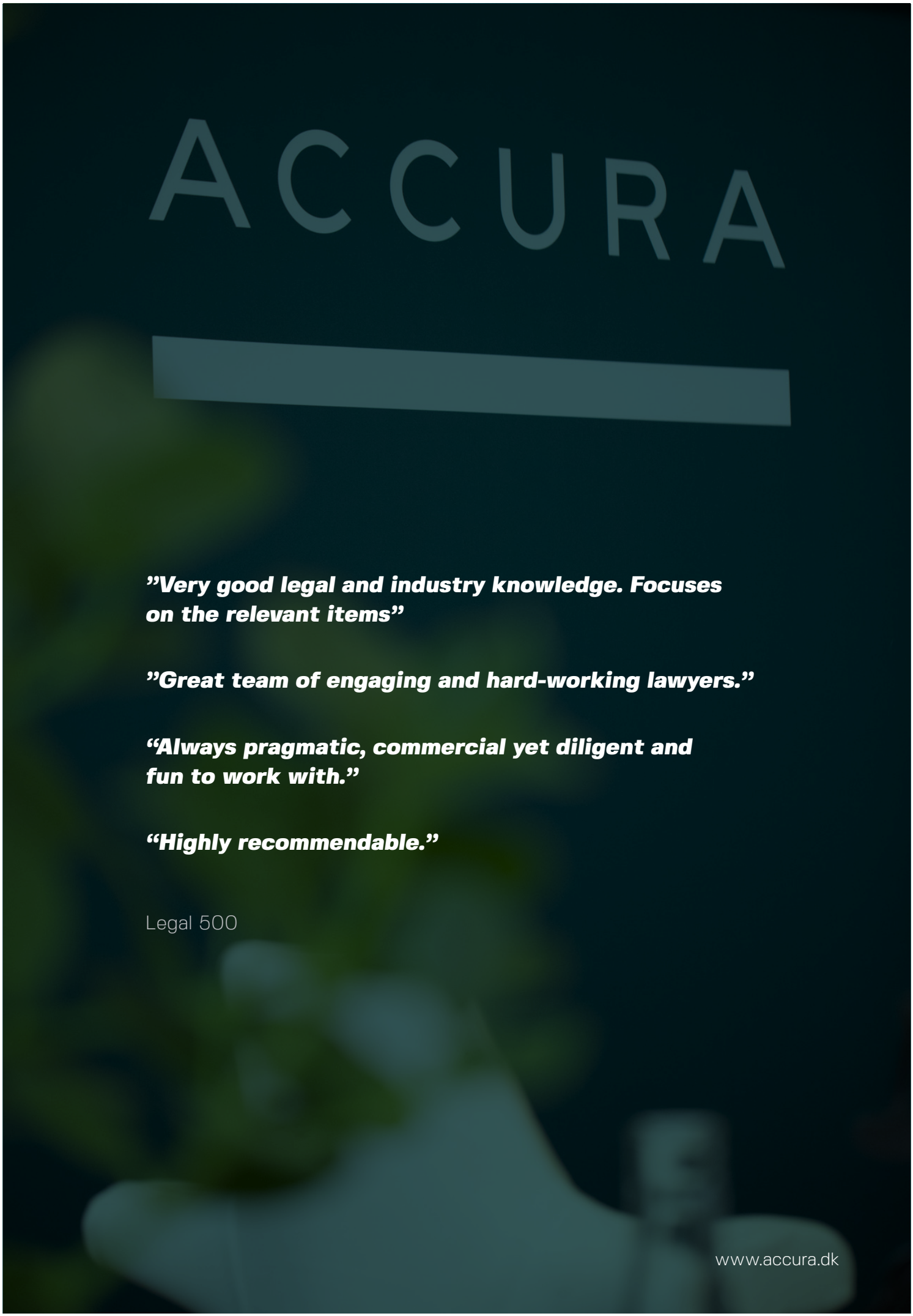
"We are experiencing a substantial increase in the demand for our services within patents and life science, both within litigation and transactions. Søren is vastly experienced and a highly recognised profile in the market, and he will be a valuable asset to our customers from his very first day. With Søren as part of our team, we become even stronger in terms of offering our customers legal services within complex IP law and the related regulatory advice," says Morten Bruus, partner and head of Accura's IP & Life Science Team.

"Accura is a dynamic firm experiencing substantial growth in several practice areas, including mine. That is a project which I would really enjoy being part of and I look forward to contributing to the continued development of Accura's IP & Life Science Team together with a strong team," says Søren Chr. Søborg Andersen.

Accura's IP & Life Science Team is one of Denmark's leading IP teams, both in litigation and as part of Accura's market-leading M&A business.

"As a law firm with a focused strategy for working with the most complex transactions and projects, a further strengthening of our IP & Life Science Team brings great value for several of Accura's customers. Our interdisciplinary collaboration and results are our strength, and it goes without saying that expert teams such as our IP & Life Science Team, who is top-tier in their field, is an important element in executing our strategy," says Thomas Weincke, partner and chairman of Accura's board of directors.

With Søren Chr. Søborg Andersen, Accura's IP & Life Science Team consists of 15 persons.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