ACCURA

February 2018

IPR & LIFE SCIENCE

NEWS

This edition of Accura's IPR & Life Science newsletter covers a broad range of topics, from a controversial new pilot programme on medicinal cannabis over key European case law on both transparency of clinical data and fraudulent trademark invoices, to the Danish court system going fully digital.

We also update you on important new guidelines significantly altering how to offer professionally relevant courses and congresses to Danish healthcare professionals.

www.accura.dk

CLINICAL TRIALS: EU COURT CONFIRMS STRICT VIEW ON TRANSPARENCY

On 5 February 2018, the General Court delivered three key judgments regarding the understanding and scope of transparency of clinical trial data under the Transparency Regulation.

In all three judgments, the General Court of the Court of Justice of the European Union upheld the European Medicines Agency's (EMA) decision to release documents included in the marketing authorization (MA) application dossier for a centrally approved medical product. The MA holders fruitlessly argued that the documents contained commercial confidential information.

The judgments mark the first time the Court of Justice of the European Union has had the chance to comment on the merits of the so-called Transparency Regulation ((EC) No 1049/2001) in relation to documents held by the EMA.

In all three cases, a competing pharmaceutical company or third party had requested the EMA to release documents included in an MA application dossier of another pharmaceutical company. All three requests were based on the Transparency Regulation together with EMA's own policy on access to documents.

With the three judgments, the General Court clarifies the scope of the commercial confidentiality defence, as set out in article 4 of the Transparency Regulation, in relation to data included in the MA application dossier for centrally approved medicinal products.

The General Court noted that no specific evidence was given on how the release of the documents would compromise the commercial interests of the MA holder. Accordingly, the claims of commercial confidentiality were rejected.

The specific cases concerned the disclosure of a) similarity and superiority reports on an orphan medicinal product (prepared by the Committee for Medicinal Products for Human use(CHMP)), b) a clinical study report, and c) toxicology study reports for a veterinary medicinal product.

While every request to the EMA for the release of documents must, naturally, undergo a specific assessment, the three judgments clearly demonstrate that the General Court of the Court of Justice of the European Union interprets the commercial confidentiality defence in the Transparency Regulation narrowly. Going forward, pharmaceutical companies wishing to challenge the release of documents under the Transparency Regulation must carefully evaluate whether adequate specific evidence supports a claim for commercial confidentiality.

Contact Accura's team of experiences life science specialists, if you would like further information on the new judgments of the General Court and/or the Transparency Regulation.

Morten Bruus
Partner, Attorney-at-Law
IPR and Life Science
morten.bruus@accura.dk

Christoffer Ege Andersen
Attorney-at-Law
IPR and Life Science
christoffer.ege.andersen@accura.dk

THE PHARMACEUTICAL INDUSTRY CAN NO LONGER DIRECTLY ADDRESS HEALTHCARE PROFESSIONALS IN THE PUBLIC SECTOR WITH OFFERS ON COURSES AND CONFERENCES

Danish Regions recently adopted a new set of guidelines stipulating that companies wishing to financially contribute to relevant training of healthcare professionals (HCPs) within the Danish public health service shall approach the hospital management and not the individual HCP.

By prohibiting companies from directly offering HCPs to pay for their participation in professionally relevant courses and conferences, Danish Region introduces an arm's length principle to minimize any undesirable direct contact between the industry and individual HCPs. This is a remarkable change in the approach.

The driving force behind these guidelines is Danish Regions' fundamental wish to ensure that the independence and impartiality of its HCPs towards the pharmaceutical industry is in any way unquestionable.

From now on, the hospital management shall take responsibility for its employees' participation in relevant supplementary education. Hence, if a pharmaceutical or medical device company wants to contribute financially to such supplementary education by paying for the HCPs' participation in professionally relevant courses or conferences, the company shall address such offer of financial contribution to the hospital management – not the HCP him-/herself.

The hospital management will then at its own discretion decide if any hospital employee(s) shall participate in the offered sponsored course, conference, etc., and if so, which employee will be allowed to attend.

In Denmark, it is quite common for HCPs to participate in public advisory committees such as the Danish Medicines Council. These have ethical rules to ensure that the HCPs on the board are impartial and unbiased.

In this regard, the hospital management shall, when deciding on which employee(s) to attend the offered course or conference, take such advisory committees into consideration to ensure that no HCP, inadvertently, becomes incompetent in regard to his/her other appointed tasks.

The new set of guidelines from Danish Regions will function as another layer on the existing, complex set of rules on the collaboration and association between pharmaceutical and medical device companies and HCPs.

Contact Accura's team of experiences life science specialists, if you would like further information on the new set of guidelines from Danish Regions.

Morten Bruus
Partner, Attorney-at-Law
IPR and Life Science
morten.bruus@accura.dk

Christoffer Ege Andersen
Attorney-at-Law
IPR and Life Science
christoffer.ege.andersen@accura.dk

NEW JUDGMENT ON FRAUDULENT INVOICES TO TRADEMARK OWNERS

On 20 December 2017, the Court of Appeal in Stockholm convicted 20 persons for fraud as they had sent hundreds of fraudulent invoices with the letterhead "OMIH" to trademark owners in the period from 2011-2014, giving the impression that they came from the official patent and trademark authority OHIM (now EUIPO).

Patent and trademark rights typically represent great commercial value to the enterprise and its goodwill. Therefore, it is also important to pay renewal fees in relation to the portfolio, but many people find it to be not all that transparent.

Unfortunately, several dubious enterprises have made it a business to send out questionable invoices to rights holders who unfortunately pay the fraudulent invoices in good faith. The invoices are often sent in the period after an enterprise has applied or registered a trademark or after the publication of a patent application; i.e. in periods when the enterprise would not be surprised by receiving an invoice. The invoices are carefully imitated with official symbols; only with a keen eye for accuracy you will be able to spot the signs indicating that the invoices were not issued by the official trademark authority.

The Swedish Court of Appeal now has adjudicated a case against a group of individuals who have sent such invoices. In its decision, the Court of Appeal gave special attention to the fact that, in the circumstances, there was no other natural explanation to the recipients' payments of the invoices than that they had been misled to make such payments. As regards the question of actual fraud, the Court of Appeal concluded that, in the assessment of whether the recipients had been misled, importance should not be attached to the absence of concrete information from the recipients on why they decided to pay the invoices.

Accordingly, the Court of Appeal convicted the main defendant for 355 counts of attempted gross fraud and actual gross fraud. One of the other defendants was convicted for being complicit in all 355 counts of actual gross fraud and for having committed additional 33 counts of gross fraud, acting on his own.

The former defendant was sentenced to 4 years and 8 months imprisonment, while the latter defendant was sentenced to 2 years and 9 months imprisonment. 18 other defendants involved were convicted of complicity in the fraud. The defendants complicit in the fraud had e.g. made their bank accounts available for use in the fraud, and some of them had also assisted in sending the fraudulent invoices.

>

The prison sentences are at the top of the scale for gross fraud in Sweden. In the sentencing, attention was given to the well-planned and extensive nature of the fraud and to the fact that the fraudulent invoices appeared to have been sent by and originate from the EU trademark authority OHIM (now EUIPO).

Both the EUIPO and MARQUES, a European association representing the interests of European trademark owners, actively supported the Swedish prosecutor in the investigation of the case and gave witness statements during the trial hearing.

Accura's comments:

The concept of sending misleading invoices to trademark owners is a well-known problem in large parts of the EU. Therefore, it is a big win for trademark owners all over Europe that the Swedish Court of Appeal gave the fraudsters long imprisonment sentences, thereby sending a clear signal that such activities are unacceptable and will be adjudicated as fraud.

Enterprises should, however, continue their alertness to fraudulent, misleading invoices as there are still many authentic-looking invoices in circulation. They are always sent directly to the rights holder; i.e. knowingly avoiding a registered representative or agent. It should also be noted that the place of business of a fraudster committing this type of fraud typically is located outside Denmark, making it particularly complicated to enforce repayment.

We therefore invite you to contact us to check the authenticity of invoices received by your enterprise for payment of registration and renewal fees.

Christina Type Jardorf
Associate Partner, Attorney-at-Law
IPR
christina.type.jardorf@accura.dk

NEW DANISH PILOT PROGRAMME ON MEDICINAL CANNABIS

In January 2018, a new statutory pilot programme on medicinal cannabis came into force in Denmark. The purpose of the pilot programme is to establish a safe framework for the use of medicinal cannabis in the Danish healthcare system.

Essentially, it provides physicians with a possibility of prescribing certain types of cannabis-based products for medicinal use in specific cases.

The pilot programme primarily concerns cannabis-based products imported from EEA member states and allows import and manufacture of so-called cannabis primary or cannabis intermediate products which technically are different from medicinal products subject to the grant of a Marketing Authorization. Under the pilot programme, a primary product may also legally be transformed into an intermediate product by an authorized manufacturer. Subject to being prescribed by a physician to an individual patient, the intermediate product will then undergo a labeling procedure at the pharmacy. Hereafter, the final cannabis end product may be dispensed for the treatment of patients.

Further, a separate development programme will run parallel to the pilot programme making Denmark one of the first countries in Europe to allow growing of cannabis for medical use. The purpose of this programme is to allow companies to provide intermediary products to the pilot programme.

Both programmes will run for four years. Based on the experiences, an overall evaluation of the programmes will then be made with a view to making a political decision about a permanent medicinal cannabis scheme in Denmark.

Consequently, for the next four years, Danish companies can grow, import, and manufacture cannabis for medical use if they obtain the appropriate (time limited) authorizations from the Danish Medicines Agency (the DMA).

>

The DMA's website contains guidance for manufacturers and importers on how to apply for such authorizations to import primary products or intermediate products and/or to manufacture imported primary products into intermediate products or to grow cannabis for medical use.

Doctors may hesitate to prescribe medicinal cannabis

As the treatment of patients with medicinal cannabis is subject to a prescription from a physician, the DMA has as part of the pilot programme issued a new set of guidelines on treatment with medicinal cannabis addressed at the physicians. Among other things, these guidelines outline the possible therapeutic indications, which the DMA assesses to be eligible for treatment with medicinal cannabis.

However, even under the new trial programme, physicians prescribing medicinal cannabis must take full responsibility for the prescription, including for any possible side effects of the medicinal cannabis, because it has not been authorised by the DMA. Consequently, the efficacy and adverse reactions of the medicine have not been tested to the same extent as medicinal products with a marketing authorization, and as the scientific basis of medicinal cannabis remains insufficient, many doctors may still be reluctant to take such responsibility and prescribe the cannabis-based products.

Contact Accura's team of experienced life science specialists if you have any questions to the pilot or development programme on medicinal cannabis.

Morten Bruus
Partner, Attorney-at-Law
IPR and Life Science
morten.bruus@accura.dk

Rasmus Torp
Assistant Attorney
IPR and Life Science
rasmus.torp@accura.dk

DANISH COURTS ARE GOING DIGITAL

On 2 February 2018, all Danish courts go digital.

This means that all legal proceedings must be instituted and heard through an online court portal www.minretssag.dk (if translated meaning www.mylawsuit.dk). Legal proceedings already in progress will be converted into the portal on a continuing basis and within 2 years.

The electronic procedure means that any communication with a court must be sent through the portal. Communication means anything from instituting proceedings, requesting an extension of time, exchanging pleadings, uploading exhibits, fixing the trial date, generating the binder of pleadings and documents filed and the trial bundle, filing appeals and referring proceedings to the courts to payment of court fees, etc. This means that you will no longer be able to send emails, secure mail, etc., to the courts.

You can access the portal by using a digital employee signature which will be created for each attorney based on the law firm's company registration (CVR) number. All the parties will also have access to the case if they have a Danish company registration (CVR) number or a Danish civil registration (CPR) number. This means that foreign companies will not have direct access to the portal, but only through a Danish attorney.

In practice, the electronic procedure means that any information about legal proceedings, the parties, claims and pleas, legal issues, statement of facts and arguments will be entered into separate boxes on the portal. The portal will then generate the writ of summons and the list of exhibits produced in the proceedings. Pleadings and exhibits must be uploaded in an OCR format (Optical Character Recognition), and all court fees must be paid using international credit cards.

The portal is accessible 24/7 and you can have any form of communication with the portal during the opening hours. Accordingly, time limits expire at 11:59 p.m. on any given date.

The electronic procedure also brings about improved options for digital assistance during the trial hearing, including with respect to an extended possibility of producing digital files, video and audio during the proceedings. It will also bring about significant improvements with respect to witness examination through online communications and video.

Court records and judgments must be read on the portal and will be collected in a comprehensive, nationwide judgment database. This will bring about great prejudicial value and allow everybody to understand the judicial decisions.

This is a very big change in legal procedure for both users and courts in Denmark. We expect that we will see some minor teething troubles, but that the system will benefit everybody and ensure increased consistency in legal procedure and a substantial increase in the due process of law.

We look forward to continuing to assist you with your legal proceedings in Denmark.

Morten Bruus
Partner, Attorney-at-Law
IPR and Life Science
morten.bruus@accura.dk

Christina Type Jardorf
Associate Partner, Attorney-at-Law
IPR
christina.type.jardorf@accura.dk

CONTACT

Morten Bruus

Partner, Attorney-at-Law

Head of IPR and Life Science
M: +45 3078 6695
morten.bruus@accura.dk

www.accura.dk

ACCURA Advokatpartnerselskab

Tuborg Boulevard 1 · 2900 Hellerup/Cph. · Denmark · CVR no. 3303 9018
Phone +45 3945 2800 · Fax +45 3945 2801 · accura.dk