



Newsletter April

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Matthias Hülsewig joins Patent Law Division in Düsseldorf

Dr. Matthias Hülsewig, LL.M., joined the Düsseldorf office on 1 March 2018 as a partner specializing in patent law. Matthias has been working as an industrial property attorney since 2008, most recently as a partner in the Düsseldorf office of Taylor Wessing. He is an experienced patent litigator specializing in the areas of mobile/telecommunication, medical devices, pharmaceuticals and technology transfer, and he has significant litigation expertise in particular before the District Courts in Düsseldorf and Mannheim.

Dr. Matthias Hülsewig, LL.M., joined the Düsseldorf office on 1 March 2018 as a partner specializing in patent law. Matthias has been working as an industrial property attorney since 2008, most recently as a partner in the Düsseldorf office of Taylor Wessing. He is an experienced patent litigator specializing in the areas of mobile/telecommunication, medical devices, pharmaceuticals and technology transfer, and he has significant litigation expertise in particular before the District Courts in Düsseldorf and Mannheim.

The team at Preu Bohlig has worked extensively with Matthias for years. He is very skilled in disputes around standard-essential patents (SEP) and the corresponding licensing on fair, reasonable, and non-discriminatory (FRAND) terms and has experience in the area of technology transfer laws, particularly regarding relations between Germany and China. Thanks to his language proficiency in English and Mandarin, Matthias will further expand his focus on the Chinese market at Preu Bohlig. In addition to litigating cases relating to patent infringement in Germany, he will offer strategic consulting for German clients regarding IP questions in China.

With Matthias, there are now eight attorneys working in Preu Bohlig's Düsseldorf office. In February 2018, Florian Barth had already joined the Düsseldorf team. Florian specializes in civil and corporate law with a focus on IP (licensing and distribution agreements, advice for patent attorney law firms, etc.). Prof. Christian Donle and Dr. Axel Oldekop are both still closely connected to the Düsseldorf office, but also work from the offices in Berlin and Munich.



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Know-How Transfer When Employees Change Jobs

An employee's departure from a business – or a law firm or patent law firm – and subsequent employment with a competitor often results in legal disputes if the employee attempts to take customers (clients) of a previous employer with him. The Schleswig-Holstein Regional Labour Court addressed this problem in a proceeding for an interim injunction. The decision has been published in GRUR-RS 2017, 111918, [Gewerblicher Rechtsschutz und Urheberrecht, digital edition, publication of the German Association for the Protection of Intellectual Property].



Luring clients away from competitors is an essential element of the free market and permissible in principle. Only under special circumstances can luring clients away from competitors be held to be unfair and therefore represent a violation of Sec. 4 (4) UWG [Gesetz gegen den unlauteren Wettbewerb, German Law against Unfair Competition] ("targeted obstruction") (cf. Köhler/Bornkamm/Feddersen, "Gesetz gegen den unlauteren Wettbewerb," 36th ed., re Sec. 4, Sec. 4.32 ff.). In particular, it is deemed unfair to lure away clients by using unlawfully obtained client lists. Client lists are classified as business secrets of a company. Anyone who, as an employee of a company, obtains, secures, utilises or discloses to a third party a business secret without authorisation violates Sec. 17 UWG and becomes liable to prosecution.

In contrast, employees may use the knowledge and know-how acquired in a previous position in their new employment. According to a general rule of thumb, employees may make use of knowledge from a pre-

vious job that they have memorised. The undersigned was involved with a case some time ago in which the employee who had left wrote an email to 200 customers of his previous employer. During the litigation that followed, the former employee defended himself by alleging that he had the email addresses "memorised." The presiding judge asked him during a hearing to list off those email addresses. When the defendant was not able to get very far, the court deemed his defence not credible and the former employee was ordered to cease and desist.

If a previous employer wants to take action against a former employee who has violated Sec. 17 UWG, it should be noted that this involves litigation "arising from the employment relationship." As a consequence, legal action against a former employee is not heard by an ordinary court but rather by a labour court, Sec. 2 (3) (a) Labour Court Act [Arbeitsgerichtsgesetz]. If a former employee uses a business secret obtained without authorization, such as a customer list, in their new employment

(which tends to occur often enough), action can also be taken against the new employer pursuant to Sec. 4 (4) and Sec. 8 (1) UWG; the new employer will also be held accountable for violations by the former employee pursuant to Sec. 8 (2) UWG. Litigation against the new employer is then heard by the regional court, Sec. 13 UWG.

In the matter that was decided by the Schleswig-Holstein Regional Labour Court, the previous employer had a specific suspicion that the employee who left had obtained customer lists and other documents without authorisation. He filed a criminal complaint on October 26, 2016, pursuant to Sec. 17 (5) UWG, which led the competent prosecutor's office to conduct a search of the former employee's house, where copies of customer lists from the previous employer were indeed found. After an unsuccessful warning, the former employer filed a motion for an injunction on December 15, 2016, i.e., about 7 weeks after the criminal complaint, with the competent labour court, which in turn dismissed the motion. The Schleswig-Holstein Regional Labour Court finally issued the interim injunction that had been requested and cited as the reason for its order its view that waiting about 7 weeks after the criminal complaint did not prejudice the urgency of the matter. The court held that the issues in the case were complex and the moving party could reasonably wait to see if the prosecutor's office would initiate more investigations, in particular if a house search and confiscation of documents would occur. If the motion for an interim injunction had been made prematurely, the respondent would

have been warned and could possibly have destroyed evidence before his premises were searched.

Other courts, such as the Munich Regional Court 1, require that a motion for an interim injunction be filed within one month of acquiring the pertinent knowledge. If this deadline is not met, the case is not deemed urgent and the motion to issue an interim injunction will be dismissed for that reason. Former employers who want to take the route of an interim injunction should therefore act as quickly as possible and not count on other courts to share the view of the Schleswig-Holstein Regional Labour Court that waiting 7 weeks does not prejudice the urgency of the matter.



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Best Lawyers 2018 – Lawyers of the Year

Peter von Czettritz is listed as

„Best Lawyer of the Year in Pharmaceuticals Law“

Countdown to GDPR implementation is almost over

The European General Data Protection Regulation adopted in April 2016 (GDPR – Regulation (EU) 2016/679 dated 27 April 2016) will become directly applicable from 25 May 2018. Compared to current legislation, it contains new and in part significantly stricter requirements for companies when dealing with personal data. In view of the drastically steeper financial penalties for breaches of up to 20 million Euros or 4% of annual global turnover, companies should promptly address the implementation of the GDPR if they have not done so already.



Following the adoption of the GDPR in April 2016, the EU gave all parties concerned two years to prepare for the significantly stricter compliance requirements. No further transition period, during which the provisions of the GDPR are not applicable either in whole or in part, is scheduled after 25 May 2018.

In contrast to the way in which the legislation was applied in the past, when the rules of the Federal Data Protection Act (Bundesdatenschutzgesetz or BDSG) were of central importance to the legal evaluation of the processing of personal data, the revised BDSG (Act to Adapt Data Protection Law to Regulation (EU) 2016/679 and to Implement Directive (EU) 2016/680 (Datenschutz-Anpassungs- und Umsetzungsgesetz) dated 30 June 2017, as reported in the Federal Law Gazette 2017, Part 1, No. 44 on 05 July 2017, p. 2097 et seq.) only supplements the GDPR. It uses the so-called “opening clauses” contained in the GDPR to regulate particular areas in derogation from or as a supplement

to the GDPR. However, such supplementary regulations may not conflict with the GDPR.

As previously discussed (see our article “Be prepared: Changes in dealing with customer data introduced by the GDPR” – Preu Bohlig Newsletter August 2017), the GDPR does not contain any specific regulations for the Internet sector such as e.g. the permissibility of cookies, tracking, social media services, etc. This area is to be covered by the new ePrivacy Regulation ((ePV) – cf. 2017/0003 (COD)), which was originally meant to come into effect in parallel with the GDPR on 25 May 2018. However, the legislative process of the ePV has been delayed due to, inter alia, differences of opinion concerning the permissibility of online-tracking and cookies. As a result, the yet-to-be finalised ePV is not expected to take effect before 2019. Any legislative gaps resulting from this delay between now and the effectiveness of the ePV should be addressed using Article 95 GDPR and its Recital 173, subject to the national

data protection regulations for the relevant area. In Germany, this is the Telemedia Act (Telemediengesetz or TMG) that was most recently adapted in October 2017. Please see Sec. 11 et seq. TMG.

Previously, when dealing with the responsible supervisory authorities for data protection, e.g. in the event of a customer complaint, it was the duty of the supervisory authority to prove a company's breach of the relevant data protection regulations. This will change fundamentally going forward, since under Article 5 para. 2 GDPR:

“The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1”

Article 5 para. 1 GDPR sets out the principles relating to the processing of personal data (lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, integrity and confidentiality). If the controller cannot account for a possible breach, the supervisory authorities now have significantly increased powers. These may include warnings or the revocation of a data protection certification as well as investigative powers, e.g. a demand to make all information in the company available in order to carry out a data protection inspection. Such investigative powers may be enforced using coercive methods, for example by imposing penalty payments. In particular, if a controller intentionally and substantially violates applicable data protection provisions, the authorities may, depending on the type, extent and duration of the relevant breach, impose a fine of up to 20 million Euros or up to 4% of annual global turnover, whichever is higher.

How can the controller, usually the company, ensure proper accountability?

Above all, this requires the legally compliant documentation of data processing, by which it can be demonstrated that the personal data of the data subject was processed in a lawful manner, for certain specific legitimate purposes, in a factually correct way. Similar to current legal regulations regarding the directory of procedures, cf. Sec. 4g para. 2, 4e BDSG, Article 30 GDPR stipulates that controllers must prepare a procedure index, which should include the name and contact details of the controller, the purposes of data processing, a description of the categories of data subjects and of personal data, as well as, if possible, the envisaged time limits for erasure of the different categories of data. In practice, the necessary record of processing activities has to be created and developed on the basis of the (hopefully) existing directory of procedures that the controller has already prepared. Along with the individual processing activities, the relevant legal basis for the processing, e.g. the underlying contract or the permission of the data subjects, should be listed in this procedure index.

With regard to the permission of the data subjects, which is particularly important in practice, please refer to Article 6 para. 1 a) GDPR, according to which the processing of personal data relating to a person is only lawful if permission has been obtained from that person “for one or more specific purposes”. Some of the blanket customer consents granted under the previous law (e.g. “I consent to the use of my personal data for



Corporate LiveWire Legal Awards 17/18

Peter von Czettritz is listed as

„Pharmaceuticals Lawyer of the Year - Germany“

marketing purposes...”) will no longer be sufficient to satisfy these new requirements and will not provide an adequate legal basis for processing personal data once the GDPR takes effect. Any corresponding personal data should be deleted if no new, sufficiently specific consent is obtained. The text of the consent together with the details of the process for which consent is being obtained must be documented (electronically), archived, and reviewed for conformity with the GDPR.

After the documentation of processing operations with respect to personal data, the controller must document the relevant internal procedural requirements and process rules, such as internal data protection guidelines, company processes when handling personal data, e.g. in the event of customer complaints, deletion requests and “data incidents”, together with the relevant organisational structures with the company management. The same applies to the area of technical data security, starting with access regulations, firewalls, encryption regulations, etc.

Existing contracts of controllers, which relate to the processing of personal data, must be reviewed with regard to compliance with the new standards introduced by the GDPR and should be adapted as necessary. The same applies to existing agreements regarding contract data processing, which must also be adapted to the GDPR standards.

If the processing of personal data is likely to result in a high risk to the data subject due to the nature, scope,

context and purposes of the processing, see Article 35 GDPR, the controller must carry out a documented data protection impact assessment. This will require an evaluation of the objectives pursued by the processing, and weighing the affected interests and rights of the relevant natural persons. Such a documented data protection impact assessment can be required, e.g. in the systematic monitoring of employees, in the scoring and profile creation of natural persons, or in the handling of sensitive personal data (relating to health, ethnicity, region, etc.).

Companies which have not yet taken the necessary measures for achieving GDPR compliance are strongly advised to initiate the process immediately.



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Who's Who Legal Germany 2018

Peter von Czettritz is listed in category

„Who's Who legal Germany: Life Science 2018 -

Patent Litigation“ und „Regulatory“

New Developments regarding the Economically Relevant Domestic Nexus as it pertains to the Use of a Trademark Abroad

In its decision of 09 November 2017 (file no. I ZR 134/16 - Resistograph) the German Federal Court of Justice has commented once more on the economically relevant domestic nexus of the use of a trademark on a website in English by using metatags.

Plaintiff owns the German word trademark “Resistograph”, recorded for several goods in class 9, and services in class 42, specifically measuring and testing instruments for determining and analysing drilling resistance, preferably on trees.

Defendants 1) and 2), whose managing director is Defendant 3), distribute measuring and testing instruments manufactured by Defendant 1) for the diagnosis



of wood, namely so-called drilling resistance measuring instruments. These instruments are advertised on the website www.i...com. The operator of the respective online shop is a company based in the United States, which is a subsidiary of Defendant 2). Defendant 2) is listed in the company details provided on the website as the contact. The drilling resistance measuring instruments are advertised on that website as follows:

In the 1990s, Plaintiff, Defendant 1) and Defendant 3) had initially worked together. In 1999 and later in 2010, there were legal disputes, in which Defendants issued two cease-and-desist declarations, stating that they would refrain from applying the labels “Resistograph” to drilling resistance measuring instruments in the course of trade, from offering them and taking them to market, owning them for the stated purposes, using this term in business documents or in advertising. Furthermore, they undertook to refrain, in the course of business with drilling resistance measuring instruments, from using the trademark “Resistograph” and from importing or exporting drilling resistance measuring instruments under this trademark.

Plaintiff considered Defendants’ advertising of the drilling resistance measuring instruments along with other information provided on the website www.i...com a violation of the cease-and-desist declarations. Furthermore, the use of the term “Resistograph” was deemed a domestic use in violation of German trademark law. The Plaintiff’s demands included that Defendants cease and desist and be ordered to pay contractual penalties.

The regional court and the appellate court found mostly in favour of Plaintiff (Higher Regional Court Karlsruhe, judgment of 25 May 2016, ref. no.: 6 U 17/15). It ruled that the acts committed by the operator of the website with the online shop are attributable to Defendants pursuant to Sec. 14 para.7 of the German Trademark Act (Markengesetz - MarkenG). The court decided that the operator of the online shop is a sales branch of Defendants 1) and 2). The German Federal Court of Justice had dismissed Defendants’ appeal on points of law.

The central theme of the dispute is the question of how to determine the economically relevant domestic nexus for a trademark in a website that is mostly geared toward other countries, and that is required for the infringement of a trademark registered in Germany, and whether Defendants used the trademark in suit domestically due to the website.

There was no option to place a direct order on the challenged website for shipments to Germany. The website primarily addressed the non-German market and was mainly written in English. The description of the sales organization listed Defendant 2) as the „Manufacturer/Head Office“ even before mentioning other companies, which were provided under the categories „... Sales Partners worldwide“ and „... Sales Offices“. Furthermore, the website www.i...de was provided as the contact for IML Germany, and information about trade fairs and seminars in Germany was provided in German under the heading „Upcoming dates“. The prices in the online shop were listed in US dollars. Defendants had used the word „Resistograph“ as a metatag for their website.

In the Federal Court of Justice's view, deciding whether a relevant infringing act has been committed domestically requires special findings if the challenged conduct mainly focuses on other countries. Therefore, not every offer of foreign services accessible online domestically triggers claims under trademark law in the event that there is a risk of confusion with a domestic trademark. Rather, it is necessary that the offer has a sufficient economically relevant domestic nexus (commercial effect). Whether such a nexus exists must be determined on the basis of an overall weighing of the circumstances. On one hand, the extent of the effects of the use of the trademark on the domestic economic interests of the holder of the mark must be considered. On the other, it is decisive whether, and to what extent, the infringement of the right is an unavoidable by-product of technical or organizational factors over which the party against whom infringement claims are asserted has no influence, or whether such party intentionally benefits from the domestic availability, e.g. by establishing means to place orders domestically, or to deliver to domestic recipients.



Legal 500 Deutschland 2018 - Patents

Patent law: dispute resolution

“Preu Bohlig & Partner has (.....) expanded the patent law practice at its Hamburg office. Since July 2017, Daniel Hoppe has been managing the patent law team, which also maintains a strong base at the München office. The team is well-qualified for a broad range of topics and has received numerous key mandates from the fields of electronics and mechanical engineering since mid-2016. The company represented PII Pipetronix in patent transfer proceedings for a pipeline testing device as well as Sandvine in patent infringement proceedings and parallel nullity proceedings in the network technology field. The team also provided legal advisement for the ZKW Group in three patent infringement proceedings regarding automotive headlights.”

The generally existing ability to access foreign websites domestically as such therefore cannot be a criterion that is relevant for the overall weighing of the circumstances, because the owner of the website has no influence over it.

With regard to the importance of the use of the word “Resistograph” as a metatag for Defendants’ website, the German Federal Court of Justice explained that making a website easier to access domestically with the help of a metatag can only be a significant aspect for the assumption of a relevant domestic nexus if it is a circumstance over which the operator of the website has an influence. However, that is not always the case.

Search engines cannot find websites without the use of metatags. Operators of foreign websites therefore cannot be prevented from using trademarks that they

legally use for their products or services abroad for advertising directed toward the public in other countries and to use them as metatags. That generally applies even when it is a trademark that is protected in Germany, as long as the advertising directed toward other countries does not have a relevant domestic nexus.

In connection with metatags, a domestic nexus of relevance for assuming trademark infringement could be justified in that the operator influences the search process specifically in Germany or does not take advantage of reasonable possibilities to exclude or limit search results on the basis of the metatag for Germany.

The appellate court did not comment on this. It was clear that Defendants had not used any ad words or key words or advertising that costs money and that would appear under the heading “Ads” before the actual list of

Chambers Europe 2018

Preu Bohlig & Partner listed in **category “Life Sciences”**



What the team is known for: „Compact life sciences practice with a following of long-standing clients in the pharmaceuticals sector. Recommended for regulatory advice on advertising law and unfair competition (...). Further capabilities in alleged misleading advertising mandates, registration of pharmaceuticals and prescription drug regulations.“

Strengths: „it's the way the lawyers work; they are pragmatic, and have a good way of handling things and a deep understanding of the businesses.“

Notable practitioners: Peter von Czetztritz garners praise from one source for his „deep understanding of the pharmaceuticals industry, pragmatic way of handling matters and ability to explain difficult legal matters to non-lawyers. „He acts on proceedings regarding unfair competition, market authorisation, product liability and compliance, as well as alleged misleading advertising matters and applications to register generics.“

hits. The German Federal Court of Justice did not have to address this question, however, because it believed that there was a sufficient domestic nexus due to the concurrent presence of other website features that are considered relevant.

It suffices that Defendants' website offer is addressed to customers in Germany as well. The German Federal Court of Justice considers this as proven on the basis of the circumstances demonstrated (listing of the website www.i...de as the contact for IML Germany; references in German to trade shows and seminars in Germany). In addition, the German Federal Court of Justice took into consideration that Defendants use the top-level domain ".com" for its websites, which is customary in Germany as well, instead of using a top-level domain that indicates a different country and that could deter domestic users from accessing its websites.

The decision substantiates the significance of the comprehensive weighing of all criteria when evaluating an economically relevant domestic nexus regarding a website geared toward other countries.

The use of metatags for a trademark that is protected domestically, but not abroad, is not unlawful per se. What must be considered, however, is the other internet presence of the user abroad, which can ultimately lead to the conclusion that there is, indeed, an economically relevant domestic nexus.



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Legal 500 Deutschland 2018 - Trademarks

“The Preu Bohlig & Partner team succeeded (.....) in acquiring several new clients: For example, Jan Böhmermann, a German TV celebrity, has been using the firm's services in trademark and competition law matters since January 2017. Other flagship mandates have included the advisement of Fossil Europe in trademark, design and competition law matters, with border seizures and distribution law problems being a particular focus of consulting activities. The team has also represented the automotive supplier Rausch & Pausch and textile retailer NKD, inter alia in infringement proceedings. Astrid Gérard and Andreas Haberl are the key figures.”

Is Germany no longer the place of jurisdiction for actions relating to the infringement of EU-trademarks and community designs? Comments on the judgment of the German Federal Court of Justice of 9 November 2017 I ZR 164/16 "Parfümmarken".

The European Union Trademark Regulation (EUTMR) and the Community Design Regulation (CDR) contain essentially identical provisions in Art. 125 EUTMR and Art. 82 CDR regarding international jurisdiction. They provide that the courts of the member state in which an infringing act was or is threatening to be committed have jurisdiction over infringement claims and counterclaims demanding that an EU-trademark or a community design be invalidated (Art. 125 para. 5 EUTMR; Art. 82 para. 5 CDR).

In the decision „Parfümmarken“ (brands of perfumes) of 9 November 2017 (GRUR 2018, 84 et seq.), the German Federal Court of Justice interpreted these provisions to mean that in cases where the same defendant is accused of infringing acts in several member states, not every individual infringing act, but the defendant's conduct as a whole should be considered to determine the place where the infringing act within the meaning of these provisions was or is threatening to be committed.



1. The German Federal Court of Justice had to answer the question whether German courts have international jurisdiction in proceedings against a company based in Italy charged with infringing an EU-trademark. The Italian defendant dealt in perfumes and cosmetic products and had a website that was available in German, as well. Although the website did not allow for ordering products directly, it provided contact information. When a company based in Germany contacted the Italian defendant by email, the defendant emailed back inventory

and price information about the requested products. The German company then ordered several perfumery products, which were the plaintiff's non-exhausted original products because they had been placed on the market within the European Union without the plaintiff's consent (cf. Art. 15 EUTMR or Art. 15 CDR respectively).

2. The Court of Appeal confirmed its international jurisdiction pursuant to Art. 125 para. 5 EUTMR by arguing that the inventory and pricing information emailed by

the defendant constituted a request to make an offer and that the defendant thus actively attempted to conclude a contract in Germany (cf. judgment by the German Federal Court of Justice, para. 18).

3. The German Federal Court of Justice rejected this interpretation of Art. 125 para. 5 EUTMR, according to which the international jurisdiction of German courts for defendants based abroad is affirmed with the argument that at least one of several infringing acts were committed domestically (cf. para. 24 et seq.).

The German Federal Court of Justice explained that a decision on the international jurisdiction of German courts in principle depends on the fact whether the plaintiff alleged an infringing act committed domestically by the defendant within the meaning of Article 125 para. 5 EUTMR and whether this act cannot be ruled out from the start (cf. para. 26).

The wording of Art. 125 para. 5 EUTMR “[place] in which the act of infringement has been committed or threatened”, however, focuses on an act committed by the infringer and therefore pertains to the member state in which the incident that the alleged infringement is based on, occurred or is threatening to occur, and not the member state in which the infringement takes effect (cf. para. 27).

4. The German Federal Court of Justice, as well as the Court of Appeal, did not consider the defendant’s German website as such as sufficient to establish an infringing act within the meaning of Art. 125 para. 5 EUTMR in Germany. The Court of Appeal justified its opinion by stating that the defendant’s German website does not offer the option to place an order. The German Federal Court of Justice holds, on the other hand, that even if it were possible to place an order online, this still would not give German courts international jurisdiction (cf. para. 30). The German Federal Court of Justice bases this opinion primarily on the assessments of the European Court of Justice (ECJ) made in the judgment „Nintendo/BigBen“ (GRUR 2017, 1120 et seq.), on which we reported in detail in the Preu Bohlig Newsletter of December 2017 (p. 4 et seq.).

The German Federal Court of Justice states that the ECJ judgment did, in fact, rule in favour of the CDR, but the ECJ decision could easily be applied to trademark law due to the similarity between the applicable provisions of the CDR and the EUTMR (cf. para. 30).

5. The German Federal Court of Justice states that the comments by the ECJ about the interpretation of the provision of Art. 8 para. 2 of the Rome-II Regulation governing non-contractual obligations, which includes wording that is similar to that of Art. 125 para. 5 EUTMR applies accordingly (para. 34). It holds that in the event of intellectual property right infringements, the same defendants are frequently accused of several infringing acts, which means that an event giving rise to damage occurs in several places. When identifying the event giving rise to damage in these cases, the defendant’s entire conduct should be considered instead of every individual infringing act to determine the place where the original infringing act was or is threatening to be committed (cf. para. 34).

6. The place of the event giving rise to damage pursuant to Art. 125 para. 5 EUTMR is, in this specific case, not the place from where the website can be accessed (Germany). Rather, it is the place where the process of the publication of the offer was set in motion by the economic participant on its website (Italy). Even if the website of the Italian defendant must be considered an offering of goods, it would have to be assumed in the event of a dispute that the process of the publication of the offer took place in Italy and not in Germany (cf. para. 31).

The German Federal Court of Justice does not consider the emailing of product and price lists to the recipient in Germany an event giving rise to damage within the meaning of Art. 125 para. 5 EUTMR, because in this case, the event giving rise to damage is the place from where the email was sent, i.e. Italy, and not the place where it was received (cf. para. 38).

7. The German Federal Court of Justice did not have to discuss the question whether, in the event the non-exhausted goods were sent by the Italian defendant to

Germany, an overall assessment of its conduct would have given jurisdiction to German courts because in the case before the court, the German company had arranged for picking up the goods through a shipping company. That meant that the defendant did not deliver directly to Germany. A different decision is hard to imagine, because in this case, the place of the event giving rise to damage again is the place that initiated the shipment of the goods (Italy) and not the place where the goods were actually received (Germany).

8. The decision by the German Federal Court of Justice has a direct effect on action taken by a court against an infringer with business seat in a member state of the European Union and based on an EU-trademark or a community design. If the infringer, however, neither is based nor has an office in a member state of the European Union, the infringer may be sued at the plaintiff's seat (cf. Art. 125 para. 2 EUTMR or Art. 82 para. 2 CDR, respectively).

For German trademarks as well as German designs, there is no prior-ranking rule of jurisdiction that corresponds to Art. 125 para. 5 EUTMR or Art. 82 para. 5 CDR, respectively. The question of international jurisdiction is governed by Art. 7 no. 2 Brussels Ia Regulation when national trademarks and national designs are infringed upon by a company with business seat abroad. Accordingly, German courts have special jurisdiction even if the event giving rise to damage occurred or is threatening to occur domestically. The wording "place where the act of infringement has been committed or threatened" refers here, contrary to the wording used in the EUTMR and the CDR, to both the place where the success of the damage is realized and the place of the events that are causal for the damage, so that a defendant with business seat abroad may be sued before a court of either of these two places at the plaintiff's discretion (cf. ECJ GRUR 2011, 806 margin no. 44 et seqq. – Coty/First Note Perfumes).

The decision by the German Federal Court of Justice therefore means that one and the same conduct of an infringer with business seat in another European member state gives German courts international jurisdiction in one case and not in another, depending on whether German property rights were infringed upon or whether the matter involves an EU-wide property right. Since, in practice, counterfeit goods are often imported to Germany from other European member states, the question is now whether it is advisable to increasingly register German property rights in order to secure German court jurisdiction and to avoid potentially lengthy and expensive proceedings in other European member states.



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Chambers Europe 2018

Preu Bohlig & Partner is listed in category **“Intellectual Property: Patent Litigation”** and **„Trade Mark & Unfair Competition“**:

What the team is known for: „Best known for its expertise in patent litigation, benefiting from long-standing expertise in the automotive, telecommunications and life sciences sectors. Represents domestic and international companies in patent infringement and parallel validity proceedings, and is highly recommended for employee invention disputes. (...) Bolstered its Hamburg office in 2017 with a team of lateral hires.

Strengths: (Quotes mainly from clients) „The strengths are the level of client orientation and the fact that the legal know-how is shared among many colleagues, meaning the client has a broad and deep knowledge base (...)“

Notable practitioners: Sources say of Andreas Haberl: Clients value his „very good technical knowledge, commercial awareness, effectiveness and client service“ and Christian Donle „(...) he is really up to date with court decisions and gives you the advice you need to make decisions. With him you know what the risks are, and your chances of winning“

Significant clients: Doka USA, Sandvine, PII Pipetronix

Conditions for pleading exhausted rights in cases where a trademark owner has not consented to its use

In principle, the exhaustion of rights conferred by a trademark only occurs if the products that are labelled with the trademark have been brought onto the market nationally, in another member state of the European Union, or in a country which is a signatory to the Agreement on the European Economic Area (EEA), with the consent of the owner, Article 15 European Trademark Regulation revised version, s 24 German Trademark Law (MarkenG).



The ECJ recently had to decide a case (ECJ decision of 20.12.2017 – C-291/16 (Schweppes SA/Red Paralela SL, inter alia), in which the consent required for the exhaustion of rights originated not from the owner of the trademark in dispute (the national Spanish trademark „Schweppes“), but from the owner of the national UK trademark „Schweppes“. The ECJ judgement is published in GRUR 2018, 191.

The decision of the ECJ concerned a reference for a preliminary ruling from the Commercial Court of Barcelona, Spain. The claimant in the infringement proceedings before the Commercial Court was Schweppes SA, which based its claim on the Spanish trademark „Schweppes“. The owner of the Spanish trademark „Schweppes“ is Orangina Schweppes Holding BV, which had granted the claimant an exclusive licence to the Spanish trademark „Schweppes“. Orangina Schweppes Holding had, already in 1999, transferred several identical national „Schweppes“ trademarks in Europe, including the trademark registered in the Uni-

ted Kingdom, to Coca-Cola Industries.

Schweppes SA then asserted a claim against a parallel importer, which purchased bottles with the mark „Schweppes Tonic Water“ in the United Kingdom (owner of the national trademark: Coca-Cola Industries), imported them to Spain (owner of the Spanish trademark: Orangina Schweppes Holding) and sold them there, on the grounds of infringement of the national Spanish trademark.

The defendant raised a plea of exhaustion of the trademark rights for the national Spanish trademark. Since the relevant provisions under the national trademark law of the EU member states originate from the EU Trademark Directive, the Barcelona Commercial Court submitted the question to the ECJ in a reference for a preliminary ruling, asking whether, in the particular case, the exhaustion of rights from the national trademark in the United Kingdom (owner: Coca-Cola Industries) could also be effective with respect to the national Spa-

nish parallel trademark (owner: Orangina Schweppes Holding). The ECJ decided in the proceedings that exhaustion of rights could be invoked against legally independent owners of parallel trademarks if such owners, through coordination of their trademark strategy or their business strategy, either promote a uniform overall appearance and image for the trademark or jointly determine the products to which it is attached.

Since the ECJ also summarised its earlier case law on the exhaustion of rights under trademark law in its decision, it is worth recapitulating the effect of exhaustion in the event of different and legally independent owners of individual national trademarks within the EU more generally:

The point of departure for exhaustion is the provision in Article 15 of the Trademark Directive as revised (2015/2436/EU), which has been implemented as national trademark law by the EU member states. According to this provision, a trademark does not entitle its proprietor to prohibit its use in relation to goods which have been put on the market in the EU or the EEA by the proprietor or with the proprietor's consent. The rights arising from a national trademark (e.g. national German trademark) are therefore also exhausted when the products bearing that trademark are put on the market in another European country (e.g. Austria) for the first time by the proprietor or with the proprietor's consent. In principle, the exhaustion of rights in a national trademark is therefore not limited to the first use in the corresponding country.

The consent of the proprietor to a third party's placement of the goods on the market is deemed to be given if a licence for manufacturing and distribution or a simple distribution licence has been granted. However, in these situations the consent must also directly relate to placement on the market within the EEA (Ströbele/Hacker/Thiering, MarkenG, 12th edition, s 24 recital 33). Indeed, in the case of pure contract manufacturing or a pure production licence there is often no consent by the proprietor of the trademark to the placement of the

products on the market (contrary to the agreement) by the manufacturer or the licensee (BGH GRUR 2011, 820 – Kuchenbesteck-Set, Nr. 18).

As the ECJ summarises in the present ruling, it is equivalent to the placing of the product on the market by the proprietor himself, if another group company (parent/subsidiary/affiliate) or another commercially affiliated company has brought the products bearing the trademark to the market in a member state of the EEA for the first time (established case law since: EuGH GRUR 1994, 614 – Ideal Standard II). This is intended to prevent the practice, through the skilful allocation of national trademarks between group companies or commercially affiliated companies, of shielding the different national markets within the EU from each other with the aid of national trademark rights and thus maintaining price differences.

On the other hand, as the ECJ points out in its decision, the function of the trademark as an exclusive right would be jeopardised if proprietors of parallel national trademarks who had no legal or commercial relationship with one another could not oppose the import of goods bearing their trademarks, merely because the exhaustion of the national trademark of another proprietor had occurred. According to ECJ case law, according to the case law of the ECJ, even the fact that the (identical) trademarks originally belonged to the same proprietor does not change this principle, irrespective of whether the division of the marks was based on a sovereign measure (such as expropriation) or a contractual transfer. . The fact of common origin of the different national trademarks is therefore not sufficient for a plea of exhaustion (established case law since: ECJ GRUR Int. 1990, 960 – HAG GF).

In the above decision dated 20 December 2017, the ECJ thus makes an important exception to this judicial practice: under certain circumstances, the exhaustion of rights in a national trademark – belonging to a company that is not legally or commercially affiliated – can also lead to the exhaustion of the rights in other identi-

cal national trademarks belonging to another company. The peculiarity of the matter in question, which was decisive for the ruling, was the fact that Orangina Schweppes Holding and Coca-Cola Industries coordinated their appearance for the „Schweppes“ trademark within the EU. Furthermore, they jointly established which drinks and products should bear the „Schweppes“ trademark and should be allowed to be brought onto the market in the EU. From the perspective of the user, a tonic water with the „Schweppes“ trademark produced by Coca-Cola Industries was, at first sight and in terms of taste, indistinguishable from a tonic water with the „Schweppes“ trademark produced by Orangina Schweppes Holding. The ECJ saw this agreement between the trademark proprietors as the effective abandonment of one of the main functions of a trademark, namely, the function as indication of origin since the relevant public would already be confused about the commercial origin of the goods through this coordination by the trademark proprietors themselves.

Therefore, the ECJ concluded that a trademark proprietor, which has itself compromised the function as indication of origin of its trademark, can no longer take legal action against third parties by arguing that they have caused confusion of origin, on account of a situation that the proprietor itself has created.

For such products the ECJ thus affirms a Europe-wide exhaustion of rights for all identical national trademarks, even where they belong to legally independent and unaffiliated trademark proprietors, if such proprietors actively and deliberately coordinate their trademark strategy in order to achieve a uniform overall appearance or image for the trademark or if such proprietors coordinate their business strategy such that they jointly determine which products the trademarks should be attached to.

Finally, the ECJ gave its opinion on the question of who should set out and prove the conditions for the extension of the exhaustion effect through the coordination of



Legal 500 Deutschland 2018

Regulatory Law: Healthcare sector

“Preu Bohlig & Partner primarily advises pharmaceutical and medical technology companies throughout the product cycle, but also covers related food law issues. The team of Peter von Czetztritz, the renowned practice group leader, includes experts for third-party proceedings between generic manufacturers and originators along with experts in pharmaceutical law, competition law and compliance law. In contract consulting for the pharmaceutical industry, the firm’s focus is on advisement regarding the implementation of clinical trials and observational studies and on supporting clients in a range of topics such as pharmacovigilance and product liability. Clients include Hexal, STADA Arzneimittel and kohlpharma.”

different trademark proprietors.

In principle, the burden of proof for demonstrating that the requirements for the exhaustion of rights are met falls on whoever seeks to rely on the exhaustion. According to the established ECJ case law, however, there is an exception to this principle where there are exclusive or selective distribution agreements since the allocation of the burden of proof could otherwise enable the trademark proprietor to partition the national markets. By naming the sources of supply by the potential infringer (as proof of the exhaustion), the trademark proprietor would immediately “plug the gap” and again close off the distribution system to outsiders. The ECJ similarly saw the requirement for a corresponding adjustment of the burden of proof in the present case. It is thus up to the proprietor of the national mark to set out and, if necessary, prove, that there is no coordination of trademark or business strategy between itself and the proprietors of the other national trademarks. The ECJ ordered the defendant, who had sought to rely on the exhaustion of rights, to first present all indications for the existence of economic ties and the joint coordination of trademark strategy by the trademark proprietors. In other words, a simple random assertion by the defendant will not be sufficient in the future.

Conclusion: even though the decision concerned an exceptional case, it does extend the possibility of relying successfully on pleading exhaustion of rights. For marketing reasons, trademarks are often supposed to be presented and marketed consistently in a uniform manner throughout a uniform market such as the EU,

even if individual national companies or individual national trademarks have been sold to third parties. Where such coordination takes place within the EU, following a division of national trademarks, it must be taken into consideration that, as soon as a product with the relevant trademark is placed on the market, all the rights in the other national parallel trademarks belonging to legally independent proprietors will be exhausted.



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Managing IP 2018

Patent contentious & Trade Mark contentious

German Federal Court of Justice offers distinction: Cease and desist claims generally do not include a recall obligation in preliminary injunction proceedings

Our August 2017 newsletter reported on the “Recall of Rescue Products” decision of the German Federal Court of Justice (GRUR 2017, 208 et seq.) and pointed out that another decision by the German Federal Court of Justice on this issue was still pending. This decision has now been published: On 11 October 2017, the German Federal Court of Justice ruled in the matter I ZB 96/16 that the obligation to cease and desist from performing an act that led to a continuing interference must, for lack of indications to the contrary, be interpreted even in preliminary injunction proceedings, to mean that this act and the ceasing and desisting from such acts includes the performance of feasible and reasonable acts for the removal of the interference as well.



The German Federal Court of Justice holds that an anticipation of the main proceedings, which is generally not permitted in injunction proceedings, has not taken place if the party liable did not recall the goods it distributes from its customers, but has only asked them not to sell the goods until further notice due to the preliminary injunction.

The German Federal Court of Justice has again affirmed that a cease and desist order not only requires the party liable to cease and desist from any further acts of distribution, but also mandates active steps to prevent the further distribution of products packaged or labelled in an infringing manner. The obligation of the party liable is limited, however, to requesting action from third parties to a feasible, necessary, and reasonable extent.

The particular nature of injunction proceedings as well as the strict requirements for the anticipation of the main proceedings and the respondent's limited ability to defend itself may result in restrictions if a recall obligation is assumed due to a cease and desist order.

The obligation of the party liable is not only established by what is feasible and reasonable, but, according to the German Federal Court of Justice, limited as well. In the opinion of the court, the party liable may not remain inactive if and to the extent the interpretation of the cease and desist order results in an obligation to take action. By the same token, the party liable does not have to take steps that don't contribute to a prevention of further infringements and are therefore not required, nor is the party liable expected to take actions

to prevent or remedy the interference that would disproportionately disadvantage the party liable in its commercial activity and are therefore unreasonable.

Since the obligation of the party required to cease and desist, which must be determined by way of interpretation, differs in terms of content from what is owed in accordance with the specific provisions governing recall claims, it is irrelevant whether the petitioner has claims against the party liable for removal and recall pursuant to Sec. 98 para. 2 of German Copyright Law (Urhebergesetz - UrhG), Sec. 18 para. 2 of the German Trademark Act (Markengesetz - MarkenG), Sec. 43 para. 2 of the Designs Act (Designgesetz - DesignG), Sec. 140a para. 3 of the German Patent Act (Patentgesetz - PatG), Sec. 24a para. 2 of the German Utility Model Act (Gebrauchsmustergesetz - GebrMG) or Sec. 37a para. 2 of the German Plant Varieties Protection Act (Sortenschutzgesetz - SortenschutzG). These provisions in special laws cannot prevent the interpretation that a cease and desist claim includes a recall as well. Typically, the recall claims based on special laws and a recall obligation based on a cease and desist order may compete in cases where a distribution of products, which are designed, labelled or packaged in an infringing manner has already taken place and it can be expected that the party liable will continue to distribute them quickly and in significant quantities. The court clarified that a separate application area remains for the recall claims based on special laws, when products, which are designed, labelled, or packaged in an infringing manner, were in fact distributed, but there is no specific expectation of any further distribution.

The German Federal Court of Justice did not explain when a “specific expectation of any further distribution” can be assumed in practice. It only established that the party required to cease and desist has the same obligation as a party liable to perform a recall claim based on a special law to persistently and seriously attempt to get the products back from its customers by referencing the infringing character of the products. However,

the party required to cease and desist is not responsible for the success of the recall.

Taking into account the fact that the main proceedings may only be anticipated in preliminary injunction proceedings under strict conditions, the German Federal Court of Justice made the following distinction:

If there are no specific indications leading to the assumption that the party liable tried to avoid its cease and desist obligation by quickly reselling the goods in question, or if the case relates to pirated products, the party generally has no obligation to recall goods that are labelled or packaged in an infringing manner and that were sold before the cease and desist order was issued. The cease and desist order can be interpreted to mean, however, that the party liable does, in fact, have to encourage third parties to refrain from continuing to commit infringing acts, but that the activities owed in this regard only have to serve the protection of petitioner’s cease and desist claims without ultimately satisfying its claims. In this regard, the German Federal Court of Justice holds that main proceedings were not anticipated in an unlawful manner if the party liable did not recall the goods it distributes from its customers due to the preliminary injunction issued against the party liable, but only asked them not to sell the goods until further notice due to the preliminary injunction. The court considers this approach reasonable with regard to the party liable, because said party already has the contractual auxiliary obligation to inform customers that they must anticipate a preliminary injunction if they resell the goods. The German Federal Court of Justice grants the party liable the option of relief, i.e. when it can be assumed that the customers of the products will learn about these measures even without the party liable informing them accordingly.

By establishing this case law, the German Court of Justice is distancing itself from parts of its “Rescue Drops” decision due to the criticism it had received.¹ With regard to the prohibition to anticipate the main proceed-

¹ cf. Köhler/Bornkamm/Fedderson/Bornkamm, Gesetz gegen den unlauteren Wettbewerb, 36th Ed. 2018, Sec. 8 margin no. 1.69 et seqq., in particular margin no. 1.71 and 1.83; von Czettritz/Thewes, Rückrufverpflichtung in einstweiligen Verfügungsverfahren?, PharmR 2017, 92 et seqq.; Voit, Zur Frage der Rückrufverpflichtung auf der Grundlage eines Unterlassungsanspruchs nach der Rescue-Tropfen-Entscheidung des BGH, PharmR 2018, 1.

dings, the German Federal Court of Justice points out the difference that in the context of preliminary injunction proceedings, removal cannot be demanded in the form of a recall, but only in the form of a request from the party liable sent to its customers not to distribute the purchased goods until further notice due to the preliminary injunction. The customers are not required to respond to this request. Specifically in the pharmaceutical sector, however, the question arises whether, in consideration of limited storage capacities, such a request would still cause wholesalers to return the goods and/or to ask the company to take the goods back, which ultimately is equivalent to a recall.

One consequence of the distinction the German Federal Court of Justice makes between the main proceedings and the preliminary injunction proceedings is that the party cautioned, who has issued a cease-and-desist declaration, but would like to avoid a recall, should specifically state that the cease-and-desist declaration to be issued does not include a claim to removal.

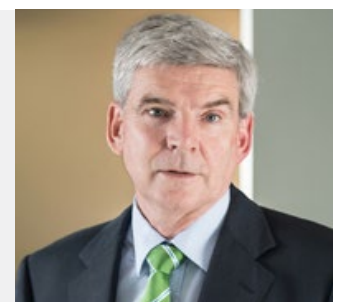
In consideration of the claim to damages pursuant to Sec. 945 of the German Code of Civil Proceedings (Zivilprozessordnung - ZPO), a party issuing a caution should, if the preliminary injunction is later set aside, specifically clarify in the petition for an injunction or the statement of facts that it is only requesting the other party to cease and desist, and that it is not demanding a recall. In a delimited economic sector, such as the pharmaceutical industry, in which the respective market participants face each other time and time again in preliminary injunctions, it would also be desirable to completely refrain from the claim to removal to avoid the respective expense and uncertainty in the market. It may be tempting to enforce such a recall or, respectively, the request not to continue distribution until further notice against a competitor. It should always be considered here, however, that pharmaceutical companies often find themselves in the reverse procedural situation with the same opponent. Furthermore, it is of relevance, especially in the pharmaceutical area, that a recall and its communication to the different levels of

trade should be reserved for a recall that is necessary under pharmaceutical law in order not to create additional uncertainty.



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General Court Upholds EMA's Transparency Policy

Since its establishment in 1993, the European Medicines Agency (EMA) has continuously worked toward increasing the transparency of its internal processes by publishing a great deal of information. In fact, virtually no other administrative organisation publishes a comparable quantity of information. Right from the outset the EMA has endeavoured to cover all phases of the pharmaceutical approvals process.¹



I. Introduction

Until 2010, the publication policy of the EMA was such that inquiries for information contained in marketing authorisation dossiers were generally rejected and the latter categorised as confidential information belonging to the approval holder.

This stance underwent a major shift in November 2010 when the EMA stopped regarding information contained in marketing authorisation dossiers (complete clinical data records) as a protectable trade secret and began to disclose such information accordingly.

To substantiate this transparency policy, the EMA cites recitals 1 and 2 of Regulation (EC) 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. Article 73 of Regulation (EC) 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for

human and veterinary use and establishing a European Medicines Agency governs the application of this Regulation to documents of the European Medicines Agency as well.

Recitals 1 and 2 on the justification of making documents as freely accessible as possible read as follows:

“The second subparagraph of Article 1 of the Treaty on European Union enshrines the concept of openness, ...

Openness enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system. Openness contributes to strengthening the principles of democracy and respect for fundamental rights as laid down in Article 6 of the EU Treaty and in the Charter of Fundamental Rights of the European Union.”

¹ Regina Kröll: „Das europäische Arzneimittelrecht – Zentrale Rechtsfragen des Arzneimittelzulassungsverfahrens“, Springer Verlag, 1st ed., 2017

II. Historical Development

The EMA published² its “European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use) – Policy/0043” on 30 November 2011 and within this framework began to grant public access to documents forming part of the marketing authorisation dossiers of pharmaceutical companies and therefore, data from clinical studies as well.

A series of additional EMA policies followed on the free access to documents, including in October 2014 the “European Medicines Agency policy on publication of clinical data for medicinal products for human use–Policy/0070”³.

Right at the outset, the introduction to the purpose and aim of the policy states that the EMA’s objectives protecting and promoting public health and ensuring transparency for patients and society in the rendering of its services are of prime importance.

Some see this EMA policy as a precursor to the regulatory content of the new EU regulation on clinical trials, which entered into force on 27 May 2014. This regulation also provides for far-reaching transparency but has not yet entered into application since it requires a new information infrastructure for which the technical basis has yet to be laid. It is expected to enter into application by 2019 at the soonest.

The interplay between the EU regulation on clinical studies and the EMA policy is intended to ensure that all clinical studies submitted within the scope of marketing authorisation procedures are publicly accessible as a

general principle.

The decision to bring transparency to entire clinical studies and marketing authorisation dossiers has been enthusiastically welcomed by the EMA and scientists⁴; yet the affected pharmaceutical companies themselves, which have invested a great deal of time and money in clinical studies and their marketing authorisation dossiers, hardly share this enthusiasm. Although many attempts have been made to obtain protection from the courts against the new policy, none have been successful.

Decisions in three primary proceedings before the European Court were recently handed down on 5 February 2018, all upholding the EMA’s transparency policy.

III. The decisions of the European Court of First Instance of 5 February 2018

In the three following cases,

– MSD Animal Health Innovation GmbH, Intervet International B.V. v European Medicines Agency, case no. T-729/15,

– PTC Therapeutics International Ltd., European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) v European Medicines Agency, case no. T- 718/15, and

– PARI Pharma GmbH v European Medicines Agency, case no. T-235/15,

the European Court of First Instance ruled on 5 February 2018 that the EMA’s publication of clinical data from marketing authorisation dossiers is legal.

² European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use – EMA/110196/2006

³ European Medicines Agency Policy on publication of clinical data for medicinal products for human use – EMA/240810/2013

⁴ Published in Medscape, 01/11/2016, Ute Eppinger: “EMA now publishes the complete clinical data for new medications – but with some redacted passages.”

In these proceedings each party sought recourse from the court to prevent the publication of clinical and non-clinical study reports, arguing that these must be regarded as trade secrets and as such, must not be disclosed.

It was the claimants' position that the entirety of the information in the CHMP reports, especially the protected confidential raw data, the compilation of publicly accessible clinical data and the analysis of this data by various third parties, as well as the general authorisation deliberations, must be generally regarded as confidential. The claimants asserted not only that the especially sensitive parts of the reports should be covered by confidentiality protection, but rather, that this protection must extend to the reports as such, because the sensitive parts are embedded in a series of arguments, which includes questions relating to their respective strategy and together with other public elements of the reports, constitute an inseparable entity with economic value.

In all three cases, the court dismissed a general presumption of confidentiality for such documents, citing the same grounds. The court found pursuant to Article 2(3) of Regulation No. 1049/2001 that the provisions regarding the public accessibility of EMA documents apply to all documents of the agency, in all of its areas of activity, i.e. to all documents the agency creates or receives and which are in its possession. Moreover, the court found that this Regulation is intended to

implement, to the greatest degree possible, the public's right to access documents of administrative bodies including when this right is subject to certain restrictions based on public or private interests. In contrast to contested documents from ongoing administrative or court proceedings, the court found that in the case of Regulations Nos. 726/2004 and 1049/2001, the principle of public access to information prevails; the only exceptions to this principle being those specified in Article 4(2) of Regulation No. 1049/2001, including the exemption for confidential business information.

In light of the need for strict interpretation, the European Court of First Instance found that the Community legislative authority implicitly presumed that the integrity of the authorisation process is not impaired by the absence of such a presumption of confidentiality. For all these reasons, there can be no general presumption of confidentiality for CHMP reports.

It is therefore not possible, the court argued, to presume that these reports are subject to general confidentiality that would cover them in their entirety based on the exception to protect the economic interests of the applicant. The economic value of the dossier on its own is not sufficient to classify it as a trade secret and therefore as confidential. Rather, it is up to the EMA to ensure, by conducting a specific, individual examination of each individual document in the administrative file to determine whether the document is covered as an exception for trade secrets within the meaning of Article



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2(4) first bullet point of Regulation No. 1049/2001. For this to be the case, the owner of the dossier must argue and justify in detail the extent to which a potential business risk does, in fact, arise through publication. The purely hypothetical possibility is expressly insufficient, according to the European Court of First Instance.

Therefore, the current status quo is that such authorisation dossiers in their entirety are not to be generally regarded as confidential documents and that non-disclosure should be the exception. As with all regulatory exceptions, the court believes that in this case as well, interpretation should be conservative, paired with strict application.

On 6 February 2018, the EMA therefore cheerfully issued a press release entitled “General Court confirms EMA approach to transparency” and emphasised that in all three cases, the court affirmed the permissibility of the EMA’s conduct per the 2010 EMA policy on access to documents.

IV. Outlook

According to this decision in the first instance, marketing authorisation dossiers are therefore not generally classified as confidential. Pharmaceutical entrepreneurs, with respect to certain passages of a dossier that they do not desire to have released, must substantially justify in detail why these passages in particular contain data worthy of protection in respect of which the entrepreneurs’ interest in non-publication should prevail.

According to the European Court of First Instance, strict requirements must be met here and all blackening must be justified in detail in light of the regulatory exception to the principle of transparency.

All three decisions are not yet legally binding. At least two of them have been appealed to the ECJ.



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Das neue Europäische Patentsystem	17. April 2018, Nuremberg	Andreas Haberl, Konstantin Schallmoser
Abgrenzungsvereinbarungen im Markenrecht	18. June 2018, Intercity-Hotel Munich	Jürgen Schneider, Dr. Volkmar Bonn
„Der Schutz von Geschäftsgeheimnissen: Zur Umsetzung der EU-Richtlinie“	28. June 2018, Preu Bohlig & Partner, Dusseldorf	Dr. Christian Kau
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