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Introduction

We welcome you to join us in ringing in 2015 with the new issue of Clifford Chance's Global Intellectual Property Newsletter. With the growing presence of and greater dependence on technology, we recognise our clients' need to keep abreast of the latest developments in intellectual property law. In this quarterly publication, we provide an overview of the most recent IP developments in major jurisdictions around the world. In this January issue, we address certain recent notable European court decisions, including the CJEU's ruling regarding copyright infringement claims based on hyperlinking to copyright protected work, the Supreme Court of Spain and Madrid Court of Appeal's guidance in connection with rights to join IPR holders in infringement proceedings and associated claims to damages, and the CJEU's clarification of international jurisdiction rules relating to Community trademark infringement. We also cover new trends and upcoming regulations in connection with the European patent with unitary effect, the ownership of IP created by R&D activities at Polish public academic institutions, and the Czech Cybersecurity Act. We also outline for you some key decisions in the medical and healthcare sector regarding patentability of medical uses and enforcement of method patents in China.

Lastly we are happy to introduce a new feature of our Global Intellectual Property Newsletter, the Industry Highlight. In each issue we are providing a non IP-related topic for interested readers. Our first article is regarding the proposed Medical Device Regulation and its anticipated impact on the European Medical Device legislation.

Our prior issues of the Global Intellectual Property Newsletter can be retrieved by clicking here: issue 10/13, issue 2/14, issue 5/14, issue 9/14.

European Union: Update on the Unified Patent Court

Establishment of the Unified European Patent Litigation System has been subject to many efforts of European leaders and legislators for more than four decades and has resulted in the creation of the so-called Unitary Patent Package, composed of the Unitary Patent Regulation and the Translation Regulation (collectively, the "Regulations") and the Unified Patent Court Agreement (the "UPCA") that establishes the Unified Patent Court (the "UPC"). The UPCA will enter into force after thirteen countries, including Germany, the UK and France, ratify it. If the Spanish challenge fails (as expected – see below), the system will, in all likelihood, go live. The final and most important steps are the following: finalisation of the Rules of Procedure of the UPC (the "Rules of Procedure"), final judgement of the Court of Justice of the European Union (the "CJEU") concerning the complaints brought by Spain, and training of the UPC judges.

Procedural rules

At the beginning of November 2014, the Preparatory Committee of the UPC released the 17th draft of the Rules of Procedure that will govern procedural aspects of the UPC process, including formal requirements for written pleadings, disclosure rules, evidentiary rules, and application for injunctions or orders to preserve evidence. On 26 November 2014, the Legal and Expert Group of the UPC held a public hearing at the premises of the European Academy of Law in Trier, Germany. Attendees included stakeholders composed of national and European organisations who provided their views on the latest draft of the Rules of Procedure. The topics discussed included, among others, opt-out provisions, permanent injunctions, procedural appeals and evidentiary rules. The Legal and Expert Group is currently in the process of further reviewing the Rules of Procedure. This review is expected to last until February 2015. It is planned that the Preparatory Committee will issue the final Rules of Procedure in May 2015.

Key issues

- The UPCA will enter into force after thirteen countries, including Germany, the UK and France, ratify it
- The Rules of Procedure of the UPC are expected to be finalised by May 2015
- Advocate-General Yves Bot has recently opined in favour of the unitary patent and proposed to dismiss the so-called "Spanish claims"
- The selection of the UPC judges is currently in progress
- The new patent litigation system will introduce considerable changes to current holders of European patents

Spanish challenge before the CJEU

Initial attempts of Spain (together with Italy) to defeat the Unitary Patent Package failed in 2013. Later efforts to confront the use of the enhanced cooperation that establishes European patent with unitary effect and translations provisions of the patent were challenged at the hearing before the CJEU in cases C-146/13 and C-147/13 in July 2014. Advocate-General Yves Bot has recently opined in favour of the unitary patent and proposed to dismiss the Spanish claims. With respect to C-146/13 concerning the challenge regarding the creation of the unitary protection, Spain argued that the Unitary Patent Regulation infringes basic principles of Union law such as Article 2 of the Treaty on the Functioning of the European Union (the "**TFEU**") in that:

- the Patent Regulation lacks legal basis and infringes Article 118 of the TFEU;
- the EU misapplies its power through the use of the enhanced cooperation mechanism;
- there is a violation of Article 291 (2) of the TFEU, which grants implementing powers to some of the EU institutions "where uniform conditions for implementing legally binding Union acts are needed", in the regulation of the system for setting the renewal fees; and
- there is a violation of the principle of autonomy and uniformity in that the entry into force of both of the Regulations should not be dependent on the entry into force of the UPCA.

The Advocate-General's conclusion was that the Patent Regulation does not breach the basic principles of the Union law as the regime does not interfere with the granting process of the European Patent Office based on the facts that:

- the Patent Regulation provides a European patent with additional quality, i.e. the unitary effect;
- the Patent Regulation contains material content in Articles 3-5

setting forth the requirements and effect for unitary patent and there is nothing in Article 118 preventing the Patent Regulation from referring to national laws (therefore, there is no misuse of power in using the enhanced cooperation); and

- concerning the principle of uniformity and autonomy, it would be contrary to the proper functioning of the system if the Patent Regulation would enter into force when the UPC has not been established.

With regard to C-147/13 concerning the translation regime, the Advocate-General's answer to the Spanish complaint – that the language regime is discriminatory – was that such regime is proportionate and appropriate in light of the purpose of the European patent with unitary effect in the first place, i.e. to create the regime with minimum of complications and maximum simplicity and harmonisation.

It is important to note that, officially, the CJEU is not bound by the opinion as it has "merely" an advisory, albeit influential and powerful, effect. In the majority of cases, the CJEU judges follow an Advocate-General's opinion. The judgement is expected in 2015.

UPC judges

In late 2013, the UPC invited candidates to submit applications for the UPC judge. As reported in the press, the demand for these positions exceeded expectations in terms of volume of interest as well as quality of applicants. The training centre in Budapest was opened in 2014 and it is expected to become operational before the end of 2015. The Preparatory Committee of the UPC approved a list of potential candidates in July 2014.

Outlook and conclusion

The big question continues to be when the Unified European Patent Litigation System will come into force as this ultimately depends on how fast all thirteen of the required thirteen Member States, in particular, the UK and Germany, will ratify it. Once set up and running, the UPC will introduce considerable changes that will greatly affect current holders of European patents. Clients are, therefore, well-advised to make preparations and consider whether and in respect of which patents the opt-out option should be used.

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Germany/USA: U.S. Discovery in Aid of German Litigation – Strategic Considerations with respect to 28 U.S.C. § 1782

U.S. courts may decline to order discovery to aid proceedings in a foreign or international tribunal under 28 U.S.C § 1782(a) ("Section 1782") if the same discovery request is pending before a foreign tribunal or would result in disclosure of highly confidential information. *Andover Healthcare, Inc. v. 3M Company*, case no. 14-mc-44 (SRN/JJK), (D. Minn October 2014). A copy of the decision is available here.

Introduction

Section 1782 allows a party to a legal proceeding outside the United States to petition a U.S. court to obtain evidence for use in the non-US proceeding. This article is the second in a multi-part series discussing strategic considerations with respect to Section 1782 proceedings based on recent court decisions. The first article can be found in our last Global Intellectual Property Newsletter (**issue 9/14**).

Relevant Facts in the Andover Decision

Andover Healthcare, Inc. ("**Andover**") sued 3M Company ("**3M**") in both German and U.S. courts, claiming infringement of its U.S. and European patents on latex-free bandages. When 3M submitted an expert report in the German case asserting its product did not infringe Andover's

Key issues

- U.S. courts may decline to order discovery to aid proceedings in a foreign or international tribunal under Section 1782 if the same discovery request is pending before a foreign tribunal or would result in disclosure of highly confidential information
- Applying for a Section 1782 discovery before filing for patent infringement in the foreign forum, therefore, may be advantageous as the foreign tribunal under such circumstances has no possibility to influence the discovery request
- U.S. court may compel production of confidential information und Section 1782

patent because it was composed of different materials, Andover sought to conduct its own testing of 3M's product and asked 3M to disclose the materials used in its product. 3M refused to disclose the materials and the German court declined to rule on Andover's request before the infringement hearing.

Andover then sought a Section 1782 order from the U.S. District Court of Minnesota to compel 3M to produce the requested information. Based on the U.S. Court's application of the Intel factors, Andover's Section 1782 request was denied.

Application of the Intel Factors

Under Section 1782, once certain threshold elements are met, a U.S. courts has discretion to order discovery for use in foreign proceedings after considering the four factors established by the U.S. Supreme Court in *Intel v. Advanced Micro Devices, Inc*., 542 U.S. 241 (2004) ("**Intel**"). (Clifford Chance's September newsletter discusses in more detail the general process of Section 1782 discovery requests).

The first Intel factor considers the respondent's connection to the foreign proceeding. Courts have held that the need for a Section 1782 order may be less when the person from whom discovery is sought is a party to the foreign proceedings and a foreign tribunal could order that party to produce evidence. In *Andover*, the U.S. court found this factor weighed against granting a Section 1782 request because 3M was a party to the German proceeding and the German court indicated it would rule on Andover's discovery request at a later time (even though Germany's discovery laws are not as broad as the United States).

The second Intel factor pertains to the nature and character of the foreign tribunal, and whether it would consider evidence obtained through a Section 1782 request. Since the German court postponed its decision on whether or not the requested evidence was necessary for the decision of the case, the U.S. court found this factor to be neutral.

The third Intel factor examines whether the request attempts to circumvent the foreign discovery restrictions. Given that Andover sought the same information in German court, the U.S. court found the Section 1782 request was an attempt by Andover to avoid or prevent an unfavourable decision in the German proceeding, and thus weighed the third factor against Andover's request.

The fourth Intel factor considers whether the request is unduly intrusive or burdensome. Here, the information sought by Andover (ingredients, formulations, and production procedure) were trade secrets, the disclosure of which 3M argued would cause it irreparable harm. Although Andover argued that limited disclosure and a protective order could protect 3M, the U.S. court found that 3M's concerns were valid given the highly confidential nature of the information and the uncertainty of whether the information would be kept confidential by the German court. Thus, the fourth and final factor weighed heavily against granting the Section 1782 request.

As a result, the U.S. court dismissed Andover's request for a Section 1782 discovery.

Practical Implications

The *Andover* decision illustrates the need for planning prior to submitting a Section 1782 discovery request. When seeking the same discovery in both a foreign tribunal and a U.S. court under Section 1782, it is essential to think critically about the timing and sequence of filing a Section 1782 request and requesting discovery from the foreign tribunal. In *Andover* the fact that the request was already pending in German court weighed against granting the Section 1782 request since the U.S court found potential circumvention of the German proceedings.

In certain circumstances, it may even be advantageous to apply for a Section 1782 discovery before filing for patent infringement with a foreign court. For purposes of Section 1782 requests, foreign proceedings need not be pending if they are within "reasonable contemplation", and thus, a U.S. court may grant a Section 1782 discovery request before the foreign proceedings have been initiated if the requesting party shows that proceedings will be initiated within a reasonable time. *Application of Consorcio Ecuatoriano de Telecomunicaciones S.A. v. JAS Forwarding (USA), Inc.,* 747 F. 3d 1262, 1270 (11th Cir. 2014) (finding that Section 1782 applied when the requesting party claimed the requested discovery was for contemplated civil and criminal proceedings in Ecuador against its former employees, even though such court proceedings had not yet been initiated).

Finally, although a U.S. court may compel production of confidential information under Section 1782, *Andover* demonstrates that requesting such information will likely require the applicant to establish that the foreign court will assure such information remains confidential in the foreign jurisdiction.

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Poland: Overview of R&D laws and latest developments on R&D with academic institutions

With effect from 1 October 2014 Poland has introduced new rules governing ownership of IP created in the course of R&D activities at Polish public academic institutions. The new laws give researchers employed at those institutions a right to take ownership of such IP if their employer is unwilling to use the IP for commercial purposes or does not proceed to do so within a certain period of time.

Outline of the new regulations

The purpose of the new law is to regulate the participation of academic researchers in profits resulting from commercial use of IP created as a result of R&D activities and motivate them to participate in innovative projects.

Under new laws an academic institution has three months (after being notified by the researcher of the outcome of the particular R&D activities and related know-how) to decide whether or not to commercialise such outcome (e.g. by way of selling IP rights, licensing those to third parties or setting up an SPV to start production on the basis of such IP rights).

If an institution decides to commercialise, the researcher remains entitled to receive 50% of commercialisation proceeds (decreased by up to 25% of certain costs incurred by it) for first five years in which such profits arise.

In the absence of a decision by the academic institution within the three month period (or if the academic institution decides not to commercialise), the relevant researcher is entitled to acquire rights to the outcome of such R&D works. The initial remuneration payable to the academic institution is symbolic (below EUR 50) but, if the researcher subsequently commercialises the outcome of R&D activities, the institution is entitled to receive 25% of the proceeds (decreased by up to 25% of certain costs incurred by the researcher).

As a result of the new regulations, Polish academic institutions may possibly become more active in looking for opportunities to put the outcome of their R&D activities into the market. The law also creates more opportunities for researchers with entrepreneurial spirit to take ownership of IP rights and active roles in their commercialisation.

The regulations may be varied by mutual agreement between the academic institution and the relevant researchers but such contractual arrangements may be put in place only after the outcome of R&D becomes known to the parties.

Key issues

- New laws create some opportunities for researchers and need to be taken into account while structuring R&D cooperation with academic institutions
- Many entities operating in Poland do not necessarily take proper measures to secure their title to such IP rights properly
- A practical risk for business organisations: it might occur that key IP is sometimes actually owned by their present or former employees instead
- Internal R&D by-laws and contracts with employees and contractors need to be carefully worded to minimise the risk of individuals claiming ownership rights to IP or additional remuneration that may be significant

General rules on IP created as a result of R&D activities

The rules set out above apply only to the outcome of R&D work created at public academic institutions. In the context thereof it might be worthwhile to outline briefly general rules applicable to the outcomes of R&D activities in Poland (and also in other situations, where IP is generated during the course of business activities). Our experience shows that many entities operating in Poland do not necessarily take proper measures to secure their title to such IP rights properly.

Tricky part: who the IP really belongs to

In general, the title to inventions, industrial designs and other forms of industrial property created as a result of performance of an employee's duties passes to the employer. Similarly, where work is performed under a civil law contract, the awarding party acquires such industrial property rights created by a contractor.

The tricky part is how to determine whether an invention was indeed created within the scope of an employee's contractual duties. This sometimes becomes problematic,

especially where the scope of duties as set out in the employment contract (as supplemented by organisational designs/charters) is not precise and/or does not indicate that the role involves innovative work.

It is worth noting that the Polish industrial property law doctrine is substantially influenced by opinions of reputable authors employed at technical universities, who usually subscribe to a pro-inventor standpoint. Therefore, the interpretation often leans towards narrowing the circumstances under which the title automatically passes to employers. As a result, where an employee creates an invention without being instructed to work on a particular matter/issue within the scope of its duties, it is not always entirely clear whether an employer has acquired proper title to it. In particular, where an employee works on something new, even if related to his/her regular work, but outside of normal working hours and not under supervision, the title may not necessarily pass to their employer. A practical risk for business entities is such that, had the narrow interpretation applied, they can easily find themselves in a situation where a substantial portion of their key IP is actually owned by their present or former employees. Fortunately, although case law is sometimes inconsistent, courts often take a more reasonable and balanced approach.

Similar rules apply in relation to the transfer of copyright. This may be relevant, for example, where the sole outcome of R&D work is protected by copyright (e.g. software) or where copyright protects documentation relating to R&D work. However, it is worth noting that the automatic transfer of copyright to the employer does not apply to copyrightable works created by self-employed contractors. Therefore, unless such transfer is separately regulated by contracts, copyright will not pass. Furthermore, where an employer acquires copyright under statutory rules, there might be some uncertainty as to the exact scope of such transfer. Automatic transfer is also unlikely to include a right to further amendments.

Right to separate remuneration for inventions and other improvement

Another issue which is often overlooked by business entities operating in Poland is that employees who are involved in the actual R&D work have the right to specific remuneration on top of their regular salary. Such right may be contractually excluded. Polish law does do not provide for clear and detail guidance as to the amount of such remuneration, providing only for some high level principles. In particular, the remuneration in respect of industrial property rights shall be linked to benefits gained by the employer in relation to the invention or other improvement and is payable for the first five years during which such benefits are gained. This leaves the court with wide discretion as to the amount of remuneration payable, and means that the underlying financial exposure for the employing entity is unpredictable.

What can be done in practice?

In order to benefit from the statutory rules providing for automatic transfer of IP rights, it is important to ensure that the employees that may potentially be involved in the creation of objects of IP rights (in particular those involved in R&D activities) have their duties properly defined.

Where copyright is a likely outcome, appropriate provisions need to be included in the relevant contract (especially for contractors working on the basis of a civil law agreement, including those self-employed).

In terms of inventions, proper internal by-laws regulating rights of employees, applicable procedures and precise algorithm for calculation of the remuneration (if applicable) should be adopted. Due to local particularities, it may sometimes be insufficient just to apply a group policy on inventions and R&D work without it being reviewed from a Polish law perspective.

Where, as is usually the case, more than a single person is involved in the creation of a particular object of industrial property rights, it will also be important to properly document the share of each contributor to avoid disputes in the future.

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INDUSTRY HIGHLIGHT: Outlook on the anticipated changes in the European regulatory environment for medical devices

For more than 20 years, medical devices have been regulated by three Medical Devices Directives (namely, the Medical Device Directive, the Directive for In Vitro Diagnostic Medical Devices and the Directive for Active Implantable Medical Devices; collectively, the "Directives") in the EU and by national medical device law of the Member States implementing the Directives on a national level. Based on increasing criticism of these framework conditions – triggered mainly by the PIP-scandal (usage of in-house manufactured industrial-grade instead of medical-grade silicone in breast implants) – as well as the technical developments in the medical device sector within the last 20 years (for example, in the fields of mHealth, tissue engineering etc.), the European Commission (the "Commission") decided to revise the European Medical Device legislation and proposed a new Medical Device Regulation (the "Proposed MDR") as well as a new Regulation for In Vitro Diagnostic Medical Devices on 26 September 2012 (collectively, the "New Regulations").

Besides changes in the classification rules and an increase in unannounced inspections after product launch and Unique Device Identification number obligation to ensure traceability, the largest impact of the Proposed MDR provisions is expected in the field of (high-)risk devices. Although the Proposed MDR will most likely not come into force before 2018 given that the Trilogues procedure has not started yet, it is important for entrepreneurs and manufacturers with medical devices in their portfolios to know how the New Regulations will impact their products as the New Regulations will come into force directly after a transition period without a national level approval process/requirement for implementation.

Current Legislation

Currently, the Directives regulate the market of medical devices. Each medical device must be classified according to the existing Directives and the manufacturers are allowed to select a Notified Body in one of the European countries to accompany the conformity assessment procedure and certify the device. In contrast to pharmaceutical law, no centralised authorisation is possible (or needed) yet.

Background and current status of the proposed MDR

As noted above, a key trigger to revise the MDD was the PIP-scandal, which involved fraudulent breast implants. The main points of criticism in this scandal were the inconsistent performance of the Notified Bodies, insufficient clinical evidence, easy market access for high-risk devices, lack of transparency and varying legislation in the European countries.

Therefore, the lead Committee of the Commission (here the Committee on the Environment, Public Health and Food Safety ("**ENVI**") proposed a regulation introducing a new scrutiny procedure inspired by pharmaceutical law. After a discussion between the Commission and the industry, the parties compromised on the Proposed MDR. This compromise is now a matter of discussion in the European Parliament and European Council.

Despite former plans to agree on the Proposed MDR before the European Parliament elections in May 2014, no decision regarding the final content of the Proposed MDR has been made yet. After heated discussions in the European Parliament, currently the compromise proposal of the European Parliament for the Proposed MDR dated October 2013 is subject to further negotiations among the European Parliament, Commission and Council. The informal Trilogue procedure is currently planned to begin not before Autumn 2015.

Potential major changes

New classification rules

Annex VII of the Proposed MDR contains new rules of classification. Pursuant to these new rules, several devices will be classified in a new category or even classified for the first time.

As an example, active, implantable devices (e.g. breast implants) as well as apheresis machines will shift from

class IIb up to class III. In addition, products which contain or consist of nano materials will be classified in class III for the first time. The same classification applies for devices utilising a substance considered to be a medicinal product and devices composed of substances or a combination of substances intended to be ingested, inhaled or administered rectally or vaginally.

Assessment of special high-risk devices according to Article 44a of the Proposed MDR

Article 44a of the Proposed MDR foresees a new procedure for special devices with high-risk potential. The new certification procedure shall apply to:

(i) Implantable Class III devices;

(ii) Class IIb devices intended to administer and/or remove a medicinal product, as referred to in Article 1(5) and point 5.3 of Annex VII (Rule 11); and

(iii) Devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable with the exception of applications to renew or supplement existing certificates and devices for which specifications referred to in Articles 6 and 7 have been published for the clinical evaluation and the post-market clinical follow-up.

According to Article 44a, the Notified Body shall notify the European Commission in case of applications for conformity assessments for the devices mentioned above. Application and accompanying documents shall immediately be transmitted to the new Medical Device Coordination Group (the "**MDCG**"). After the transmission the MDCG is able to request the Special Notified Body for further information and shall issue a MDCG opinion to the Special Notified Body within 60 days. 15 days after the receipt of the opinion, the Special Notified Body shall indicate whether or not it agrees with the opinion. If it does not agree, it has to give written notice to the MDCG regarding re-examination of their opinion within 30 days of receipt.

However, depending on the decision of the MDCG, the Notified Body may proceed (favourable opinion) with the certification or shall not deliver the certificate of conformity (unfavourable opinion). Nevertheless, the Notified Body is allowed to provide further information to reach a reassessment of the opinion.

Although the lead Committee and the European Commission declares this new procedure of certification as a compromise between the first proposal and the industry, the new procedure is similar to the centralised authorisation process in pharmaceutical law. The Special Notified Bodies are dependent on the MDCG's decision (i.e. the EU). They seem to be taking the role as a middleman. Clock-stops in context with requests for further information will also prolong the assessment of innovative medical devices.

New requirements for Notified Bodies & Special Notified Bodies

Annex VI of the Proposed MDR determines the mandatory requirements for the Notified Bodies. Compared to the current MDD, there are some novelties which may not only lead to a higher financial burden of the Notified Bodies but also to a higher workload.

The Notified Bodies shall be obliged to work with their in-house staff. In case the Notified Bodies are allowed to hire external experts on an ad-hoc and temporary basis, it has to publish the list of external experts as well as their declarations of interests and the specific tasks for which they are responsible. Furthermore, the Proposed MDR foresees further duties regarding the monitoring (e.g. duty to conduct unannounced inspections at least once a year) which is going to additionally increase the Notified Bodies' workload.

According to the Proposed MDR, only the Special Notified Bodies shall be allowed to validate the conformity of the following products:

(i) Implantable devices, devices incorporating a substance, as referred to in Article 1(4) and point 6.1. of Annex VII (Rule 13);

(ii) Class IIb devices intended to administer and/or remove a medicinal product, as referred to in Article 1(5) and point 5.3 of Annex VII (Rule 11);

(iii) Devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or are rendered non-viable or all other class III devices, as referred to in Article 43a of the Proposed MDR.

Specific requirements for the Special Notified Bodies are laid out in Annex VI of the Proposed MDR (e.g. staff with expertise in clinical investigation design, product specialists, training and maintenance qualification).

Developing Eudamed

According to the recitals of the Proposed MDR, one of its aims is to further develop the existing database Eudamed to "enhance overall transparency through better access to information for the public and healthcare professionals" (recital 36). Especially the data in context to the Unique Device Identification Number (the "**UDI**") (which concerns not

custom-made or investigational devices) shall be made public in the future (with access for every interested person). According to Annex V Part B, the manufacturer must submit, *inter alia*, clinical size (including volume, length, gauge, diameter), storage and/or handling conditions.

Summary and Conclusion

The whole development of the European medical device law seems to lead to difficulties not only for the industrial sector but also for authority holders and the Notified Bodies. Experts predict that the Proposed MDR can hardly prevent further scandals like PIP which are rather a problem of criminality than of the current regulatory system. In addition, the proposed procedure regarding high-risk devices may also lead to delayed market access and, therefore, will harm patients and the industry at the same time. Accordingly, it is highly recommended to deal with the potential new regulatory framework as soon as possible.

As there are several rules regarding the classification and monitoring requirements, the proposed regulation may have an indirect impact on intellectual property as well. In particular, the development of the already existing database Eudamed can be considered difficult in case the disclosure of data endangers a competitive advantage.

Key issues

- The Proposed Medical Device Regulations will revise the medical device law on a European level
- In particular, high-risk devices are affected by the introduction of a tightened conformity assessment procedure resembling central marketing authorisation procedures for pharmaceuticals
- Other changes, such as changes in the classification rules, an increase in unannounced inspections of the Notified Bodies and competent authorities, a UDI number obligation to ensure traceability and further restrictions
- and requirements on the Notified Bodies, will affect (i) the entire medical device industry in Europe as well as (ii) indirectly, the patients (for example, through potential brakes on innovations, increased prices based on more complex conformity assessment procedures, etc.)

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United Kingdom: Clinical trials now exempted from patent infringement in UK

On 1 October 2014 amendments to the Patents Act 1977 (UK) came into force which mean that the existing experimental use exception now applies to both innovative and generic drugs. The amendments are not retrospective in effect so they will only apply to activities which take place from 1 October 2014.

For activities before 1 October 2014

Section 60 of the Patents Act 1977 (UK) contains two exceptions from patent infringement for activities relating to research and experimental use. Accordingly, an act does not constitute an infringement of a patent for an invention if:

- it is done for experimental purposes relating to the subject-matter of the invention (Section 60(5)(b)); and,
- it consists of an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of para. 1 to 5 of Article 13 of Directive 2001/82/EC (relating to veterinary products) or para. 1 to 4 of Article 10 of Directive 2001/83/EC (relating to medicinal products) (Section 60(5)(i)).

Exception 1 has been interpreted narrowly in the UK courts.

Exception 2 contains what is known as the "Bolar" exception which exempts from patent infringement certain activities carried out for the purposes of regulatory approval of generic drugs. That there was no equivalent protection from infringement claims in respect of clinical trials in the UK for new drugs has long been viewed as an obstacle to conducting clinical trials in the UK.

Potential issues

- Use of patented tools in the process of conducting experiments on a patented invention for a medicinal product assessment. According to the UKIPO Guidance Notes, these research tools fall within the new amendments (click here). If so, it will diminish the commercial value of such research tools given that once the particular technology has been used in a trial, there is nothing further to licence to the organisation conducting the trial
- Relationship of this new exemption with Unified Patent Court Agreement. Article 27 of this agreement currently contains a narrow exemption as per the position for activities before 1 October 2014. Therefore, unitary patents could have different exemptions to those which are not unitary in effect

For activities after 1 October 2014

The new Section 60(6D) provides that anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention. Further, the new Section 60(6E) states that "medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes:

- obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);
- complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;
- enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of
  - providing health care on behalf of such a government or public authority, or
  - providing advice to, or on behalf of, such a government or public authority about the provision of health care,

to carry out an assessment of suitability of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care.

The aim of the new amendment is to make the UK a more attractive location to conduct such trials. It will also be consistent with other EU countries such as Germany who already have similar exemptions for clinical trials.

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China: Pharmaceutical IP Cases Updates

Given that pharmaceutical products rely heavily on patent protection, in addition to patents directly protecting compounds or components of pharmaceutical products, pharmaceutical companies often employ method patents to protect medical uses and manufacturing processes of pharmaceutical products to prolong their monopoly period and life cycle. This article summarises the PRC Supreme Court (the "SPC")'s current opinions on the patentability of medical uses and enforcement of method patents in China.

Cubist Case

In the Cubist case *(Cubist v. the PRC Patent Reexamination Board of SIPO SPC. 2012 [75]),* the SPC examined Cubist's patent claim protecting the medical uses of one of its best selling drugs, i.e. "Cubicin (Daptomycin)". For the first time, the SPC clarified its position with respect to the patentability of medical uses. Specifically, the SPC answered the following three questions:

How should a claim protecting a medical use be written?

In China, medical uses per se, such as "use for the diagnosis or the treatment of diseases", are not patentable. However, the SPC has affirmed a long-time practice that a medical use may be patentable if it has been written as a use for preparing a pharmaceutical product for the treatment of a disease (so called "pharmaceutical manufacturing method claim"), and the claim has been defined by the features relating to pharmaceutical manufacturing processes.

Can features relating to drug administration define claims protecting medical uses?

In practice, claims protecting medical uses are often defined by drug administration features such as drug administration dosage, intervals, objects, routes, etc. For example, Cubist's patent claim was defined by the feature "3 to 75 mg/kg of Daptomycin … administrated …once every 24 hours to once every 48 hours". The SPC held that this feature only addresses how to administer a drug in human bodies, which has no direct relation to any pharmaceutical manufacturing process, and cannot distinguish the subject claim (written as a pharmaceutical manufacturing method claim) from the prior art.

Can features relating to side effects define claims protecting medical uses?

Similarly, the SPC held that the feature of "not resulting in skeletal muscle toxicity" merely relates to side effect reduction, which neither changes the indication and/or treatment objects of Daptomycin nor discovers any new use of Daptomycin. Therefore, this feature cannot distinguish the use of Daptomycin from the known use in the prior art.

This SPC case makes it more difficult to patent medical uses. However, some medical uses, such as oral or intravenous mode of administration, may still be patentable if the relevant features have an impact on pharmaceutical manufacturing processes and can distinguish the relevant pharmaceutical manufacturing method claim from prior art.

Weifang Case

In cases of non-innovative products, under PRC law, it is a patentee's burden to prove infringement of a patented method. However, proving such infringement is quite difficult in practice since relevant evidence is typically under an alleged infringer's control.

In the Weifang case *(Yibin Changyi v. Weifang Lianheng and Chengdu Xinrui SPC. 2013 [309])*, although the patentee videotaped the manufacturing site, relevant manufacturing equipment and parts of the manufacturing processes, the videotape still could not sufficiently prove the entire manufacturing process in a precise manner as depicted in the method patent.

To alleviate this situation, the SPC has loosened the burden of proof requirements and clarified that the patentee's burden of proof is fulfilled and the infringement is presumed if

Key issues

Patentability of Medical Uses:

- To be patentable in China, a medical use should be written as a pharmaceutical manufacturing method claim which is defined by features relating to pharmaceutical manufacturing processes

Enforcement of Method Patents:

- Burden of Proof – Infringement of a method patent will be presumed if (i) an alleged infringer manufactures the same product; (ii) the likelihood of infringement is high; and (iii) the alleged infringer refuses to cooperate in evidence production
- Protection Scope – A method patent only protects the patented method and the product directly obtained by such method. It does not protect any follow-up products and the use thereof

the patentee is able to prove that (i) the alleged infringer has manufactured the same product as the product obtained by the patented method; (ii) based on common knowledge and experience, the likelihood of infringing is high; and (iii) the alleged infringer has refused to cooperate in evidence production.

This case brings good news to pharmaceutical companies, since many of their products are protected by method patents.

Zhongqi Case

Under the PRC Patent Law, a method patent protects both the patented method and the product obtained directly by the method (the "**Original Products**"). However, whether a method patent protects any follow-up products derived from the Original Products (the "**Follow-up Products**") and the use thereof is in question.

Last year, in its 2014 draft opinions, the SPC clarified that the protection scope of a method patent does not extend to the act of using any Follow-up Products.

The above draft opinions echo the SPC's decision in the Zhongqi Case in 2009 (*Zhang Xitian v. Zhongqi SPC. 2009 [84]*). In this case, the SPC held that a method patent only covers the intermediates obtained directly by the patented method (i.e. the Original Products) and does not cover any API products and/or final products subsequently processed from the intermediates (i.e. the Follow-up Products). Thus, these Follow-up Products and the use thereof have not infringed upon the method patent in question.

This means that in cases where Follow-up Products are derived from Original Products infringing any method patent, pharmaceutical companies may be relieved from patent infringement liability when (i) they import such Follow-up Products into China; or (ii) when they manufacture final pharmaceutical products in China by using such outsourced Follow-up Products, except that they also solicit or aid relevant infringement acts.

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Spain: *Locus Standi* to claim damages in IPR infringement proceedings: Anyone else on top of the right holder?

Situations where infringement acts adversely affect parties other than the Intellectual Property Right ("IPR") holder are very common. Can non-registered licensees, subsidiaries, distributors, etc. join the IPR holder in Court proceedings and claim their own damages? Two recent judgements given by the Spanish Supreme Court and the Madrid Court of Appeal shed some light on this controversial question.

Introduction

A key aspect of most IPR infringement actions relates to the recovery of damages. Doubtless, it is in the interest of IPR holders to take the appropriate measures to maximise both prospects of obtaining compensation and its amount. Therefore, some relevant questions, including who the claimants should be and/or whether or not any formalities are required, should be carefully considered when preparing Court proceedings.

Who is entitled to claim damages in IPR infringement actions?

As a matter of principle, the *locus standi* of the IPR holders and of exclusive licensees whose licences are registered with the relevant registry (SPTO, OHIM, etc.) is straightforward. However, infringers are keen to challenge (sometimes successfully) the entitlement of non-registered exclusive licensees, non-exclusive licensees and mere distributors (including subsidiaries of the IPR holders) to take part in the proceedings and claim their own damages.

This uncertainty is prompted by several provisions of the specific laws governing IPR in Spain. For instance, as regards the grant of licences, Article 79 of the Patent Act requires them to be in writing to be valid and to be registered with the SPTO if the rights conferred by the licences are to be enforced against *bona fide* third parties. Likewise, infringers usually rely on the unclear wording of Article 124.1 of the Patent Act to challenge the ability of non-exclusive licensees and mere distributors (either subsidiaries or third parties) to take part in infringement proceedings.

Two recent decisions handed down by the Supreme Court and the Madrid Court of Appeal shed some light on these questions.

Supreme Court (Civil Chamber): Judgement no. 343/2014, 25 June 2014: non-licensees cannot bring actions foreseen in the Design Rights Law

This case involved a design infringement action brought by a German company (design right holder) and its fully-owned Spanish subsidiary.

The latter was the distributor of the products manufactured by the parent company and had little independence to make commercial decisions. No licence over the design right had been granted in favour of the Spanish subsidiary.

Key issues

- Situations where infringement acts adversely affect parties other than the IPR holder are very common
- While the *locus standi* of exclusive licensees whose licences are registered is straightforward, the entitlement of non-registered exclusive licensees, non-exclusive licensees and mere distributors to join the proceedings and claim their own damages is usually challenged by infringers, sometimes successfully
- A recent judgement handed down by the Supreme Court decreed that third parties (distributors) not holding licences over enforced design rights could not bring actions arising from it in order to claim damages
- On its end, the Madrid Court of Appeal of Madrid recently found that non-registered exclusive licensees may join the patent holder in infringement proceedings, but cannot bring infringement actions on their own
- Ideally, exclusive licences should be executed and registered if at all feasible. If not, *ad hoc* alternative solutions could still be devised to maximise

The first instance decision upheld the claim brought by the design right holder, but dismissed it in relation to the Spanish distributor on the grounds that it did not hold any licence over the design. In practice, this meant that compensation was awarded covering the damages suffered by the design right holder only (the distribution margin was left out). The Madrid Court of Appeal agreed that a mere distributor lacked *locus standi* to enforce actions based on design rights.

The Supreme Court shared this view. It decreed that third parties not holding licences over the enforced design right could not bring actions arising from it. The Supreme Court understood the "injured party" reference contained in Article 13 of Directive 2004/48/EC (on the enforcement of intellectual property rights) to refer exclusively to the right holder, but not any other third party adversely affected by the infringement acts. Significantly, the Supreme Court expressly confirmed that the fact that said third party was a fully-owned subsidiary of the design right holder did not make any difference.

Madrid Court of Appeal (Chamber 28th): Judgement no. 231/2014, 18 July 2014: non-registered licensees may seek compensation for their own damages if they act together with the right holder

This judgement decided a patent infringement action brought by a Swiss patent owner, a Swiss non-registered exclusive licensee and the Spanish distributor of the latter's products. The patent owner and its exclusive licensee belonged to the same group of companies. While the patent owner carried out the R&D activities of the group and owned their results, the licensee manufactured and marketed the patented products. Both companies had executed a written licence agreement that was never registered with the SPTO.

In the first instance, the Commercial Court upheld the complaint brought by the patent owner, but dismissed the one brought by the exclusive licensee and its Spanish distributor on the grounds that the former's licence was not registered and therefore could not be enforced against third parties. Thus, the compensation awarded by the Court covered the lost profits of the patent owner only.

The Madrid Court of Appeal upheld the appeal lodged by the exclusive licensee and found that, although Article 79 of Spanish Patent Act actually required the licence to be registered to be enforceable against third parties, the non-fulfilment of this requirement would only have prevented the exclusive licensee bringing infringement actions on its own. However, as long as the patentee was acting alongside the non-registered licensee, the existence of the exclusive licence could not be disputed and therefore said requisite should be deemed met. Otherwise, said the Court, less satisfactory alternatives (like allowing patent owners to collect damages suffered by licensees) should be accepted to prevent the unfair enrichment of infringers.

Conclusion: You are well advised to execute and register an exclusive licence, but there may be alternatives

In cases where the infringement of IPR adversely affects parties other than the right holder, it is highly recommendable that exclusive licences

be executed and registered with the SPTO before bringing Court proceedings. Carrying out these steps is likely to avoid debates regarding the *locus standi* of said third parties to claim their own damages.

However, where this is not possible, Spanish Courts may still protect the interests of non-registered licensees. Acting alongside the right holder, or relying on more general rules (like unfair competition or general tort rules), may under certain circumstances be suitable solutions for maximising prospects of obtaining adequate financial compensation.

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European Union: Does the enforcement of a standard essential patent qualify as an abuse of a dominant position?

On 29 April 2014, the European Commission handed down two important decisions in the *Motorola* (AT.39985) and *Samsung* (AT.39939) cases regarding the enforcement of standard essential patents ("SEPs"). The European Commission found that the application for an injunction in relation to an SEP against implementers of the relevant standard can be deemed an abuse of a dominant position contrary to Article 102 of the Treaty on the Functioning of the European Union ("TFEU") to the extent the alleged infringers were willing to obtain a license on Fair, Reasonable and Non-Discriminatory ("FRAND") terms.

Motorola – Enforcement of GPRS SEPs (AT.39985)

In this case, Motorola and Apple had been unsuccessful in negotiating a license for Motorola's SEPs. As no agreement could be reached, in April 2011, Motorola requested that the Mannheim District Court order interim measures against Apple on the basis, *inter alia*, of two SEPs relevant to the GSM Packet Radio Service ("**GPRS**") and Universal Mobile Telecommunications Services ("**UMTS**") standards. By its decision dated 9 December 2011, the Mannheim District Court granted the interim measures requested against Apple, ordering it temporarily to cease offering the infringing products over the internet to German consumers. This interim measure was subsequently enforced by Motorola.

During the course of the litigation, Apple made multiple, incrementally improved offers for a license to Motorola's SEPs with a view to resolving the conflict in accordance with the Bundesgerichtshof (German Supreme Court) Judgement dated 6 May 2009 on the *"Orange Book Standard"* (*Philips v. SK Kassetten*, No KZR 39/06). The first offer made by Apple was found not to be sufficiently "willing" under the European Commission's "willingness" standard, which requires a party to agree to have a third party determine the FRAND terms where bilateral negotiations fail. Apple's second offer, however, did anticipate third-party FRAND determination. Notwithstanding this fact, Motorola also rejected this offer (as it did with the subsequent offers made by Apple).

After analysing the relevant market, the European Commission concluded that Motorola had a dominant position, as it held 100% of the market share of the relevant market, defined as the licensing of each individual SEP, specified in the GPRS standard. Contributing to the determination of dominance was the European Commission's finding that implementation of this standard was indispensable for manufacturers of mobile telephones due to lock in of the industry into the GPRS standard.

Having established Motorola's dominant position, the European Commission assessed whether Motorola's conduct was abusive. As holders of SEPs voluntarily assume the undertaking to grant a license on FRAND terms when their patents are declared essential, they have a special responsibility to ensure that any party willing to have a license in FRAND terms will have access to the SEP. Taking this into account, the European Commission concluded that Motorola's request for injunctive relief against a "willing" licensee was abusive and contrary to Article 102 TFEU, as it (i) rejected Apple's second offer, even though this offer already demonstrated Apple's "willingness" to obtain a license, and (ii) enforced the interim measures granted by the Mannheim District Court, forcing Apple to conclude a license agreement under terms it would have never accepted absent such coercive conduct.

Notwithstanding its finding of abuse, the European Commission did not impose a fine against Motorola as there was no consistent EU case law and the case law of the various national courts had been contradictory.

Samsung – Enforcement of UMTS SEPs (AT.39939)

In *Samsung*, the European Commission made legally binding the commitments offered by Samsung, by means of which it agreed not to seek injunctive relief on the basis of certain of its SEPs against third parties if such third parties demonstrate their willingness to obtain a license to the relevant SEPs by entering into a pre-defined licensing framework.

This commitment decision concludes the investigation opened against Samsung for having sought injunctive relief against Apple in several Member States on the basis of Samsung's UMTS SEPs, notwithstanding Apple's alleged willingness to obtain a license to those SEPs on FRAND terms. The European Commission preliminarily found that Samsung's request for injunctive relief was an abusive attempt either to exclude Apple or extract excessive royalty terms under the threat of such exclusion.

In its binding commitments, Samsung has agreed not to request injunctive relief on the basis of its relevant SEPs for a period of 5 years against manufacturers of smartphones and tablets that have agreed to enter into a pre-defined licensing framework, which is annexed to Samsung's commitments. The licensing framework agreement requires Samsung and the potential licensee to negotiate terms of a license for a period of 12 months and, if they fail to reach an agreement, to request either a court or an arbitrator to determine the applicable FRAND terms. However, Samsung can defend itself against potential licensees who themselves seek injunctive relief on the basis of their SEPs against Samsung without willing to enter into a similar licensing framework.

What's next? The Huawei case

Through the above-mentioned decisions, the European Commission has sought to provide *"clarity to the industry on what constitutes an appropriate framework to settle disputes over 'FRAND' terms in line with EU anti-trust rules"* (IP/14/490, 20 April 2014).

However, although these decisions provide some guidance, they open new debates, such as when a third party can be deemed "willing to accept a license" under FRAND terms and what terms can be considered as FRAND, an assessment which the European Commission expressly delegates to the courts and arbitrators (MEMO/14/322, 29 April 2014).

Further clarification on this debate from the European Court of Justice ("**ECJ**") is anticipated in the pending preliminary reference case C-170/13 *Huawei*. Advocate General Wathelet recently handed down his Opinion in this case.

According to the Opinion, the enforcement of an SEP against an infringer, which may lead to the exclusion from the markets covered by the of the products and services supplied by the infringer of an SEP, may constitute an abuse of the SEP-holder's dominant position under Article 102 TFEU if the SEP-holder has failed to honor its FRAND undertaking even though the infringer has shown itself to be objectively ready, willing and able to conclude such a licensing agreement on FRAND terms. In this respect, prior to taking any legal action for an injunction and unless it has been established that the alleged infringer is fully aware of the infringement, the SEP-holder should alert the alleged infringer in writing of the infringement and specifying the SEP concerned and the manner in which it is being infringed. Moreover, the SEP-holder should also, in any event, present to the alleged infringer a written offer for a license on FRAND terms which contains all the terms normally included in a license in the relevant sector, specifically the precise amount of the royalty and the way that amount is calculated. The Advocate General also stated that if negotiations are not commenced or are unsuccessful, the alleged infringer can request that FRAND terms be fixed either by a court or by an arbitration tribunal. In that event, according to the Opinion, it would be legitimate for the SEP-holder to ask the alleged infringer either to provide a bank guarantee for the payment of royalties or to deposit a provisional sum at the court or arbitration tribunal in respect of its past and future use of the patent.

It will be interesting to see whether the CJEU Judgement will adopt the

Key issues

- Seeking injunctive relief in relation to an SEP can constitute an abuse of a dominant position if the infringer was willing to negotiate a license under FRAND terms
- Motorola's request for injunctive relief against Apple was found abusive, although no fine was imposed
- Samsung has committed not to seek injunctive relief on the basis of its SEPs against those who subscribed to a pre-defined licensing framework, which is annexed to Samsung's commitments
- The CJEU is anticipated to provide further clarity in the *Huawei* preliminary reference

approach suggested by the Advocate General, thereby also endorsing the European Commission's approach in *Motorola* and *Samsung*, or whether it will adopt a different standard for "willingness" and abusive conduct in relation to SEP injunction cases.

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European Union: In search of EU copyright rules that are "fit-for-purpose"

The European Commission (the "Commission") under President Jose Manuel Barroso had repetitively underscored the importance of examining ways to modernise the EU copyright framework. In December 2013, the Commission launched a public consultation seeking views on a broad range of issues related to the shortcomings of the EU copyright framework as a whole. Following the consultation, the Commission was about to adopt a White Paper outlining policy options for an overhaul of EU's copyright law. However, in July 2014, the publication of the eagerly awaited White Paper was postponed due to political disagreement. The new Commission President, Jean-Claude Juncker, asked the responsible Commissioner in charge of the digital economy and society, Guenther Oettinger, to prioritise the modernisation of EU copyright rules. It is expected that a potential legislative initiative may be launched in 2015.

Some background

In May 2011, the Commission announced it aimed to develop "innovative copyright licensing solutions" through a number of initiatives. Some of these have already been implemented. The Commission, however, also made note of its aim to "adapt copyright to the internet and the internet to copyright." In particular, the Commission announced its plans to look into the creation of a European Copyright Code, and the feasibility of an optional "unitary" copyright title, as well as to examine how the current exceptions and limitations to copyright granted under Directive 2001/29/EC (the "**Copyright Directive**") are functioning, and whether these need to be updated or harmonised at EU level.

A public consultation on the review of EU copyright rules

In the context of its first couse of action, in December 2013, the Commission launched a public consultation on its review of the EU copyright rules. It invited stakeholders to opine on issues including:

- Difficulties in accessing online content services from anywhere in the EU;
- Lack of clarity related to the scope of which digital transmissions require authorisation (and which not);
- The provision of a hyperlink subject-matter protected under copyright;
- The creation of a system of registration of copyright-protected materials;
- The optional nature of many limitations and exceptions to copyright in EU copyright-related Directives, and whether any new limitations or exceptions are needed, or if existing ones should be removed from the catalogue; and
- The effectiveness and efficiency of copyright enforcement.

The Commission also asked broader questions on text and data mining as well as user-generated content.

In addition, it contained questions on the national implementation of the exceptions or limitations to the reproduction right for copies made for private use and photocopying. It referred to the levy systems applied by Member States *"with a view to compensating right-holders for the harm they suffer when copies are made without their authorisation by certain categories of persons (i.e. natural persons making copies for their private use) or through use of certain techniques (i.e. reprography)."* The consultation focused on the differences among the levy systems throughout the EU considering the varying products to which levies are applied and the different tariffs in force in Member States. The public consultation sought input on, among other things, whether levies should be applied to certain types of cloud-based services such as personal lockers, or personal video recorders.

Finally, the Commission consultation also considered questions concerning the establishment of a single EU Copyright Title, which would harmonise copyright law in the EU and replace national law.

The Commission received 9,500 responses to the consultation. A summary was released in July 2014.

Next steps

In February 2014, Michel Barnier, the former Commissioner for internal market and services, announced that a White Paper on copyright would be released before June 2014.

In April 2014, parts of a draft of the Impact Assessment were leaked, outlining four policy options being considered by the Commission. The Commission has been exploring a number of legislative and non-legislative solutions, including relying on the status quo (i.e. the current Directives) and on the market itself, the Member States, and the Court of Justice of the European Union (**"CJEU"**) to apply EU copyright rules; issuing guidance to relevant participants and Member States in the form of, for example, Green or White Papers or Memorandums of Understanding; making a legislative proposal to revise the current EU copyright framework (including the Copyright Directive); or creating a unitary European Copyright Code which would offer consistency and benefit consumers and recipients of exceptions.

In June 2014, an internal draft of the White Paper on "A Copyright Policy for Creativity and Innovation in the European Union" was leaked. According to the draft, topics that would be covered by the review of the EU copyright rules included the cross-border dissemination of creative content in the single market; assistance for knowledge and heritage institutions to fulfill their public interest objectives by clarifying the exceptions provided under the Copyright Directive; and user-generated content.

Ms. Neelie Kroes, the then Vice President of the Commission in charge of the digital agenda, criticised the White Paper as not being ambitious enough. As a result, due to a political dispute between Ms. Kroes and Mr. Barnier, the adoption of the White Paper was postponed.

President Juncker has stressed the importance of modernising EU copyright rules to adapt to the needs of the digital economy. For that reason, he moved the relevant portfolio from the internal market Commissioner to Commissioner Guenther Oettinger responsible for the digital economy and society. During his confirmation hearing, Commissioner Oettinger promised to prepare in the first part of the new Commission's mandate *"a targeted proposal on the reform of copyright, to take account of new technologies, new uses and new market conditions, which, while supporting innovation, will ensure fair remuneration for creators and allow creative industries to exploit the potential of the digital single market while increasing consumers' choice beyond national borders"*. A revised White Paper and its accompanying Impact Assessment, which will present detailed policy considerations and options in advance of decisions on specific legislative and non-legislative Commission initiatives, is expected in 2015.

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Key issues

- The European Commission will present its policy considerations on the review of the EU copyright framework in 2015
- The ongoing review covers all areas of EU copyright rules, including the Copyright Directive, the Rental and Lending Directive, as well as the Software Copyright and the Database Directives
- The European Commission has consulted all interested parties on a broad range of issues in December 2013
- The Commission's plans to issue a White Paper on this matter were postponed due to political disagreement among the previous College of Commissioners
- The Juncker Commission deals with the "modernisation of EU copyright rules" as a matter of priority

European Union: Embedding, framing and copyright infringement

The use of hyperlinks and embedding via framing of content on third party websites has become more and more common on the internet. In the case of *Svensson* C-466/12, the Court of Justice of the European Union (the "CJEU") ruled that hyperlinking to copyright protected work does not infringe the rights of copyright holders if the original content has already freely and lawfully been made available on another website. The reason hereof is that hyperlinking does not lead to the works in question being communicated to a new public (if the original content was already available to the same public to whom the works at issue have been communicated by means of a clickable link). While hyperlinking links users to the website where the original content was already

stored and publicly available, framing is used to embed content on one's own website without referring users to the original website, which can lead to situations where users are led to believe that the content is originally hosted on the third party website. In a recent matter, the CJEU confirmed that the *Svensson* rule also applies to framing/embedding.

Background

Bestwater International GmbH, a German manufacturer and producer of water filter systems, produced a video for advertising purposes. This video was then made available on Youtube allegedly without Bestwater's permission. Two competitor sales representatives embedded this video from Youtube on their own website via embedded framing. Bestwater sued the two sales representatives and turned to the German Federal Court of Justice, claiming that copyrights were infringed since the video was made available to the public without its consent. The German Federal Court of Justice then referred questions to the CJEU.

CJEU's order

According to Article 3 of the Directive 2001/29/EC of the European Parliament and the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (the "**Directive**"), the copyright holder has an exclusive right to make its work available to the public. Every act of communication of a work to the public must be authorised by the copyright holder. In the *Svensson* case, the CJEU ruled that hyperlinking does not lead to the works in question being communicated to a new public (if the original content was already available to the same public to whom the works at issue have been communicated by means of a clickable link).

In the *Bestwater* case, the CJEU decided that the same applies to embedded content via framing. When the embedded work is (i) made available by the same technical means as the initial work and (ii) is not directed to a new public (i.e. a public that was not taken into account by the copyright holder when it authorised the initial communication to the public), no consent from the copyright holder is needed. There is no communication to a new public when the (embedded) copyright protected work is already freely accessible to all internet users with the consent of the copyright holder. Users of the third party website must be deemed to be potential recipients of the initial communication and as being part of the public taken into account by the copyright holder when it authorised the initial communication. It is insignificant whether the user is led to believe this third party website is the original source of the embedded content.

The conclusion of this case is that framing of copyright-protected work does not constitute copyright infringement if the work is already freely available on another website to the same public to whom the works at issue have been communicated by means of a clickable link through the use of embedded framing and the embedded work is made available by the same technical means as the initial work. There is, however, still some uncertainty as to whether the original embedded work needs to have been lawfully made available with the copyright holder's consent. Bestwater had not given its consent for the original placing of the video on Youtube. Although the CJEU was aware of this fact, it did not address this point because this factual issue was not included in the question raised to the CJEU.

Key issues

- Embedding work is not copyright infringement if the work is already freely accessible to the same public on the internet and the embedded work is made available by the same technical means as the initial work
- Still unclear whether the original embedded work must have been lawfully made available with the copyright holder's consent
- Website holders are well advised to check if embedded content on their website has been freely and lawfully made available with the copyright holder's consent

Website holders should accordingly be careful when embedding copyrighted protected work on their websites if such work was placed on the internet without the consent of the copyright holder. Furthermore, such work should not be directed at a new public, for example if the original work requires a login or contains other restrictive technical measures.

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Czech Republic: The Czech Cybersecurity Act

After years of expert discussions, the Czech Cybersecurity Act (the "Act"), the first comprehensive act to address the issue of cybersecurity in the Czech Republic, entered into force on 1 January 2015. As our dependence on information technologies and systems increases, it has become essential to enact a legal framework that clearly specifies the rights and duties of individuals in the area of cybersecurity as well as the authority of public institutions. The Act is partly based on the EU Directive Proposal on measures to ensure a high common level of network and information security across the Union (the "Proposal") and also reflects the concerns addressed during 2010 Lisbon NATO summit that emphasised the necessity to address cybersecurity issues. Supportive legislation was adopted and a government resolution established the National Centre for Cybernetic Security (the "NCCS") as a part of the National Security Authority (the "NSA"). The NCCS was established to coordinate immediate reactions to cybernetic incidents and to represent the Governmental Computer Emergency Response Team in the terms of the Proposal.

Scope of the Protection

The Act principally aims to enhance cybersecurity by setting up a mechanism for active cooperation between the private sector and public authorities. It primarily targets the protection of a large part of the cyber infrastructure, the disruption of which would jeopardise the functioning of the country and could lead to grave financial or material losses or even life-threatening situations. A large part of the cyber infrastructure is mainly represented by "**Substantive Information Systems**", which encompass almost 100 information systems operated by key public authorities, such as ministries, the NSA or the Energy Regulatory Office. All the Substantive Information Systems are listed in supporting legislation and, for example, comprise the information system for the Commercial Register and Insolvency Register or the information system for healthcare services. Interestingly, the information systems for Prague and other municipalities are not considered Substantive Information Systems. This is due to the lower public interest in their protection in comparison with systems with nationwide impact.

Besides Substantive Information Systems, the Act also protects "**Critical Information Structure**". This is a more general concept that includes information systems that are (i) operated by either public or private entities, (ii) not subsumed under Substantive Information Systems, and (iii) whose dysfunction could negatively affect a significant part of the population or the country's economy. For instance, Critical Information Structure covers the control systems of power plants exceeding installed capacity of 500 MW (e.g. both Czech nuclear power plants), transmission systems such as pipelines for oil and natural gas, mobile network exchanges, networks for radio and television broadcasting, and many others.

System of Cybernetic Security Measures

Due to their sensitive nature and the major public interest in securing the proper functioning of Substantive Information Systems and Critical Information Structure (together the "**Relevant Systems**"), the Act sets out preventive security measures to protect them. These take the form of obligations imposed on the administrators of the Relevant Systems and are of either an organisational or technical nature. Organisational measures cover control and management policies for processes related to implementation and operation of the Relevant Systems, such as rules for choosing suppliers and storing related documentation. Technical measures, on the other hand, specify concrete solutions to ensure the security of the Relevant Systems, including detecting, evaluating and resolving cyber-attacks. In particular, technical measures include logging and

Key issues

- The Czech Cybersecurity Act is the first comprehensive act addressing the issue of cybersecurity in the Czech Republic
- It enhances cybersecurity by setting up a mechanism for active cooperation between the private sector and public authorities
- The Act established the National Centre for Cybernetic Security, which coordinates immediate reactions to cybernetic incidents
- A large part of the cyber infrastructure is protected by means of technical and organisational measures such as rules for choosing IT suppliers, rules on logging and authorisation control tools or cryptographic instruments

authorisation control tools, a system for detecting cyber-attacks or harmful encoding, or cryptographic instruments.

Besides preventive measures, the Act prescribes procedures which the administrators of the Relevant Systems are obliged to carry out in the event of a cyber-incident. The core element of these procedures is the notification duty to the NSA, which then analyses the incident and coordinates further steps on the nationwide level.

Role of the NSA

The NSA is the principal body authorised to supervise and control cybersecurity. The NSA keeps announcements about cybernetic security incidents from the administrators of the Relevant Systems on file and provides aggregated information to other affected public authorities and private entities. It also issues warnings of threats in the cybersecurity area. Its third main role is to impose reactive and protective measures for dealing with cybersecurity incidents. If a cybersecurity incident is capable of affecting a non-specified wider part of the population, the NSA is authorised to issue an administrative measure applicable to all citizens and entities. The NSA may also declare a state of cybernetic danger, which must be immediately announced to the public through a nationwide radio and television broadcast. The state of cybernetic danger is a reaction to a threat that may jeopardise the fundamental interests of the Czech Republic. It must be approved by the NSA's director and it may be consulted with the government. A state of cybernetic danger should be declared only for the period of time necessary and cannot last longer than seven days. It may, however, be prolonged by the NSA up to 30 days.

Conclusion

The Czech Cybersecurity Act is the first comprehensive legal norm to deal with the issue of cybersecurity in the Czech Republic. It sets out and unifies national cybernetic security measures and establishes the NCCS as a new authority with supervisory and advisory roles, while enhancing information exchange between private entities and public authorities. And yet the Act itself does not require the administrators of the Relevant Systems to order any particular software or hardware, or even specific solutions for information system

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European Union: Court of Justice of the European Union, 5 June 2014: Coty Germany GmbH v. First Note Perfumes NV, C-360/12

On 5 June 2014, the Court of Justice of the European Union had the opportunity to clarify the rules of international jurisdiction relating to Community trademark infringement in a preliminary ruling.

According to the order for reference, Coty Germany GmbH ("**Coty Germany**"), a German company producing and distributing perfumes and cosmetic products, notably marketed a ladies' perfume in a bottle registered as a three-dimensional Community trademark. In January 2007, First Note Perfumes NV ("**First Note**"), a Belgian perfume wholesaler, sold a perfume called "Blue Safe for Women" to Stefan P. Warenhandel ("**Stefan P.**"), whose place of business was in Germany. The order for reference stated that Stefan P. took delivery of those products at the premises of First Note in Belgium and subsequently resold them in Germany.

Claiming that the distribution by First Note of that perfume in a bottle similar to that represented in its trademark is infringement, Coty Germany brought an infringement action against First Note before the German courts.

It furthermore brought claims on the grounds of unlawful comparative advertising and unfair competition which will not be analysed here.

The peculiarity of this case is that Coty Germany's action was only brought against First Note and not against Stefan P., the reseller of the infringing products in Germany. Though First Note had not acted itself in Germany and had only indirectly contributed to infringing acts committed there by a third party, it was nevertheless brought before the German courts.

Coty Germany's action was dismissed in Germany both in the first instance and on appeal on the grounds that German courts had no international jurisdiction. Coty Germany brought an appeal on that point of law before the Bundesgerichtshof, claiming that First Note committed infringement acts in Germany within the meaning of Article 93§5 of Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trademark (the "**CTR**").

Article 93§5 of the CTR provides for several grounds of international jurisdiction. In particular, it establishes

jurisdiction in favour of the courts of the Member State where *"the act of infringement has been committed or threatened".*

The Court of Justice of the European Union, therefore, had to determine what was meant by *"the act of infringement has been committed or threatened"* and notably whether this language could cover both the place where the event gave rise to the damage and the place where the damage occurred, i.e. the place where the infringement produces its effects.

This interpretation was maintained by Coty Germany, in so far as Article 93§5 of the CTR is drafted in similar terms to Article 5(3) of the Brussels I Regulation which states that *"a person domiciled in a Member State may, in another Member State, be sued: […] 3. in matters relating to tort, delict or quasi-delict, in the courts for the place where the harmful event occurred or may occur".*

Under settled case-law, the expression *"place where the harmful event occurred"* in Article 5(3) of the Brussels Convention refers both to the place of the causal event giving rise to the damage and to the place where the damage occurred, with the result that the defendant may be sued, at the option of the applicant, in the courts in either of those two places (Although that option is also available under Article 5(3) of the Brussels I Regulation which replaced that convention, uncertainty persists as to whether that option can be extended to include a connecting factor relating to acts committed by a person against whom no action has been brought, more specifically from the perspective of the place where the damage occurred).

The Court of Justice of the European Union held that Article 93§5 of the CTR must be interpreted separately from Article 5(3) of the Brussels I Regulation, [with] the CTR expressly precluding the application of the Brussels I Regulation to trademark infringement actions.

According to the Court of Justice of the European Union, both the terms of Article 93§5 and the context of the CTR militate in favour of the jurisdiction of the courts only of the Member State where the defendant has committed the alleged unlawful act. Indeed:

- the wording of the article suggests that the linking factor relates to active conduct on the part of the person causing that infringement;
- the EU legislature intended to derogate from the rule on jurisdiction provided for in Article 5(3) of Brussels I Regulation in the light, in particular, of the inability of the rule on jurisdiction to respond to the specific problems relating to the infringement of a Community trademark.

The solution of the Court of Justice of the European Union, which only accepts one linking factor (namely the place where the alleged infringing act has been committed), is dictated by the intention not to multiply several grounds of jurisdiction and thereby limit the risks of forum shopping. It, however, compels owners of Community trademarks to sue all the actors of a chain of action, resulting in an infringement in a given Member State, before different courts to obtain compensation for their damage.

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Italy: A partial win for Gucci in the second round of its battle against Guess

The recent decision of the Milan Court of Appeal is significant in the worldwide battle involving the use of the "G" figurative trademark between the two famous fashion houses Gucci and Guess. The Court of Appeal has overturned part of the first instance decision, recognising the existence of unfair competition acts from Guess, although it confirmed that no counterfeiting of Gucci's trademarks existed
because Guess' products, although reminiscent of Gucci's, are not likely to generate confusion in customers because of their graphic differences taken as a whole.

Introduction

The Milan Court of Appeal found that (i) no counterfeiting existed because of the graphic differences that, when taken together, exclude the likelihood of confusion between the products at issue, and that (ii) the continued imitation of the elements characterising a competitor's works falls within unfair market practice.

The first instance decision by the Court of Milan had rejected all of Gucci's claims, both those regarding the trademarks and those alleging unfair competition.

By ruling that no confusing infringement existed, the Court of Appeal held that three of Gucci's trademarks were invalid, because of

Key issues

- The Court of Appeal finds that no counterfeiting exists because of the graphic differences which, when taken together, exclude the likelihood of confusion between the products in question
- The tort of unfair competition identifies multiple forms of entrepreneurial behaviour which can consist in a variety of unfair conducts and techniques
- Unfair competition is characterised by the same negative value as contrary to the constitutional principals of freedom of private economic initiative and freedom of competition

their lack of distinctiveness.

Background

With a decision dated 15 September 2014, the Court of Appeal in part confirmed and in part reversed the first instance decision. The Court of Appeal confirmed the lack of distinctiveness of the three Gucci trademarks; however it found that Guess had carried out unfair competition acts, specifically acts of parasitic competition.

The Court of Appeal stated that *"in all the cases, Guess products – because of their shape, shades, materials, graphic or decorative choices, or a combination of these elements together – are reminiscent of the style recently created by Gucci, in its recent collections."*

The Court of Appeal, however, confirmed the first instance decision in relation to Gucci's trademarks, holding that they were not counterfeited by Guess because not likely to generate confusion in the customers.

Indeed the Court of Appeal reasoned that the "G" figurative trademarks suggest, in the mind of the public, the association with the Gucci fashion house because of the graphic and decorative element of the two inverted and reversed "G"s, although not in a sufficient measure to generate confusion.

For the "Flora" trademark, instead, the Court of Appeal held that its core element is purely aesthetic and ornamental, consisting of elements that could be used in every floral depiction; and consequently held that the trademark cannot be protected.

As regards to the trademark formed by the green-red-green tape, the Court of Appeal stated no risk of confusion exists with the tape used by Guess, because of the different colours used by the two fashion houses.

Unfair competition for servile imitation, passing-off and parasitic competition

The Court of Appeal held recognised the existence of unfair competition acts (and specifically, servile imitation, passing off and parasitic competition) and, consequently, that Gucci has the right to monetary compensation from Guess.

The Court of Appeal found that Guess has willingly implemented certain measures to avoid a full overlap with the distinctive signs of its competitor, but from a global analysis it is clear that Guess' aim has been to imitate Gucci's typical motifs, through conduct devised especially not to be unlawful, if each act is considered individually, but that becomes contrary to professional business fairness, taken as a whole and if repeated overtime.

Regarding Gucci's right to be compensated for damages, the Court found, from the evidence collected and evaluated during the proceedings, specific intent by Guess to imitate Gucci's signs, proving the subjective element required to give rise to the righ to compensation. As to the harmfulness of the conduct, the Court of Appeal held that this element, the harmful element, consists in the misleading of the consumer (*"sviamento della clientela"*) and client solicitation. Indeed, Guess uses trademarks and signs that remind of Gucci's products, but offers its products at a lesser price.

The term for an appeal of this decision to the Supreme Court has not yet expired. Pending any appeal, this decision by the Court of Appeal grants Gucci a win and compensation for damages by punishing the unfair business conduct of its competitor; however, the serious blow inflicted not only to Gucci, but to all the fashion houses that use monograms or alphabet letters to distinguish their products, by the first degree decision remains.

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