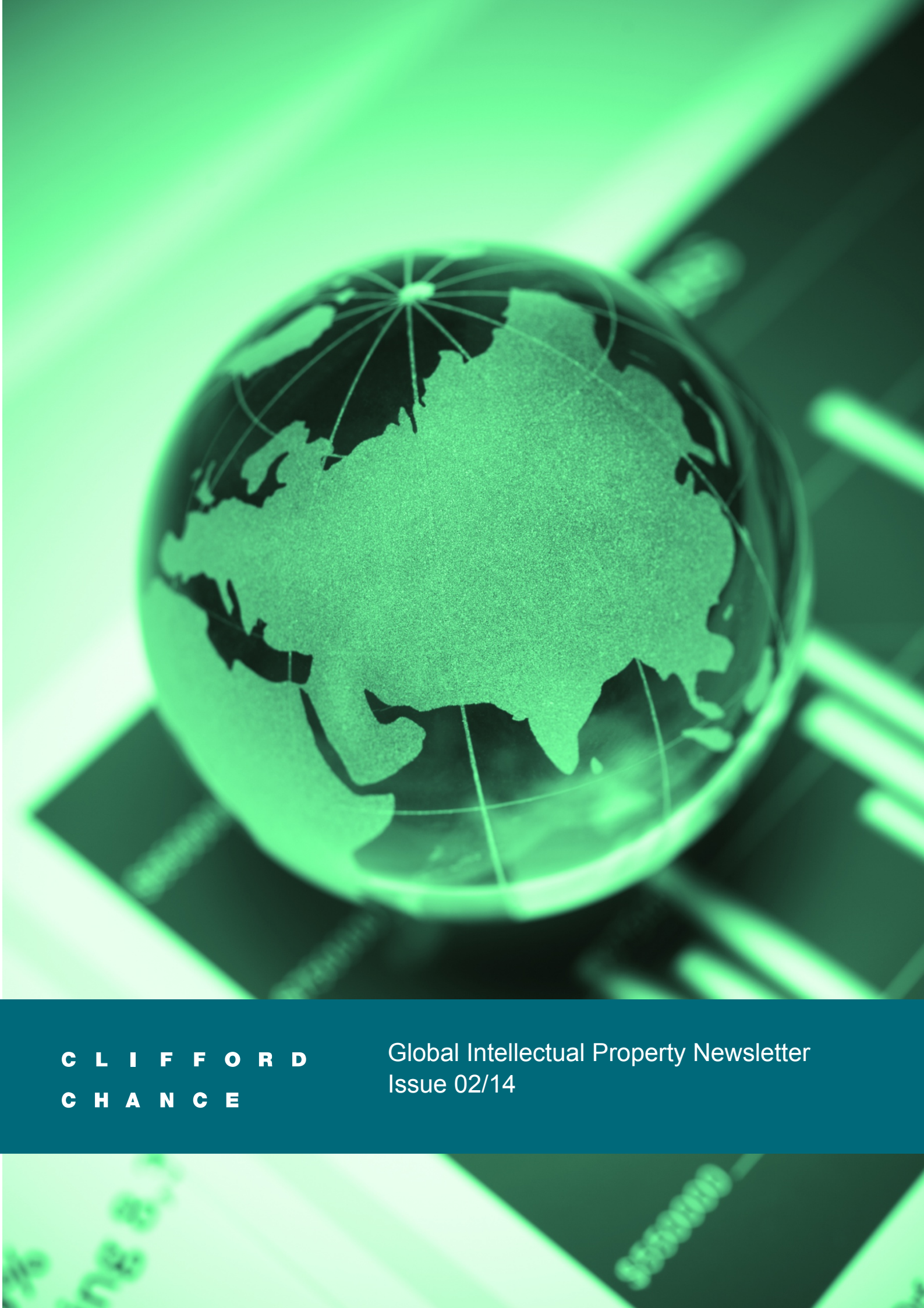

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Contents

Welcome to Clifford Chance's quarterly Global Intellectual Property Newsletter in which current IP developments taking place in major jurisdictions around the world are reviewed.

The current issue looks at EU developments on the Unified Patent Court, CJEU cases on supplementary protection certificates, EU national court decisions on the dichotomy of who owns the rights to "Bud" and "Budweiser", parallel importers duties in Germany, moves towards IP reforms in Russia and China, USA-amended reporting requirements for patent transfer licenses in pharmaceuticals, and developments in Italy to assist SMEs to access the national fund for the development of patent and design rights.

Our prior issue of the Global Intellectual Property Newsletter can be retrieved here.

European Union: Updates on the Unified Patent Court

The "Patent Package" creates a single patent with unitary effect in 25 EU Member States and introduces a single and specialized patent court. The latest developments are discussed here.

Introduction

The introduction of a single patent with unitary effect ("**Unitary Patent**") and a unified patent court ("**UPC**") is a historical development for Europe, the ramifications of which will affect innovation-driven industries. The history and the main elements of the "Patent Package" have been set out in our previous newsletters, which can be retrieved by clicking here. This article will discuss the UPC in more detail and will set out the latest developments regarding its entry into force.

One step closer to the Unified Patent Court

The UPC will come into existence and start its operations immediately after the respective agreement signed by 25 Member States on 19 February 2013 ("**UPC Agreement**") enters into force. The UPC Agreement will take effect on the first day of the fourth month after fulfilment of both of the following two requirements:

- Ratification by thirteen member states, with Germany, the United Kingdom and France being the mandatory signatory states (as these are the Member States with the highest number of registered European patents in 2012); and
- Entry into force of the amendments to Regulation (EU) No 1215/2012 ("**Brussels I Regulation**") concerning its relationship with the Agreement.

The Preparatory Committee is working towards a target date of early 2015 for accomplishing these requirements.

Status of ratification

At present, Austria is the only Member State that has ratified the UPC Agreement. France has taken steps to ratify the UPC Agreement as soon as possible, and Denmark is planning a referendum in May 2014 regarding the decision to ratify. Other Member States are also working to speed up the ratification process, but doubts concerning the commitment of

the United Kingdom towards the European Union create uncertainty as to the UPC's future. The United Kingdom has maintained a critical stance towards ratification, especially with regard to the problems that may occur due to increased forum shopping as a consequence of bifurcation being permitted in the UPC, increased litigation costs and the quality of judges. Moreover, Spain, Poland and Croatia have not yet signed the UPC Agreement establishing the UPC.

Brussels I Regulation

The Brussels I Regulation governs the jurisdiction, recognition, and enforcement of judgements in civil and commercial matters in EU countries. The UPC Agreement cannot enter into force until the Brussels I Regulation is amended to ensure that the UPC has international jurisdiction and its decisions will be afforded the same treatment and effect as the decisions of other courts of the EU Member States. On 6 December 2013, the European Council of the Ministers of Justice acted with unusual speed to approve the European Commission's proposed amendments to the Brussels I Regulation. It is now up to the European Parliament to approve or reject the proposed amendments, which is expected to occur in March 2014.

Structure of the Unified Patent Court

The UPC will be composed of a Court of First Instance, a Court of Appeal and a Registry. The Court of First Instance will consist of local and regional divisions, which will primarily hear infringement cases, but will also have jurisdiction to invalidate a Unitary Patent. To what extent this will bring a change, for instance to the German bifurcated system, is currently subject to discussions. Furthermore, the Court of First Instance will consist of a central division which will be competent to hear cases regarding the validity of Unitary Patents. Therefore, in a Unitary Patent infringement proceeding, the local or regional division can rule on the infringement, as well as on the validity of the patent, on behalf of all Member States. This will be substantially different from the current system (whereby 'regular' European patents are brought before the national courts).

Member States can host a local division and/or participate in a regional division with other Member States. Alternatively, Member States can choose not to have a local or regional division, in which case all infringement cases in their territory will be heard in the central division. It is anticipated that local divisions will be established in Belgium, the UK, France, Germany, Italy and the Netherlands and that a Regional Division will be set up in Scandinavia and the Baltic states. Both types of divisions will be staffed with judges from various Member States. The judges will be required to speak the language of the Member State where the division is situated or one of the official languages of the European Patent Office (English, French or German).

The central division will have its principal seat in Paris (dealing with software and other patents) and will have two specialist seats in London (dealing with pharmaceutical among other matters) and Munich (dealing with mechanical engineering among other matters). The Registry and the Court of Appeal will be seated in Luxembourg.

Key issues

- The UPC will come into existence after (i) ratification of the UPC Agreement by thirteen member states, including Germany, the UK and France, and (ii) entry into force of the amendments to the Brussels I Regulation
- The European Council has approved proposed amendments to the Brussels I Regulation which are now being considered by the European Parliament
- At present, only Austria has ratified the Agreement; other countries are trying to catch up; the UK's commitment is still unclear
- The UPC will be comprised of a Court of First Instance (with local and regional divisions), a Court of Appeal and a Registry
- The draft Rules of Procedure are still being discussed

The Rules of Procedure

While the UPC Agreement includes the basic principles of procedural law, the procedural details are covered by the Rules of Procedure ("**Rules**") which now also includes a rule and reference to the Patent Mediation and Arbitration Centre as a means of settlement or exploring a settlement of a dispute. These Rules have now been re-drafted on several occasions. The 15th draft was made public on 31 May 2013 and has been heavily discussed by numerous stakeholders in public consultations. Corporations have expressed their concerns regarding bifurcation and the availability of injunctions. After closure

of the written phase of the public consultation the Drafting Committee has been asked to evaluate the contributions received and to make proposals and comments ensuing from the public consultation. Further, the Committee intends to organise a public hearing on the draft rules of procedure in early 2014. The publication date of the final set of Rules is as of yet unknown.

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For more information please click here:

Patent Law Series "The EU Patent - One Step Closer?"

Patent Law Series 'EU patent - almost there?'

Patent Law Series - Update: The EU Patent - (Finally) One Step Closer!

Patent Law Series: Setting up a European patent litigation system - slow and steady wins the race?

Patent Law Series 'European Council approves proposed amendments to Brussels I Regulation - one step closer to the Unified Patent Court'

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European Union: Proposed amendments to the CTM Directive and the CTM Regulations

On 31 July 2013, the Legal Affairs Committee of the European Parliament published its Draft Report on proposals to amend the CTM Directive (2008/95/EC) and the CTM Regulations ((EC) No 207/2009). The Draft Report of Rapporteur Cecilia Wikström is available here.

The main changes may be summarised as follows:

Proposed substantive law changes

- **Extended "trademarkability".** The proposed amendments would abolish the requirement that the sign must be capable of being represented graphically before it can be registered. Instead, a sign would need to be capable of being represented in any form which enables both competent authorities and the public to determine the exact subject and scope to be granted to its owner. For example, signs could be applied for electronically, such as by MP3 files.
- **New protection for non CTM registered trademarks.** Owners of trade marks which are registered outside of the EU would be able to oppose the registration of a CTM application if there is a risk of confusion in the EU market and if the CTM applicant acted in bad faith.
- **Counterfeit goods.** CTM owners would have the right to prevent the distribution and sale of labels and packaging or similar items which may subsequently be combined with infringing products. Further, CTM owners would no longer have to prove that goods in transit will enter the EU market before infringement claims could be brought.
- **'Genuine use' starts from CTM application date.** The five year period in which a registered CTM must be genuinely used would be calculated from the date of the CTM application, not the date of its publication as is presently the case.

Key issues

- Proposals to change a number of aspects of both TM substantive and procedural law
- Proposals intended to make TM registration in Europe cheaper, quicker and more reliable

Proposed procedural law changes

- **EU-wide absolute grounds for refusal.** A national office would assess the absolute grounds for refusal not only on a national level but also for all other EU Member States. This would restrict a CTM applicant's ability to circumvent a refusal on absolute grounds for its CTM application in one EU Member State by "cherry picking" several national registrations in other EU Member States.
- **Class headings.** Following recent Court of Justice of the European Union ("**CJEU**") case law, class headings from the Nice Classification may only be used in CTM applications if they are sufficiently clear and precise. If a CTM applicant uses general terms, only goods or services clearly covered by the literal meaning of the words would be protected. Owners of CTMs registered before 22 June 2012 would have four months in which to seek protection in respect of

goods and services which went beyond a literal interpretation of the class heading. This proposed amendment has been criticised for allowing CTM owners to retrospectively broaden the scope of their CTM registrations and for introducing uncertainty into the state of the register.

- **Ex officio examination notices now limited to absolute grounds only.** This means that CTM owners would no longer receive notices that a third party has sought to register a similar CTM. CTM owners would need to arrange for their own "watching service" to receive notifications of such CTM applications.
- **Opposition and cancellation proceedings before national offices.** This means that CTM opposition and CTM cancellation proceedings in all EU Member States could be determined in national offices (rather than in the courts, as happens in some Member States). This change is designed so that parties can obtain decisions more quickly and cheaply.
- **Fees.** The proposals would introduce the principle "one class – one fee" rather than the present system where the CTM application fee covers up to three classes of goods and/or services.

Next steps

These and the other proposed amendments have been subjected to intense scrutiny. On 30 October 2013 Rapporteur Cecilia Wikström published a number of suggested amendments to the proposals contained in her Draft Report.

These proposals are intended to be adopted by the European Parliament in Spring 2014. If adopted, all EU Member States would have two years in which to implement the amended CTM Directive into national law. The CTM Regulation would have direct effect so no national implementation would be necessary in EU Member States.

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WIPO: Brand survey

On 14 November 2013, the World Intellectual Property Organization ("WIPO") published its Report entitled Brands – Reputation and Image in the Global Marketplace. The Report is available here.

Introduction

The Report is divided into three chapters. Chapter 1 explores how the economic contribution of brands has shifted and how branding behaviour has evolved. Chapter 2 examines the economics of the trade mark system and presents evidence informing future trade mark policy decisions. Finally, Chapter 3 investigates how companies' branding strategies interact with their innovation strategies and how this in turn affects market competition.

Chapter 1

Some of the more salient findings from this Chapter are as follows:

- Advertising spend was 0.6% to 1.5% GDP in most high-income countries and equivalent to about 1/3 of global R&D spend.
- In 2011, global branding spend was approximately US$ 466b. Rapidly growing middle-income economies such as China and India today spend more on branding than high-income countries did when they were at a comparable stage of development.
- In the US, branding investments have increased since the 1990s and in 2010 were US $340b. From 1987 to 2011, branding investments were approximately 25% of all US investments in intangible assets and exceeded investments in R&D and design.
- The total value of the top 10 brands in 2013 according to three widely used brand rankings grew by between US $46b and US $91b. Further, from 2008 to 2013, the top 100 global brands grew by between 19% and 24%.
- Among the top 100 brands, the technology sector – including brands such as Apple, Google, IBM, Intel, Microsoft and Samsung – dominates all three rankings.
- By 2001, China's trade mark office had become the top recipient of trade mark applications (by comparison, it was the top recipient of patent filings by 2011). In general, trade mark applications between 1985 and 2011 increased by a factor of 1.6 in high-income economies and by a factor of 2.6 in middle-income economies.
- The limited data available suggests that the highest number of trade mark licences is granted in the entertainment and sports sectors.
- Franchising activity is high in almost all countries. Europe has the largest number of franchising

brands, whereas Asia has the highest number of franchising establishments.

- The number of cross-border trade mark licensing and franchising transactions is growing, but seems modest when compared with other IP-based transactions (with software, copyright and industrial processes accounting for the bulk of IP-related cross-border trade).

Key issues

- WIPO has published an important report on brands and their role in the marketplace
- Report analyses empirical evidence to explore the economic value of brands, the changes in branding behaviour and the relationship between branding and innovation
- Report also considers future TM policy decisions as a result of these empirical finding

Chapter 2

Some of the policy questions discussed in this Chapter are as follows:

- To what extent trade mark offices should limit the "cluttering" of their trade mark registers. "Cluttered" registers risk reducing the space of names and other signs available for new trade marks. While the precise extent of cluttered registers and their costs are uncertain, there is some evidence that they negatively affect at least some market participants.
- To what extent trade mark registration should be conditional on the applicant actually using the trade mark in the marketplace.
- To what extent trade mark offices should examine whether new applications pose a conflict with earlier trade marks in different ownership – in particular, whether their co-existence would likely cause confusion in the marketplace.
- To better define what qualifies as a "well-known" trade mark. It is suggested that a framework be established for exchanging information on well-known trade marks, such as through a directory of such trade marks.

Chapter 3

Some of the more important findings from this Chapter are as follows:

- Branding is one of the most important mechanisms for firms to secure returns on R&D investments: companies which invest in innovation also invest in branding.
- The relationship between branding activities and innovation investments depends upon a number of product-specific and industry-specific characteristics. For instance, can consumers immediately ascertain a product's innovative features upon purchase, or do they need to experience the product before assessing the usefulness of those features? It is suggested that advertising mainly plays an informative role in the former case, whereas it plays a persuasive role in the latter case.
- Some companies find it more profitable to differentiate themselves through image rather than through product innovation, *e.g.*, for mature and inexpensive convenience goods, such as ready-to-eat cereals, soft drinks and chocolate bars.
- In two instances competition authorities have assessed the competitive consequences of strong brands (high barriers to market entry as new competitors may not have the advertising budget to induce consumers to switch to their products) and have intervened:
  - M&As can lead to the concentration of brands in the hands of one or a few companies, posing the risk of collusive behaviour and the formation of dominant market positions.
  - Owners of strong brands may impose certain restrictions on licensees for their trade marks - such as resale price maintenance or limits on carrying the products of competitors – which can unduly extend the brand owners' market power.

Conclusion

This Report provides new data, analysis and insight into how companies use their brands to differentiate themselves from their rivals - and what the ever increasing use of brands means for consumers, market competition and innovation. Through this Report, WIPO aims to foster evidence-based policy making which can only benefit trade mark law and practice as it faces the challenges posed by an ever changing global marketplace.

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Russia: Russian Civil Code reform: what's new in the IP sector?

The Russian Civil Code has been extensively reformed, including as related to IP rights. Although amendments to Part IV of the Russian Civil Code ("Amendments") are still pending, several new developments can be highlighted, including simplified registration of the disposal of IP rights, new options for patentees to defend their rights, and expanded liability for infringement of IP rights on the Internet.

Registration of IP rights: no need to register the contract

Under the current legislation a contract under which a registrable IP right (*e.g.*, a right to trade marks or patents) is disposed of (alienation, licensing or pledge) must be registered. Under the Amendments, by contrast, it will be sufficient for both or either of the parties to the contract to file an application detailing the terms of the contract. Where the application is filed by only one of the parties, the applicant will have to attach a notification of disposal signed by both parties, or a notarized extract from the contract, or the contract itself (at the applicant's discretion). Thus, the registration of contracts will no longer be mandatory.

No transfer of IP rights between commercial organizations without consideration

The general civil law prohibition on gifts between commercial organizations continues to be reflected in the Amendments. New draft provisions specify that the alienation of exclusive rights and provision of a worldwide exclusive licence for the full duration of an exclusive right is prohibited between commercial organizations if effected without consideration.

New options for defence of patent rights

The Amendments introduce compensation as a remedy for the infringement of patent rights. The patentee may claim compensation from the infringer instead of damages (which is usually difficult to prove in such cases), along with the use of other remedies (recognition of rights, injunction, winding-up of the infringer *etc*.). The amount of compensation is left to the discretion of the courts and can be up to 5 million roubles (approximately USD 143,000). It may also equal twice the value of the infringed patent right.

Broadening the definition of know-how

Know-how is any information or knowledge which relates to IP in a scientific or technical area and methods of conducting professional activity which are potentially valuable because they are unknown to third parties. Under the current edition of the Civil Code, for information or knowledge to be considered know-how it must be handled under the statutory regime that governs commercial secrets (i.e. compliance with a number of requirements, including, amongst others, creation of a list of confidential information, keeping records of all persons having access to confidential information and marking as confidential all tangible media containing confidential information), which in practice is very difficult to comply with. The Amendments take these difficulties into account and provide for the right of the know-how owner to protect confidential information by other means, *i.e.*, not necessarily by introducing a commercial secrecy regime.

Key issues

- The Amendments provide for simplified registration of disposal of registrable IP rights
- They also prohibit the transfer of IP rights between commercial organizations without consideration
- The Amendments permit compensation as a remedy for the infringement of patent rights
- The Amendments broaden the definition of know-how
- They also define IP infringements on the Internet
- The Amendments provide for simplified licences for software
- They also entitle employers to use an employee's copyright under the terms of a non-exclusive license for consideration

IP rights infringements on the Internet

The Amendments extend liability for infringement of IP rights to the Internet, including liability for persons who gave instructions in relation to (or exercised control over) the infringement. The Amendments also provide for a detailed list of exceptions from intermediary liability, *e.g.*, if a person did not initiate the transfer of material containing IP, did not modify the material, was not aware of the infringement, and took all necessary steps as soon as the infringement became known to it.

Simplified licences for software use

The Amendments provide for a simplified procedure for entering into software licence agreements. The terms of such agreements may be listed on the packaging of the software or may be provided electronically. The user accepts the terms of the license by starting to use the software. Unless provided otherwise in the agreement, this simplified licence is granted without consideration.

Licences for copyrights created by employees

The exclusive rights to works of science, art or literature created by employees are generally held by the employer. In cases where such rights rest with the employee, the Amendments entitle the employer to use the copyright under the terms of a non-exclusive licence for consideration (and not only for the purposes stipulated in the employee's official job description).

Conclusion

The proposed amendments to the Civil Code tend to provide rightholders with greater possibilities to protect their IP rights and to make their circulation easier and with fewer formalities.

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Italy: Recent developments on funding of investment projects for the valorisation of patent and design rights

Italy has created the National Innovation Fund ("NIF") to develop and facilitate funding of innovation initiatives through the exploitation of intellectual property rights (mostly invention and design patents). The NIF was created pursuant to, and is governed by, Italian Decree No. 107 of 11 May 2009 of the Ministry of Economic Development (*Ministero dello Sviluppo Economico*, "MiSE").

Now that the NIF is finally operational, small and medium-sized enterprises that rely on patentable inventions can look forward to accessing the incentive scheme.

Hard times for SMEs?

Small and medium-sized enterprises ("**SMEs**") are a crucial part of the Italian economy, which mainly relies on small companies with high competitive value. Globalization and trade liberalization have ushered in new opportunities for SMEs, although old challenges remain.

The Enterprise Europe Network, the Italian network aimed at supporting SMEs, has recently conducted a survey to identify how SMEs can best access an increasingly global market. The survey revealed that SMEs with potentially profitable businesses face difficulties in raising the venture capital or obtaining the bank financing necessary to reach higher levels of commercial or technical innovation. These difficulties consist mainly of the inability to provide sufficient guarantees and to sustain high investment costs.

The National Innovation Fund

To assist SMEs in overcoming these difficulties, MiSE has set up a SME-dedicated fund of approximately EUR 80M to fund the research, innovation and inventions of SMEs. Most of the capital injected in NIF consists of application and maintenance fees for patents and other inventions.

NIF selects the entities authorized to lend to the SMEs in the context of the programme, and facilitates access to funding for SMEs involved in innovative projects that rely on intellectual property rights. NIF is available to any SME that is an Italian joint-stock company, whatever its sector focus (except for the coal industry, which is expressly excluded from the programme), provided that it shows high-growth potential.

Nevertheless, access to the incentive program is not permitted to companies that (i) have been rated as being "in financial difficulties", (ii) have received unlawful aid or incentives in contravention of the European Union's antitrust principles, (iii) have been granted incentives or concessions by MiSE that were later revoked, or (iv) have failed to repay loans owed to MiSE.

Eligible companies may also apply for MiSE's funding jointly, by entering into a "network agreement", whereby several companies undertake to develop an innovation programme together with the understanding that their collaboration will be limited, as to the duration and expenditure, exclusively to the innovation project, without resulting in the formation of a corporate relationship or joint venture.

Funding option I: risk capital

In the context of the program, support to SMEs that rely on innovative invention patents can be in the form of contributions to their equity capital.

Within NIF, MiSE has set up a closed-end investment fund named IPGest, which is run by Innogest, an asset management company. IPGest has investment capital of up to EUR 40.9M, derived from funds injected by MiSE for approximately 50% and by private investors for the remaining half. The purpose of NIF is to be a means to fund SMEs that wish to develop projects based on innovative patents (design patents are carved out from this funding option).

IPGest purchases a minority or majority interest in the participating SME, either in the form of an equity holding or in the form of quasi-equity instruments issued by the SME, the value of which generally varies on the basis of the SME's performance. The only limitation on investment is that each tranche of investment in any one SME must not exceed the EUR 1.5M threshold over a period of 12 months.

IPGest shall determine the duration of the investment on a case-by-case basis, provided that the entire investment should not exceed 10 years, although at the end of the tenth year it may be renewed for an additional 4 years.

Participation in this funding option offers a number of benefits: (i) private equity and venture capital investments in the SMEs' risk capital does not require the target SMEs to issue specific guarantees; (ii) investors are requested to contribute proactively to the target SMEs' business; and (iii) the presence of an investment fund enhances the SMEs' standing, potentially improving its performance.

Funding option II: debt capital

As an alternative to investment of risk capital, MiSE promotes reduced interest rate loans by certain banks, pre-selected through public tender bids (*i.e.*, Deutsche Bank, Mediocredito Italiano, and UniCredit), to SMEs whose business is focused on innovative invention and design patents.

The portion of NIF allocated to this second funding option, amounting to EUR 39.1M, is structured as a cash collateral aimed at minimizing the risk of first loss of the pool of loans lent to the SMEs by the eligible banks.

The loans are guaranteed by the tranched cover issued by MiSE, by means of which the pool of loans is split into two tranches: (i) the 'junior tranche', the risk of which is borne by MiSE up to 100% of the cover granted, and (ii) the subsequent 'senior tranche', the risk of which is borne by the lender for the remaining portion.

The amount of the loan to any SME is capped at EUR 3M, and the term for repayment must range from 3 to 10 years.

This funding mechanism is expected to create availability of resources that the banks will be ready to lend: it is estimated that the EUR 39.1M fund allocated by MiSE will actually generate loans for up to EUR 375M.

Key issues

- MiSE's goal is to encourage investors and lenders to acquire stakes in and lend to SMEs focused on innovation initiatives
- The risks relating to investments in and loans to SMEs will be mitigated by MiSE through a EUR 80M fund allocated to the project

The advantages of this incentive mechanism include: (i) mitigation of the lenders' risk of non-repayment; (ii) issuance of loans to SMEs within reasonable deadlines and under transparent conditions; and most importantly (iii) assurance that the loan will not be conditioned on guarantees other than MiSE's tranched cover.

Conclusion

The funding of investment projects, through the acquisition of equity capital in the SMEs or the promotion of reduced interest rate loans by certain banks, could be very useful for small innovative firms. Typically, SMEs face difficulties developing

innovation because they must rely exclusively on their resources, which rarely suffice. NIF creates an efficient system to allow SMEs to collect external financial resources for the valorisation of patent and design rights, and, consequently, to increase their competitiveness on the global market.

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European Union: New wave of Court of Justice of the European Union decisions address Supplementary Protection Certificates

At the end of 2013, the Court of Justice of the European Union ("CJEU") issued five decisions regarding Supplementary Protection Certificates ("SPCs"). In its two Orders, dated 14 November 2013, the CJEU confirmed the doctrines detailed in *Novartis* (C-207&252/03) and *Massachusetts Institute of Technology* (C-431/04), regarding, respectively, the determination of the SPC duration and the definition of "combination of active ingredients", in accordance with the Regulation (EC) No 469/2009 concerning the SPC for medicinal products ("SPC Regulation"). And in its three Judgments, dated 12 December 2013, the CJEU clarified its controversial *Medeva* Judgment (C-322/10) and provided further guidance on the requisites stated in Article 3 of the SPC Regulation for obtaining an SPC.

Introduction

By the end of 2013, the CJEU handed down five decisions dealing with four open and controversial questions regarding SPCs and the interpretation of the provisions of the SPC Regulation:

- Can a Swiss market authorization be considered the "first authorisation to place the product on the market in the Community" for determining the duration of an SPC (Article 13 of the SPC Regulation) even though the set of clinical data upon which it was granted did not satisfy the conditions stated in the applicable EU regulations (*AstraZeneca*, C-617/12)?
- Can a combination of an active ingredient with a coadjuvant with no therapeutic effects, but which enhances the therapeutic effects of the active ingredient, fall within the definition of "combination of active ingredients" (Article 1(b) of the SPC Regulation) (*GlaxoSmithKline Biologicals*, C-210/13)?
- When can a product be understood as being "protected by the basic patent" (Article 3(a) of the SPC Regulation) and how should the criteria stated in the controversial *Medeva* Judgment be interpreted (*Eli Lilly*, C-493/12)?
- Can more than one SPC be granted for one same basic patent (Article 3(c) of the SPC Regulation) (*Georgetown*, C-484/12; *Actavis*, C-443/12)?

AstraZeneca C-617/12

In its Judgment of 25 April 2005 in the *Novartis* joint cases (C-207&252/03), the CJEU found that a Swiss market authorization, automatically recognised by the Principality of Liechtenstein, could be considered when determining the duration of an SPC pursuant to Article 13 of the SPC Regulation when that authorisation predates any other marketing authorization issued for the same medicinal product, either by the European Medicines Agency ("**EMA**"), or by the competent authorities of any EU Member State.

In *AstraZeneca*, the CJEU considered whether this *Novartis* doctrine should be maintained in cases where (i) on the basis of similar clinical data to that examined by the Swiss authority when granting AstraZeneca's market authorization, the EMA refused to grant AstraZeneca's marketing authorization as it failed to satisfy the conditions for the grant stated in the EU regulations; and (ii) AstraZeneca's Swiss authorisation was suspended by the Swiss authority and subsequently reinstated only when AstraZeneca submitted additional data. In its Order, dated 14 November 2013, the CJEU stated that these facts were irrelevant and that its former *Novartis* doctrine should be fully confirmed (para. 60).

GlaxoSmithKline Biologicals C-210/13

On 14 November 2013, the CJEU handed down an Order in *GlaxoSmithKline Biologicals* (C-210/13), in which it discussed whether the combination in a vaccine of an antigen with an adjuvant that, although it does not have therapeutic effects on its own, enhances the therapeutic effect of the antigen, falls

within the definition of "combination of active ingredients" within the meaning of Article 1(b) of the SPC Regulation. The CJEU, confirming its former Judgment, dated 4 May 2006, in *Massachusetts Institute of Technology* (C-431/04), stated that this combination did not fall within the definition of a "combination of active ingredients", as the adjuvant had no therapeutic effects on its own and, thus, it could not be regarded as an "active ingredient" within the meaning of this provision (para. 28 and 45).

Eli Lilly C-493/12

On 12 December 2013, in *Eli Lilly* (C-493/12), the CJEU interpreted the concept "protected by the basic patent" in Article 3(a) of the SPC Regulation and clarified the criteria stated in its former *Medeva* Judgment, dated 24 November 2011, according to which, in order to verify whether the requisite stated by this provision is fulfilled, the product should be "specified in the wording of the claims of the basic patent". This decision opened a new debate regarding what "specified in the wording of the claims" meant, debate that the *Eli Lilly* Judgment has tried to clarify.

The CJEU stated that in order to verify whether a product is "protected by a basic patent" it is not necessary for the active ingredient to be identified in the claims of the patent, just by a "structural formula". The active ingredient can also be deemed "protected" by the basic patent if it is covered by a "functional formula" in its claims provided that, after interpreting these claims," *inter alia*, in the light of the description of the invention, as required by Article 69 of the European Patent Convention ("**EPC**") and the Protocol on the interpretation of that provision", it can be concluded that "the claims relate, implicitly but necessarily and specifically, to the active ingredient in question" (para. 44).

Key issues

- A Swiss market authorization can be considered the "first authorisation to place the product on the market in the Community", even if the set of clinical data upon which it was granted does not satisfy the conditions for the grant of a marketing authorization under the applicable EU regulations
- A combination of an active ingredient with a coadjuvant with no therapeutic effects, but which enhances the therapeutic effects of the active ingredient, is not a "combination of active ingredients"
- In order to determine whether "the product is protected by a basic patent in force", the claims must be interpreted in the context of the description as prescribed in Article 69 of the EPC and its Protocol
- It is possible to obtain several SPCs over the same basic patent provided that each SPC relates to a product that is protected "as such" by that basic patent

Moreover, the CJEU pointed out that it would undermine the objective of the SPC Regulation if an SPC were granted to a patent holder that is not the holder of the marketing authorization for the medicinal product developed from the specifications of the source patent as it had failed to make investments in research to clearly ascertain the active ingredient covered by its basic patent which could be commercially exploited in a medicinal product (para. 43).

Georgetown C-484/12 & *Actavis* C-443/12

In the other two Judgments, dated 12 December 2013, *Georgetown* (C-484/12) and *Actavis* (C-443/12), the CJEU clarified its statement in *Medeva* that "no more than one certificate may be granted for a basic patent" (para. 41 of *Medeva*), and stated under which circumstances a patent holder can obtain several SPCs over the same basic patent. In this respect, the CJEU has clarified that, if a patent protects several different "products", it is possible to obtain several SPCs in relation to each of those different products, provided that each of them is "protected as such by that basic patent" within the meaning of Article 3(a), in conjunction with Article 1(b) and (c), of the SPC Regulation, and is contained in a medicinal product with a marketing authorization (para. 29 of *Actavis*). The CJEU explained in *Actavis* that a product is not "protected as such" if the active ingredient is simply referred to in the wording of the claims of the patent in "general terms".

The CJEU's holding raises the question of when a combination of active ingredients can be considered as "protected as such" by the basic patent. This issue will be analysed on a case-by-case basis.

In *Georgetown*, the CJEU held that the patent holder should be entitled to obtain several SPCs over the same basic patent because both the HPV-6, HPV-11, HPV-16 and HPV-18 and the HPV-16 and HPV-18 combinations, on the one side, and HPV-16 alone,

on the other side, were protected "as such" by the basic patent.

However, in *Actavis* the CJEU considered that, as Sanofi already was granted an SPC for its basic patent for "irbesartan", it was not able to obtain a second SPC over the same basic patent for the combination "irbesartan + hctz" because this combination was not "protected as such" by the basic patent. In this respect, the CJEU confirmed that the patent comprised the second active ingredient (hctz) only generally by way of a functional definition (diuretic) and that the number of active ingredients, which fulfilled this functional definition, was "not limited". The CJEU understood that in these cases, accepting that all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients, "not protected as such" by the basic patent conferred entitlement to multiple SPCs would contradict the requirement to balance the interests of the pharmaceutical industry and those of public health related to the encouragement of research within the European Union through the use of SPCs.

Conclusion

With these five decisions, the CJEU has given further guidance on how to interpret the SPC Regulation and provided welcomed clarification of its controversial *Medeva* Judgment. However, with those decisions handed down on 12 December 2013, the CJEU may have sparked new issues. It remains to be seen how the national courts and authorities put into practice the criteria stated therein for determining whether the SPC application fulfils the requisites stated in Article 3(a) and (c) of the SPC Regulation and, mainly, whether the product is protected "as such" by the basic patent.

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European Union: EMA's increased publication of secret clinical studies

The European Medicines Agency ("EMA") proposed a new policy ("Draft Policy") in June 2013 that permits the proactive disclosure of certain data contained in clinical study reports. In addition, the European Parliament ("EP") recently agreed on an amendment to the rules governing clinical trials (COM(2012) 369; "Draft CT Regulation") effectively deeming clinical study reports non-confidential. Both initiatives may significantly impair the interests of drug originators.

Introduction

Private investments in R&D are encouraged by the protection of such investments and their results, thus providing possible advantages against competitors. Although pharmaceutical products are patentable under certain circumstances, the data resulting from pre-clinical and clinical studies is not. Nevertheless, such information is often very valuable.

Currently, clinical study and other data is protected in the US, Europe and Japan, where so-called "data exclusivity" (cf. Art. 39 para. 3 TRIPS) was introduced many years ago. For example, the European Commission recently proposed new rules on the protection of trade secrets (COM(2013) 813; "**Trade Secret Proposal**") aiming to enhance the overall protection for trade secrets by harmonizing the currently existing laws of the Member States.

Background

Until 2010, EMA did not proactively disclose confidential information, especially secret clinical data contained in a marketing authorisation, to the public. Since 2010, however, EMA has increasingly disclosed such data on a request-by-request basis.

The Draft Policy, in particular in combination with the Draft CT Regulation, may signify a shift in favour of the generic pharmaceutical manufacturers industry's interests to the detriment of drug originating companies active in R&D.

Past and current practice

In 2010, EMA started to disclose individual data of clinical studies necessary for obtaining marketing authorisation in Europe to research institutions and pharmaceutical companies on a request-by-request basis according to:

- EU Regulation (EC) 1049/2001 regarding public access to European Parliament, Council and Commission documents ("**Regulation 1049/2001**"); and
- EMA's policy on access to EMA documents dated 1 December 2010 ("**EMA Access Policy**").

Key Issues

- Under European initiatives, clinical study report data will no longer be considered "commercially confidential"
- Under European initiatives, disclosure will no longer occur only on a request-by-request basis. Documents will be available in a publicly accessible database
- Legal basis for proactive disclosure uncertain
- Technical data will still be protected
- Clinical trial data might easily be used in countries with weak patent protection

Although it is in the general public interest to be informed about clinical studies, many pharmaceutical companies are concerned about the publication of their confidential and valuable commercial information contained in such studies.

AbbVie, Inc. and InterMune, Inc. have each applied for a preliminary injunction before the General Court (European Union) against EMA's decision to grant the requested access to non-clinical and clinical information (including clinical study reports) submitted as part of marketing authorisation applications.

The General Court granted the preliminary injunctions on 25 April 2013, concluding that the public interest does not prevail over the interest of non-disclosure of confidential information in these cases. EMA appealed the General Court's decision, and in December 2013 the Court of Justice of the European Union decided the General Court had incorrectly applied the test for an injunction and sent the case back to the General Court for reconsideration. It is uncertain how the General Court will ultimately decide the case.

Draft Policy

Now, EMA's quest for transparency has gone even further: On 24 June 2013, EMA released a Draft Policy on publication and access to clinical-trial data allowing for the proactive publication of such data.

The Draft Policy released for public consultation in June 2013 was expected to apply to data underlying all marketing authorisations submitted from 1 March 2014 onwards (although this may now be delayed – see further below). The Draft Policy foresees that clinical study reports shall be published (i) at the time of publication of the European Public Assessment Report ("**EPAR**") for positive decisions, negative decisions or withdrawals, or (ii) 30 days following withdrawal if no EPAR is published.

EMA seeks to create a publicly accessible database to contain the details of all clinical trials to:

- Make drug development more efficient by establishing a level playing field that allows all drug developers to learn from past successes and failures;
- Enable the scientific community to use clinical trial data to develop new knowledge; and
- Allow independent replication of clinical trial data to enable third parties to verify the regulatory authority's positions and challenge them where appropriate.

According to the Draft Policy, three categories of data shall be established which determine the level of publication required:

- Category I encompasses clinical studies data containing commercially confidential information ("**CCI**"), such as details of the investigational medicinal product, some in vitro studies, *etc*. Category I data will only be made available on a request-by-request basis under the EMA Access Policy, but the EMA indicated that different procedures will apply in the future. Besides, the Draft Policy foresees that "in general clinical trial data cannot be considered CCI; the interests of public health outweigh considerations of CCI."
- Category II data is all data that does not raise any concerns regarding the protection of personal data ("**PPD**") (*e.g.*, summary tables presenting aggregated data, or where personal data has been de-identified). Category II data will be openly accessible and available to download from EMA's website.
- Category III comprises data that raises PPD concerns (*e.g.*, individual patient data sets, documentation explaining the structure and content of data sets). Such data will only be available for requesters fulfilling certain requirements and having agreed to a legally binding data sharing agreement *i.e.*, encompassing a commitment that data is solely used in the interest of public health.

Draft CT Regulation

In addition, the EP recently agreed on an amendment to the Draft CT Regulation governing clinical studies,

effectively deeming clinical study reports non-confidential.

According to Rec. 20a(4) of the amended Draft CT Regulation, "*data included in clinical study reports should not be considered commercially confidential once a marketing authorisation has been granted or the decision-making process on an application for marketing authorisation has been completed.*" (Emphasis added.)

Impact

The change in EMA's disclosure policy in the past years is already noticeable. Although information on clinical studies is not yet disclosed to the public automatically upon marketing authorisation, EMA has handled requests more permissively in recent years: From November 2010 to April 2013 it released more than 1.9 million pages of information relating to clinical trials upon requests by third parties. In 2012, most requests were submitted by pharmaceutical companies (91 requests), consulting agencies (27 requests) and lawyers (40 requests), which suggests that such information is not primarily being requested by organisations acting for public health or research purposes.

The proposed changes to the Draft CT Regulation might lead to an even more liberal approach than the one already envisaged by EMA: clinical study reports will be proactively published by EMA as long as there are no PPD concerns and a publication does not go against Regulation 1049/2001 (cf. amended Article 78(3) Draft CT Regulation).

It is possible that the disclosed data will be misused by third parties to ride on the back of innovators' R&D expenditures and easily obtain marketing authorisations in countries providing for no or weak patent protection of pharmaceutical products,.

Technical data included in the studies, *e.g.*, details on the production process, will remain confidential. From an intellectual property perspective, however, this does not help in cases where no patent protection for the active ingredient or the production process exists.

Innovators also regard their own trial designs with some secrecy and as being commercially confidential because large expenditures of R&D and intellectual effort go into optimizing such trial designs. Freely disclosing such trial designs to competitors undermines the financial investments that go into trial design and the competitive advantages gained from investment.

Uproar not without effect

In an EMA press release, dated 13 November 2013, the agency said it received more than 1,000 comments on the proposed policy change. Such a reaction was "unprecedented" and has lead to a delay in the original timetable for the new policy to commence in March 2014 in order to allow for in-depth analysis.

EMA's continued work on the Draft Policy will be to further clarify and fine-tune the proposed rules. This work will be guided by the following key principles announced after EMA's December Management Board meeting:

- A stepwise approach for implementation with, as a first step, preparation for the publication of clinical study reports redacted as appropriate.
- Development of a methodology for de-identification of patients.
- Definition of a standard format for the submission of data.

EMA is aiming to approve an updated Draft Policy and a timeline for implementation at its Management Board meeting in March 2014.

Comment and outlook

The detrimental effects of extensive publication are obvious: it could discourage pharmaceutical companies from investing in R&D activities, especially by allowing non-innovative competitors to benefit from their efforts. Increased numbers of market entries would lead to a decrease in margins, undermining the economics of drug development programs. This needs to be appropriately balanced against the benefits sought by EMA in developing the Draft Policy.

The proposed new approach is also somewhat contradictory to the rationale of the Trade Secret Proposal which seeks to enhance the protection level afforded to this information. The Trade Secret Proposal will not apply if clinical trial data is not considered CCI.

Also the protection of data exclusivity does not prevent the use of publicly available data.

It will be interesting to see how EMA finally develops its Draft Policy and to what extent it addresses the industry's concerns in relation to the protection of R&D and intellectual property.

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USA: Federal Trade Commission amends reporting requirements for the transfer of exclusive patent licenses in the pharmaceutical industry

The U.S. Federal Trade Commission amended the Premerger Notification Rules under the Hart Scott Rodino Antitrust Improvements Act that govern reporting requirements for patent transfers in the pharmaceutical industry, broadening the notification requirements for transfers of pharmaceutical patent rights.

Introduction

The U.S. Federal Trade Commission ("**FTC**"), with the concurrence of the Antitrust Division of the U.S. Department of Justice ("**Antitrust Division**"), amended the Premerger Notification Rules ("**Rules**") promulgated under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended ("**HSR Act**"), on 6 November 2013, to clarify and expand the HSR Act's application to proposed transfers of exclusive patent rights in the pharmaceutical industry where the licensee acquires "all commercially significant rights" to the patent. The amendments to the Rules were approved by the FTC by a 4-0 vote and became effective on 16 December 2013.

Background

The HSR Act and Rules require parties proposing to acquire voting securities, non-corporate interests, or assets above certain thresholds to notify the FTC and the Antitrust Division and wait a specified period of time before closing a transaction. The Rules now include a clarified obligation to report the grant of certain exclusive patent licenses. An exclusive patent license will only be reportable if the $15.2 million size-of-person threshold and the $75.9 million size-of-transaction threshold established under the HSR Act are satisfied. (The FTC recently announced its annual amendments to these jurisdictional thresholds, which are expected to be effective in the latter part of February.) The HSR Act and Rules permit the FTC and Antitrust Division to review such transactions to determine whether they would violate the U.S. antitrust laws if consummated.

Previously, the acquisition of a patent license was potentially reportable as an asset acquisition only where the license covered all three exclusive rights to "make, use and sell" the product covered by the patent for a specified geographic area or field of use. According to the FTC, "it has become more common for pharmaceutical companies to transfer most but not all of the rights to 'make, use, and sell' under an exclusive license" and for "licensors [to retain] the right to co-develop, co-promote, co-market and co-commercialize the product along with the licensee," raising challenges to the "make, use and sell" approach. As a result, the FTC amended the Rules, enacting a new test based on whether the licensor transfers "all commercially significant rights" to the licensee, despite having retained some statutory patent rights.

Key Issues

- The grant of certain exclusive patent licenses in the pharmaceutical industry is potentially reportable as an asset acquisition under a new test where the licensee acquires "all commercially significant rights" to the patent. This new test is broader than the old test, under which the grant of a pharmaceutical patent license was potentially reportable as an asset acquisition only where the licensee acquired all rights to "make, use, and sell" under the patent
- The retention of co-rights and limited manufacturing rights does not affect whether the transfer of "all commercially significant rights" has occurred
- The "all commercially significant rights" test may have implications for other industries

The new "all commercially significant rights" test

Under the amended Rules, the reportability of the transfer of rights under a patent license is no longer based on strict exclusivity to "make, use and sell" a product covered by the patent, but rather on a newly-defined concept of the transfer of "all commercially significant rights". A licensor will be deemed to have transferred "all commercially significant rights" to a licensee in the pharmaceutical industry even where

the patent holder retains "limited manufacturing rights" – that is, the right to manufacture the product for the licensee – provided that the other exclusive rights to the patent within a specific therapeutic area (which covers the intended use for a part of the patent, such as for cardiovascular use or neurological use) or indication (which encompasses a narrower segment of a therapeutic area, such as Alzheimer's disease within the neurological therapeutic area) have been transferred. Previously, the license was not deemed to be exclusive if the licensor retained any rights to manufacture the product and thus no potentially reportable asset acquisition occurred for the purposes of the HSR Act.

The amended Rules make clear that "all commercially significant rights" will be deemed transferred where the licensor retains "co-rights", a term which refers to shared rights whereby the licensor will assist the licensee in developing and commercializing the patented product and includes rights to co-develop, co-promote, co-market, and co-commercialize. "Co-rights" is not extended to the right of the licensor to commercially use the patent or part of the patent, a commercially important exception to the expanded reporting obligation under the Rules. A transfer of "all commercially significant rights" is thus deemed to have occurred even when the licensor retains certain co-rights. The FTC has stated that the retention of "co-rights" by the licensor does not serve to make a license non-exclusive.

In response to criticism that the amended Rules unfairly target the pharmaceutical industry and increase the burdens under the HSR Act and Rules, the FTC noted that exclusive patent license agreements, which involve the transfer of "all commercially significant rights", frequently occur in the pharmaceutical industry. According to the FTC, the Agency often comes across the situation where an innovator discovers and patents a pharmaceutical or biomedical compound, but that innovator does not have the financial resources to seek FDA approval or to market or promote the drug after FDA approval, prompting the innovator to enter into an exclusive licensing agreement (rather than a patent sale) transferring all the rights to the patent or part of the patent to a large pharmaceutical company. The FTC further noted that exclusive patent license agreements are increasingly common, and that the new test of "all commercially significant rights" more accurately determines whether the license has transferred the exclusive right to commercially use a patent.

Implications

The amendments to the Rules apply to the transfer of patent rights in the pharmaceutical and medicine manufacturing industry, including biologics. However, the FTC cautioned that while the amended Rules apply solely to the pharmaceutical industry, other industries that engage in similar exclusive patent right transfers should consult with the FTC to determine whether notification under the HSR Act and Rules is required. Further, the FTC stated that it will "continue to assess the appropriateness of a rule for other industries".

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Germany: Düsseldorf District Court specifies examination duties of parallel importers

The Düsseldorf District Court has further specified the duties of parallel importers to examine the composition of parallel imported goods for potential patent infringement. In the future, parallel importers may face an increased likelihood of liability if product deviations indicate that the imported good does not originate from the patent holder, provided a suitable analysis method is available.

Introduction

The establishment of the European Single Market ("**ESM**") led to an increase in parallel import activities. As a general rule, parallel imports are permitted, even if related intellectual property rights exist in the relevant country of importation, if the respective product has been placed on the market in any other ESM country by or with the authorization of the patent holder. Although parallel imports are permitted, infringing goods may not be parallel traded.

On 24 October 2013, the Düsseldorf District Court delivered a ruling in a case where the defendant, a parallel importer, allegedly imported original products which did not originate from the original manufacturer. The defendant argued that it was not aware that the products were

counterfeited and, moreover, that he was not able to undertake a chemical analysis of the products that would have disclosed their origin. The Düsseldorf District Court dismissed the defendants' arguments, concluding that a parallel importer is responsible if there is any possibility that the parallel importer can identify the counterfeit character of the imported product. If affirmed on appeal, the Düsseldorf District Court's decision will lead to an increased likelihood of liability for parallel importers.

Facts of the case

The plaintiff is the holder of a German patent concerning the use of alkyl carboxylic acid dimethyl amides for inhibiting crystallisation, on the basis of which the plaintiff produces a pesticide.

The defendant, a parallel importer, distributed products in Germany which were allegedly offered to him in Ireland and Belgium as original products. An analysis carried out in the plaintiff's research laboratory revealed that none of the products were originally manufactured by the plaintiff.

After the plaintiff informed the defendant of its analysis, the defendant argued that (i) the deviations between the parallel imported goods and the original products resulted from production variances inherent in the plaintiff's production process, and (ii) he would not have been able to detect these deviations from the original products, as he was not aware of their underlying chemical composition and was therefore unable to analyse the products.

Furthermore, the defendant claimed that the plaintiff's rights in the imported products had already been exhausted when the products were imported and distributed. Even if the products are not original products the defendant argued that he was not liable because he did not know of any chemical deviations. Furthermore, and most importantly, the defendant invoked the German Federal Supreme Court's *Delan* decision ([*Bundesgerichtshof*], "**BGH**"; Case No. I ZR 117/10) and argued that he was not able to carry out random checks of the products and, therefore, was unable to analyse the products and detect any deviation from the original products. Lastly, the defendant refused to disclose the details of its business relationship with its business partners in Ireland and Belgium (which could have proven the origin of the parallel imported goods), claiming that those details were business secrets that could not be laid out in a public proceeding.

The Düsseldorf District Court's ruling

The District Court ruled in favour of the plaintiff and ordered the defendant to disclose the amount, origin, and profits generated from the respective deliveries of the parallel imported goods during the period under examination.

Firstly, the District Court relied on the BGH's *Converse I* decision (Case No. I ZR 52/10) holding that the party invoking exhaustion is obliged to present any circumstances which serve as a basis for exhaustion. According to the District Court, the party invoking exhaustion may not withhold information supporting its claim of exhaustion by arguing that such information represents a business secret. Rather, under certain conditions, those alleged business secrets may be presented to a person appointed by the court – and not in open court – which would prevent the opposing party from learning sensitive information.

Key Issues

- The party invoking the principle of exhaustion is obliged to present any circumstances that support exhaustion
- The party invoking exhaustion may not withhold information supporting its claim for exhaustion by arguing that such information represents a business secret
- The German Federal Supreme Court's *Delan* ruling is not applicable to patent law cases, in particular where the parallel importer has any opportunity to identify the counterfeit character of the imported product
- Parallel importers will face further difficulties preventing liability if chemical product deviations have been identified, provided a suitable analysis method is available

Secondly, the District Court held that the BGH's *Delan* ruling (Case No. I ZR 117/10) was not applicable in this case. In *Delan*, an unfair competition case, the German Federal Supreme Court held that a parallel importer shall not be held liable for any loss caused by the distribution of a parallel imported counterfeit product if the parallel importer was not able to conduct an analysis of the product and, consequently, was not aware of deviations from the original product.

In this case, the District Court held that a parallel importer – although not aware of the details of the original product's composition – shall be responsible if there is **any** possibility that the parallel importer can identify the counterfeit character of the imported product. The District Court explicitly stated that actual knowledge of the original product's composition is not relevant in this regard. In fact, there are several chemical analysis methods (*e.g.*, chromatography techniques) which allow a full assessment of the chemical composition of a product without knowing the details of the product's manufacturing process. A review of the products may not be necessary, however, if there is no method available which allows a comparison of the imported product and the original product.

The District Court further clarified that the *Delan* ruling may not be interpreted in such a way that random checks of the imported products are not necessary in general. To the contrary, a parallel importer is obliged to carry out random product checks which allow verification of the chemical composition of the product.

Impact of the decision

The Düsseldorf District Court's current ruling further strengthens the position of producers of original goods and holders of the respective patent rights. The District Court's decision is generally in line with the German Federal Supreme Court's previous decisions; however, the Düsseldorf judges have emphasised that the German Federal Supreme Court's *Delan* ruling is not applicable in a patent law case.

For future cases parallel importers will need to be prepared to demonstrate that a suitable analysis method allowing a thorough examination of the parallel imported good was not available. Otherwise, a court will proceed from the assumption that the parallel importer knew about and is liable for any chemical deviations. The Düsseldorf District Court's decision is not yet legally binding and may be subject to appeal proceedings before the Higher District Court Düsseldorf.

(LG Düsseldorf of 24 October 2013, Case No. 4c O 3/13)

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China: PRC Supreme People's Court – increasing success in IPR-related litigation in Chinese courts: the *BMW* and *Ashland* cases

The Supreme People's Court ("SPC") of the People's Republic of China ("PRC" or "mainland China") announced eight "representative" IP cases on 22 October 2013 that, in its opinion, reflect worthy IP practices. Among them is "BMW", a case in which a subsequent amendment of the PRC Trademark Law ("Trademark Law") was applied to increase damages for wilful trademark infringement, and "Ashland", in which the Court introduced a more helpful approach for patent holders, by permitting a lowering, or even reversal, of the "burden of proof" required to prove patent infringement.

Introduction

The SPC has long held a tradition of publishing cases each year that it regards as exemplary. The SPC recently published eight IP litigation cases that reflect its determination to enhance the protection of IP rights ("**IPR**") in mainland China. Of particular interest are the *BMW* and *Ashland* cases, both of which demonstrate a more forward-thinking direction for IP enforcement in mainland China.

The *BMW* case

Brief facts

BMW AG (Germany) ("**BMW**" or "**Baoma**" in Chinese) filed a bad faith trademark dispute against Guangzhou Century Baochi Clothing Ltd. ("**Century Baochi**"), a Chinese clothing company. Century Baochi had registered the trademarks "Feng**baoma**feng", " 丰 **宝 马** 丰 (Chinese characters of "Feng**baoma**feng") and "Feng**baoma**feng and Device", a blue and white design similar to BMW's characteristic logo. BMW claimed that the use of "Baoma" in "Feng**baoma**feng", " 宝 马 (Chinese characters of "Baoma")" in "丰宝马丰", in combination with the blue and white design, intentionally caused market/consumer confusion with BMW's trademarks. BMW claimed infringement of BMW's trademarks for "Baoma", " 宝 马 " and "BMW and

Device" and requested compensation of 2,000,000 RMB.

The Beijing Second Intermediate People's Court considered the case in 2011 and ruled in BMW's favour. Century Baochi was ordered to cease infringement of BMW's trademarks. However, BMW was only awarded 500,000 RMB compensation because, allegedly, BMW produced insufficient evidence to show that it was entitled to a greater amount.

Both parties appealed to the Beijing High People's Court in 2012. BMW contended that it was entitled to 2,000,000 RMB as compensation in light of Century Baochi's extensive and flagrant use of BMW's infringing trademarks and the resulting enormous profits generated to Century Baochi. BMW submitted additional evidence including records of infringed products worth over 30,000,000 RMB which had been seized by the Shanxi Industry and Commerce Bureau. Century Baochi countered that there was a lack of evidence showing it had infringed BMW's trademarks and requested dismissal of BMW's claim.

On appeal, the Beijing High People's Court increased the compensation awarded to BMW to 2,000,000 RMB and upheld the rest of the Beijing Second Intermediate People's Court's decision. The Court also imposed a civil sanction on Century Baochi of 100,000 RMB and recommended that the State Administration for Industry and Commerce open a nation-wide investigation into Century Baochi's infringement. The appellate decision in *BMW* is a good example of the increasing attention paid by the courts of mainland China to the protection of IP rights.

Analysis

The *BMW* case was decided before the amendment of PRC's Trademark Law 2001. According to Article 56 of the Trademark Law 2001, 500,000 RMB is the maximum compensation that may be awarded to a trademark owner if the amount of illegitimate profits derived from the infringement and the damage to the IPR holders cannot be clearly determined.

Key issues

- The statutory maximum of monetary damages awarded in trademark infringement cases may be increased where there is clear and sufficient evidence of malicious infringement by the infringer
- The statutory maximum of monetary damages awarded in trademark infringement cases was amended from 500,000 RMB to 3,000,000 RMB, shortly after the BMW appeal was decided
- A lower burden of proof or even a reversal of the burden of proof may be permitted by the courts in cases where the patent holder has exhausted available methods for collecting evidence to show infringement and where there is a high likelihood of infringement based on known case details and common knowledge in the industry
- The two cases discussed here show that mainland Chinese courts seem to be moving towards a more proactive approach in enforcing IP rights

The Beijing High People's Court chose to depart from the statutory compensation limit of 500,000 RMB by granting 2,000,000 RMB to BMW. The court explained the significant penal increase due to the infringer's malicious infringement, the length of time during which the infringement had persisted and the substantial profits generated to Century Baochi. The BMW case also indicates that there is the potential for plaintiffs to request that civil sanctions be imposed by a court on infringers when serious infringement occurs.

After the *BMW* appeal, PRC amended its Trademark Law 2001 on 30 August 2013. One of the main changes in the new Trademark Law is the significant increase in the maximum statutory compensation available in respect of trademark infringement, now raised six-fold from 500,000 RMB to 3,000,000 RMB. An award of punitive damages of up to three times the actual loss of profits suffered by a trademark holder in respect of any malicious infringement is also planned.

The *Ashland case*

Brief facts

Ashland Licensing and Intellectual Property LLC ("**Ashland**") raised a patent infringement case against Beijing Ruishibang Fine Chemistry Technology Co. Ltd. ("**Ruishibang**") and Wei Xingguang ("**Wei**"). Ashland claimed Ruishibang and Wei were working together to use Ashland's patented process for manufacturing polymer dispersion ("**dispersion**"). Wei was the former director of Ashland China before joining Ruishibang as a shareholder and director. Ashland claimed that Ruishibang was producing and selling the same dispersion product made from its "water-in-water method for

making polymer dispersion" as that made by Ashland. Ashland claimed patent infringement by Ruishibang with Wei's assistance.

Ashland tried various methods to collect evidence on the Ruishibang production process, including a "request for evidence preservation" by the court. However, none of its collection strategies provided Ashland with sufficient access to Ruishibang's complete manufacturing process, which was necessary for Ashland to prove infringement of its dispersion product.

Ultimately, the Suzhou Intermediate People's Court decided to shift the burden of proof from Ashland to Ruishibang to require proof from Ruishibang that its production of dispersion did not infringe the Ashland patent. Ruishihbang was unable to provide such evidence. Accordingly, 15,000,000 RMB was awarded as compensation to Ashland and an additional 7,000,000 RMB in respect of Ruishibang and Wei's infringement of Ashland's commercial secret.

Analysis

According to Article 61 of the PRC Patent Law, the "burden of proof" for patent infringement can only be reversed when the disputed product is a "new product". The SPC, however, issued a judicial opinion in 2011 that stressed the reversal of the "burden of proof" should also be expanded to "*non*-new products". In the 2011 opinion, the SPC set out circumstances by which the court may consider reversing the burden of proof from the patent holder to the infringer. If the patent holder, after reasonable diligence in gathering evidence, cannot prove that the infringer has used the patented process, but from the known facts and practical experience there is a substantial likelihood that the product is produced by the patented process, the burden of proof can be shifted to the infringer. Because the Ashland products were industrial chemicals for a specific target customer group, it was impossible for Ashland to obtain infringing product samples from the open market. It was also impossible for Ashland to access Ruishibang's premises to obtain evidence of its manufacturing process and methods. However, given that Wei, as well as other key technical personnel, were Ashland former employees who had had access to Ashland's patented manufacturing process, the Suzhou Intermediate People's Court found it was more than likely that the Ashland's manufacturing process was being used by Ruishibang. Given that Ashland had exhausted all available means to collect evidence, the Suzhou Intermediate People's Court decided to reverse the burden of proof and found that Ruishibang was unable to prove *non*-infringement of the patented process.

Impact

As the Chinese legal system does not have binding precedent, it is unclear whether these representative cases will be followed by other mainland Chinese courts in the future.

However, both cases illustrate that courts in mainland China appear willing to take a more proactive role in improving the protection of legitimate rights and interests of IPR holders. In the two cases mentioned, the courts exercised their inherent discretion resulting in more favourable outcomes than would otherwise have been the case for the IPR holders. By using means such as increased compensation awards and reversal of the burden of proof for the IP claimant, the courts are demonstrating that they are approaching difficult IP cases with creativity and resolve.

Going forward, the hope is that the mainland Chinese courts will play an increasingly active role in addressing IP infringement in mainland China.

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France: "BUD", an appellation of origin? Outlook on recent decisions

For over a century, the struggle for exclusive use of the names "Budweiser" and "Bud" has generated serious conflicts between the Czech-based Budejovický Budvar (Budweiser Budvar, hereinafter "Budvar") and the US-based Anheuser-Busch (now the Belgium AB InBev).

Could the latest decisions rendered by EU courts and its Member States' courts mean the end of a never-ending dispute?

Introduction

Increased trade on both sides of the Atlantic gave birth to a conflict over the use of the names "Budweiser" and "Bud" that dates back to 1880. Since that time, legal proceedings relating to the use of the names "Budweiser" and "Bud" have been brought in many countries, with widely differing outcomes. The courts of the European Union and its Member States, in particular, have rendered

many decisions related to the conflict addressing the issue of which entity should own the rights to the "Budweiser" and "Bud" names specifically and the legal dichotomy of appellation of origins versus trademarks generally.

European Union court decisions

In the late 1990s, Anheuser-Busch, Inc. filed four applications for registration of a Community trademark at the Office of Harmonization for the Internal Market ("**OHIM**". Each trademark included the verbal sign BUD. Budvar notably opposed the applications, relying on (1) its international appellation of origin BUD relating to beer in France, Italy and Portugal, which Budvar registered with the World Intellectual Property Organization on 10 March 1975, and (2) its national appellation of origin BUD relating to beer in Austria under the bilateral convention signed on 11 June 1976 between Austria and the Czechoslovak Socialist Republic.

OHIM agreed with Budvar, concluding that there was a risk of confusion in Austria and France over Budvar's trademarks and the Community trademark applied for by Anheuser-Busch relating to beer, but denied Budvar's opposition with respect to other goods. Both parties appealed the decision to OHIM's Board of Appeal. The Board of Appeal dismissed all of Budvar's grounds for appeal. In ruling in Anheuser-Busch's favor, the Board of Appeal held in several decisions as follows:

- It was difficult to see how the sign BUD could be considered an appellation (or designation) of origin, or even an indirect indication of geographical origin.
- The evidence provided by Budvar to show use of the appellation of origin BUD in Austria, France, Italy and Portugal was insufficient.
- Budvar had not demonstrated that the appellation of origin in question gave it the right to prohibit use of the word BUD as a trademark in Austria or France.

Budvar appealed to the General Court (then the Court of First Instance of the European Union), which allowed the appeal. On 16 December 2008, the General Court overturned the Board of Appeals' decisions. The General Court ruled that OHIM's restriction of the factual basis of its examination did not preclude it from considering both the facts expressly put forward by the parties and facts which are well known, *i.e.*, facts which are likely to be known by anyone or which may be learnt from generally accessible sources. The fact that the registration and listing continues to exist at the time of the opposition is sufficient to establish the validity of those earlier rights for the purposes of proceedings before OHIM's Board of Appeal. According to the General Court, a court can only consider judicial decisions that are final and no longer subject to appeal.

Anheuser-Busch appealed the General Court's decision to the Court of Justice of the European Union ("**CJEU**"), which allowed the appeal. The CJEU held that the General Court made a number of significant mistakes in its ruling and returned the case to the General Court to apply guidance from the CJEU's ruling. Three lessons can be taken from the CJEU's ruling:

- The significance of the sign concerned cannot be evaluated exclusively by referring to the territory in which the sign is protected, without taking account of its use in that territory.
- The relevant territory for the purpose of evaluating the use of that sign is necessarily the territory in which the sign is protected.
- The use of the sign has necessarily to occur before the date of the application for registration of the Community trademark.

Key issues

- In order to evaluate the significance of a sign, one has to take in account its use in the territory in which the sign is protected
- Use of a sign has to occur before the date of the application for registration of the Community trade mark
- A sign relied on in the course of trade means that use needs to take place in the context of a commercial activity with a view to economic advantage
- Regulation 510/2006 precludes protection under national law or a bilateral agreement for designations, such as the designation of origin BUD, where registration has not been sought in accordance with that Regulation

On 22 January 2013, the General Court examined the factual elements of the case in the light of the CJEU's ruling and rejected Budvar's oppositions. In its decision, the General Court reaffirmed the

definition of a sign relied on in the course of trade, which means that use needs to take place in the context of a commercial activity with a view to economic advantage and not as a private matter.

Recent national court decisions

On 9 August 2011, the Supreme Court of Austria decided, referring to a preliminary ruling of the CJEU, that a designation protected in the Czech Republic as an appellation of origin cannot be protected at the same time as a simple and indirect indication of geographical provenance. Hence, no protection of the designation "BUD" as a simple and indirect indication of geographical provenance in the Czech Republic could exist and thus Austria is not entitled to such protection by way of a bilateral treaty.

On 13 September 2013, the Italian Supreme Court reversed the previous judgment of the Court of Appeal of Rome. It laid down the legal rule following which it is sufficient for the public to know about a geographical name, to consider a subsequent trademark designating this geographical original, deceptive, regardless of the fact is no longer officially in use. As such, it ruled that Anheuser-Busch's trademark "Budweiser" could deceive the public as to the geographical origin of the beer.

On 6 November 2013, the Colmar Court of Appeal invalidated the effects of the international appellation of origin BUD in France, confirming the judgment of the Strasbourg Tribunal de Grande Instance. It grounded its decision on Regulation 510/2006. The Colmar Court concluded that the word BUD is a simple and indirect indication of the geographical origin of the product, in other words a name with which there is associated no particular quality, reputation or characteristic attributable to geographical origin.

Conclusion

Though the issue of whether or not the BUD appellation of origin could be recognized as a pre-existing right enabling a subsequent trademark BUD to be registered is a factual one, all the decisions rendered on this issue lay important legal principles which, no doubt, have created a precedent.

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Germany: Federal Supreme Court lowers standard for copyrightability of industrial designs

The German Federal Supreme Court issued a recent decision lowering the standard for copyrightability of industrial designs. While the decision may result in harmonisation with the copyright laws of other European countries, such as France and Belgium, it will likely result in significant litigation over both copyright infringement and additional consideration to be paid to designers of successful industrial designs for sales made after 1 June 2004. In general, the transaction costs for designers and exploiters dealing with works of applied art are expected to increase.

On 13 November 2013, in *Birthday Train*, the German Federal Supreme Court ([*Bundesgerichtshof*]; "**BGH**") overruled its long-standing test for copyrightability of works of applied art under the German Copyright Act ("**Copyright Act**"). Works of applied art no longer require an enhanced level of originality to enjoy protection under the Copyright Act. The change results from revisions to the German Act on Registered Designs, effective 1 June 2004, in the context of the transposition of European Directive 98/71 EC on the legal protection of designs into German law ("**New Design Act**").

Facts of the case

Birthday Train centred on a wooden toy train on which candles and letters could be mounted to celebrate a birthday. The train was designed by a German freelance toy designer in 1998. Under the agreement with the manufacturer, the designer was paid EUR 400 for the design. Over the years, the toy train enjoyed tremendous commercial success and generated substantial revenues for the manufacturer.

In 2009, the designer sued the manufacturer under section 32a of the Copyright Act for additional consideration reflecting the actual market success of the toy train. Section 32a of the Copyright Act provides that if the agreed consideration is grossly disproportionate to the income from the use of the work of authorship, the other party is required to agree to a change in the agreement to secure for

the author an equitable share of the income (the so-called "bestseller provision").

The lower courts' decisions

The lower courts dismissed the designer's complaint by applying the test previously established in the BGH's *Silberdistel* decision (Case No. I ZR 119/93) in 1995. In *Silberdistel*, the BGH held that works of applied art, typically industrial designs, must meet a higher standard of originality [*Gestaltungshöhe*] than regular works of art. While only a modicum of creativity [*kleine Münze*] is required for the protection of regular works of art like writings, painting or sculptures, articles that are commercially useful were required to have "extraordinary design features that go well beyond the skills of regular craftsmanship" [*deutliches Überragen der Durchschnittsgestaltung*]. In essence, the rationale behind this strict test was that the German Act on Registered Designs that was in force until 31 May 2004 ("**Old Design Act**") which required a design to bear a certain degree of originality [*Eigentümlichkeit und Gestaltungshöhe*] – among other things – to be registerable. The presence of the originality requirement in both the Old Design Act and the Copyright Act led the BGH in *Silberdistel* to the conclusion that additional protection under the Copyright Act is only justified if the level of originality significantly exceeds the level of originality required under the Old Design Act.

The lower courts concluded that the toy train could not be considered a work of authorship within the meaning of the Copyright Act, a prerequisite for awarding additional consideration pursuant to section 32a of the Copyright Act, because it did not have any extraordinary design features. Since the toy train was designed in 1998, long before the enactment of the New Design Act, the lower courts declined to look into whether the New Design Act requires a revision of the *Silberdistel* test.

The BGH's ruling

In *Birthday Train*, the BGH overruled *Silberdistel*, holding that the same test applies to works of applied art as for any other work of authorship. The BGH concluded that the German parliament had replaced the originality requirement with the requirement of "individual character" when it enacted the New Design Act. For a design to bear individual character it must be distinctive from the previously know forms and shapes; originality in the strict sense is no longer required. Hence, the BGH reasoned, a hierarchical distinction between the laws on registered designs and copyright law, which was the logical foundation of the higher standard under *Silberdistel*, can no longer be justified. In fact, copyright protection and design protection might well coexist, provided that the requirements under the relevant statutes are met.

The BGH stressed, however, that the Copyright Act confers protection only to the aesthetic features of an item which are not functionally-driven. Moreover, items bearing only a modicum of creativity may enjoy only a very limited scope of protection.

Lastly, the BGH held that the new test applies to all works of applied art regardless of whether they were created before or after 1 June 2004. The legal consequences provided by the Copyright Act (*e.g.*, claims for additional consideration under section 32a of the Copyright Act or claims for damages) only apply, however, to infringing acts committed after 1 June 2004.

The case was sent back to the lower courts to determine whether the toy train at issue bears at least a modicum of creativity, and, if so, to determine the appropriate amount of additional consideration owed to the designer, if any.

Key issues

- Works of applied art, similar to any other work of authorship, enjoy protection under the Copyright Act if they bear a modicum of creativity and the relevant aesthetical features are not determined by function
- The time of creation of a work of applied art is irrelevant, but only acts of exploitation committed after 1 June 2004 can be subject to a copyright claim
- Industrial designers may be required to put more effort into clearing the copyright situation to avoid infringement suits after launch of a product
- Exploiters of industrial designs may face claims for additional consideration for successful designs, making more complex agreements with designers necessary to secure exploiters' interests and balance all risks

The impact of the decision

The decision is expected to have significant repercussions. Previously, it was fairly safe to assume that

intellectual property-related issues with respect to industrial designs were comprehensively governed in the Design Act. Now, *Birthday Train* has created a high level of uncertainty for both designers and exploiters, ultimately resulting in higher transaction costs for both sides when commercialising industrial designs.

On the one hand, while the rights of the individual designers are clearly strengthened, designers may at the same time be exposed to a higher risk of infringing third-party copyrights, unless comprehensive searches have been conducted prior to market launch.

Exploiters, on the other hand, apart from potentially being subject to a wave of claims for additional consideration by external designers – just as in *Birthday Train* – are now well-advised to carefully calculate their external designer's remuneration and to spend more time drafting comprehensive agreements to secure all exploitation rights and properly allocate the risks associated with potential copyright infringement.

The new test harmonises to a certain extent German copyright law with, for instance, the practice in France and the Benelux, where a uniform standard of originality applies across different types of works. The experience in these jurisdictions will help German practitioners to quickly adapt and provide suitable solutions.

(BGH of 13 November 2013; Case No. I ZR 143/12)

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