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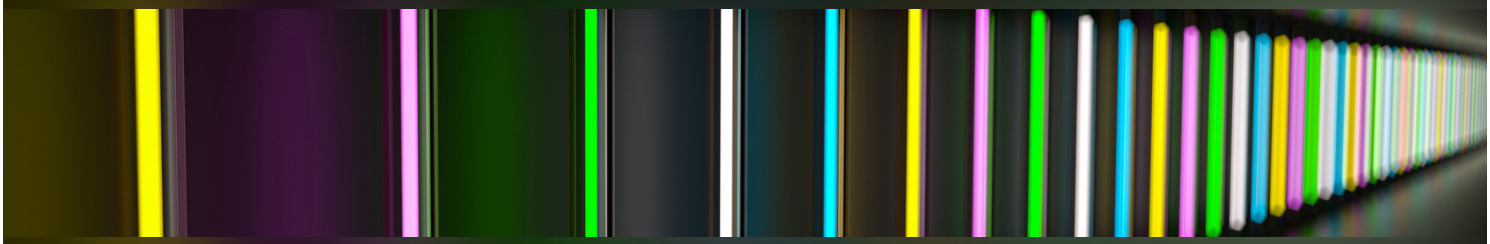
26TH EDITION



GLOBAL INTELLECTUAL PROPERTY NEWSLETTER

IP TOPICS FROM AROUND THE GLOBE

ISSUE 06/20

26TH EDITION

Introduction

Welcome to the 26th edition of the Clifford Chance Global IP Newsletter that hopefully finds all of our readers well and in good health in these odd times.

In terms of content, this edition clearly reflects how enormously the Corona crisis has impacted our everyday and business lives within the past months. Therefore, you will find several articles from different jurisdictions covering legal issues evoked by this unprecedented crisis.

Our **London** team gives you an **overview of measures recently implemented by courts and Intellectual Property Offices around the world** in response to COVID 19.

Then, our **Paris** team also adopts a comparative approach and provides you with an overview on the topic of **compulsory licensing** in France and many other countries around the globe. The **balance between private and public health interests** underlying the aforementioned compulsory licensing regimes is then discussed in detail by our **German** team.

Italy has been greatly affected by the crisis which also triggered demands for **"virus free" certificates** for Italian food products. Our Italian colleagues discuss why such demands are unlawful.

Our **Italian** team also discusses the conflict between the **contributions Big Data can make to collective safety** on the one hand and the guarantee of data protection safeguards on the other hand, whereas our **German** team takes the increased use of 3D printers to manufacture medical equipment as an occasion to shed some light on the **IP implications that come with 3D printing**.

However, some important recent legal developments in the world of IP are wholly unrelated to the Corona crisis. For example, the **efforts of establishing a Unified Patent Court** have suffered a major setback resulting from a decision by the German Federal Constitutional Court, which is discussed by our German team.

Furthermore, the CJEU recently handed down a **judgment on SPC for medicinal products in the Royalty Pharma case** that is discussed by our Spanish colleagues. Our Spanish colleagues also have a look at the **amendment of the Spanish Copyright Act**, which entered into force on 2 March 2020. Further, in Italy, the Italian Supreme Court has clarified how to assess **equitable remuneration of an employee inventor**.

Returning to the issue of data, our Italian colleagues discuss **digital heritage** in light of its legal framework.

Last but not least, our German team takes China into focus, and sets out the relevant legal obstacles to the **exploitation of German IP rights in the aftermath of an M&A transaction**.

We hope you enjoy this edition of our Newsletter, and look forward to receiving your feedback.

Take Care!

Your Global CC IP Team

CONTENTS

LONDON

Vanessa Marsland / Uche Eseonu

MEASURES IMPLEMENTED BY INTELLECTUAL PROPERTY OFFICES AND COURTS AROUND THE WORLD IN RESPONSE TO THE COVID-19 PANDEMIC

As the COVID-19 pandemic continues, Intellectual Property Offices and courts around the world have implemented various measures to accommodate for inevitable disruptions caused by the outbreak. The pandemic is a rapidly changing situation, and this update will be subject to change as further announcements are made. We will update the online version on the *Talking Tech website* on a rolling basis.[1]

The Benelux Union – Benelux Office for Intellectual Property (BOIP)

On 20 March 2020, BOIP announced that from 16 March 2020 until a date where the BOIP determine that staff can work reasonably again ("BAU date"), BOIP will not withdraw any requests or procedures because a deadline has not been met. At present, the BAU date is set for 25 May 2020. This also applies to opposition proceedings. An additional period of one month will be given for all requests and procedures for which current deadlines have expired between 16 March 2020 and the BAU date, or for which deadlines are less than one month on BAU date. This month will be counted from the BAU date. As a result, the register may not reflect the accurate status of certain trademarks during this period. BOIP will not be able to communicate a new time limit for all individual requests and proceedings during this time.

BOIP have confirmed that the announcement does not apply to actions at the Benelux Court of Justice, including the deadlines for appeal against decisions from the BOIP. Further, priority deadlines do not fall under this extension at present.

Courts:

Belgium

All proceedings are suspended until further notice apart from summary and urgent proceedings. All physical hearings are adjourned, and all deadlines have been extended until further notice. New proceedings cannot be initiated until further notice.

The Netherlands:

All Courts in The Netherlands were closed between 17 March to 6 April 2020. Physical hearings resumed on a limited scale from 11 May onwards. However, as far as possible, court cases will continue to be handled by telephone, with a video link or dealt with in writing. The court buildings have extended their opening hours to reduce excessive visitor numbers at peak times.

Vanessa Marsland
IP Stars: Trade mark star 2020
IP Stars: Copyright star 2020
IP Stars: Transactions star 2020

Stephen Reese
IP Stars: Patent star 2020
IP Stars: Transactions star 2020

Key issues

- Intellectual Property Offices around the world have taken various steps to mitigate the impact of the ongoing pandemic.
- In the midst of interruptions, delays and uncertainty around changing lockdown measures, one factor has remained the same: the pressing need for users to have the ability to protect their intellectual property rights.
- Some courts have taken steps to handle urgent or essential court hearings through telephone calls or video conferencing platforms.
- Many Intellectual Property Offices are using their respective online systems to process filings and user documents.
- Despite the fact that many Offices have granted automatic extensions of deadlines, many of those offering such extensions have encouraged users to meet their original deadlines where possible to avoid a surge of filings once the Offices reopen.

1 See https://talkingtech.cliffordchance.com/en/ip/other/measures-implemented-by-intellectual-property-offices-around-the.html. The version printed in this edition of the Global IP Newsletter covers updates until 20 May 2020.

Luxembourg

All physical hearings are adjourned until further notice. All deadlines and litigation proceedings are suspended until further notice.

Canada – the Canadian Intellectual Property Office (CIPO)

The Canadian Intellectual Property Office (CIPO) has further extended patent, trademark and industrial design deadlines that are fixed under relevant legislation. All time limits due to end between 16 March 2020 and 29 May 2020 have been extended until 1 June 2020.

The CIPO may decide to extend deadlines further, depending on how circumstances surrounding the COVID-19 pandemic evolve. The CIPO remains open and in operation at this time, and all online solutions remain available. However, clients should expect delays with respect to some services.

Canadian Courts:

Many courts in Canada are offering a reduced service. Filing deadlines have been extended or suspended in certain provinces.

The Federal Court has extended its period of suspension to 29 May 2020, and will not hold hearings until 29 June 2020 at the earliest. Apart from "urgent or exceptional" matters, or case management hearings, all hearings that were previously scheduled to take place between 16 May 2020 and 28 June 2020 are adjourned. All General Sittings in this period are cancelled. This includes hearings that were scheduled to proceed by way of a telephone conference (unless specific agreements have been made with the court).

The Federal Court of Appeal has also extended its period of suspension to 29 May 2020. To determine which cases should progress, the Court is continually reviewing its list of pending cases on the basis of nature and complexity of the case, the extent to which the record is or can be made electronic, and the ongoing resource challenges facing the Registry. The cases that are chosen to progress are being conducted by teleconference or video conference.

China – China National Intellectual Property Administration (CNIPA)

The CNIPA was closed from 24 January until 2 February 2020 and reopened on 3 February. Deadlines falling during the closure were automatically extended to 3 February.

An application can be made to extend certain IP deadlines where ability to comply is affected by a COVID-19 related "obstacle". For example, applications for trade mark renewal can be extended to two months from the date of the elimination of the obstacle. Recognised obstacles include hospitalization, quarantine and periods when work has been suspended in a certain geographical area. The relevant provisions can be found in the CNIPA Notice on the Effect of the Epidemic on Deadlines Relating to Patents, Trademarks and Integrated Circuit Layout Designs (No. 350) and associated official guidance.

Chinese Courts:
At present, court filings in China are done by post or online, and hearings are being conducted by video-link. All hearings before the Beijing Intellectual Property Court have been adjourned. In situations where the parties disagree with the method of online hearing or there are technical obstacles, hearings will not be conducted online and the hearing will be rescheduled.

Europe – European Patent Office (EPO)
In view of the disruptions to public life caused by the COVID-19 outbreak, the EPO announced that deadlines falling after 15 March 2020 would be extended to 2 June 2020, pursuant to Rule 134 of the European Patent Convention.

Since 1 April, oral proceedings in examination are being held by videoconference.

Oral hearings in opposition proceedings were initially postponed until 30 April, and this has now been extended to 2 June unless it has already been confirmed that they will be held by video conference, or the hearing is converted into an oral hearing by video conference with the consent of the applicant.

On 15 May it was announced that the Boards of Appeal will resume the holding of oral hearings, to a limited extent, at their premises in Haar from Monday 18 May. Parties will be asked to confirm they expect to be able to attend in person and do not expect to be affected by travel restrictions. Parties and their representatives must each complete a screening questionnaire. Any person answering in the affirmative will not be allowed to attend. The competent board will then decide if the procedure can be held without that person or should be postponed.

Oral proceedings can also be held by videoconference with the consent of the parties.

Measures have been put in place to allow limited public attendance at both in person proceedings and videoconferences.

European Union – the European Union Intellectual Property Office (EUIPO)
A decision made by the EUIPO on 29 April 2020 further extended until 18 May 2020 all time limits expiring between 1 May 2020 and 17 May 2020 inclusive, to further support and assist users during the COVID-19 pandemic.

The extension covered all procedural deadlines, irrespective of whether they have been set by the Office, or are stipulated directly in the Regulations. The effect of the extension was automatic.

European Union Courts:
No specific guidance has been issued to date. The European Court of Justice has postponed a number of cases and continue to prioritise urgent proceedings. Deadlines for lodging appeals are unaffected, but others have extended by one month. Hearings listed for dates in April were postponed.

France – French Patent and Trademark Office (INPI)

On 26 March 2020, an Order was published outlining the rules around extension of missed deadlines as a result of the current health emergency. The Order covers deadlines falling between the dates of 12 March 2020 to 24 June 2020 (the "Covered Period"). Most of the deadlines established by the French Intellectual Property Code (including formality, opposition proceedings, and payment required for the acquisition or maintenance of a right) will be postponed. The postponement will not apply to deadlines resulting from international agreements or European tests, such as the priority deadlines for an international extension.

Non-completion of certain proceedings can produce legal effects such as sanction, prescription or forfeiture of a right. As a result of the first Order of 26 March 2020, when such proceedings cannot be completed before 24 June 2020, they can be completed at the latest within two months following the Covered Period. The Order also provides for suspension of deadlines under which an administrative decision may be taken on the basis of the administration's silence. All deadlines falling in the Covered Period are postponed either to 24 July 2020 (if the original deadline was one month), or to 24 August 2020 (if the original deadline was two months or more). Deadlines that expired before 12 March 2020, or that will expire after the end of the Covered Period are unaffected.

French Courts:

Apart from "essential litigation" matters, all hearings that were scheduled to take place since 16 March 2020 have been postponed.

On 27 April 2020, an Order was published outlining that French courts' decisions will be issued without postponement according to a procedure without trial hearings in the following cases:

- cases on the merits for which written proceedings have been closed and the planned hearings have been cancelled between 16 March and 10 May 2020, and pleas of inadmissibility for which a hearing has been scheduled in the same period; and
- cases on the merits for which written proceedings have been closed and a hearing has been scheduled between 11 May and 24 June 2020, and pleas of inadmissibility for which a hearing has been scheduled in the same period.

The 3rd chamber of the Paris First Level Court, which specialises in intellectual property, resumed operations on 11 May 2020. The priorities of the chamber are to (i) hand down judgments that have been pending during confinement and (ii) to reschedule procedural hearings that were due to be held from 17 March 2020 and have been postponed due the pandemic. Pre-hearing status conferences will use electronic communications only, until at least mid-June.

The Paris Court of Appeal have announced that all cases scheduled between 16 March 2020 and 24 May 2020 will be decided without hearings for oral arguments. Where there are cases scheduled for oral argument between 11 May and 24 May 2020, parties may object within 15 days of the notice of receipt from the presiding judge notifying them that the case will be decided without oral arguments (unless the procedural calendar for the case had already been rescheduled).

Proceedings before the French Supreme Court have been suspended until further notice.

Germany – German Patent and Trademark Office (DPMA)

Time limits set by the DPMA were extended for all pending IP procedures, and no decision will be made because of the expiration of any time limit until 4th May 2020. Time limits to be set by the DPMA will be as generous as the situation requires. However, this extension of all time limits does not apply to time limits in connection with applications for international registration of marks or requests for subsequent designation.

Staff will not be able to process incoming paper-based mail and faxes and outgoing paper-based mail from the office without delays due to remote working arrangements. The Office have requested that users utilise the DPMAdirektPro and DPMAdirektWeb e-filing system as an alternative to paper applications.

German Courts:

In March and April all hearings in German Courts were adjourned except for urgent cases. Business operations are now gradually resuming in accordance with the hygiene recommendations of the Robert Koch Institute. At the Federal Court of Justice, prior written telephone registration is required for certain negotiations. Video proceedings are permitted pursuant to Section 128a of the German Code of Civil Procedure, subject to the permission of the presiding judge and/or the parties, however many German courts are reluctant to use this technology due to a lack of adequate equipment in the court buildings.

Hong Kong – Hong Kong Intellectual Property Department (IPD)

The IPD continues to provide online search and e-filing services and to publish the Hong Kong Intellectual Property Journal. With effect from 27 April the IPD's public service counter located on 24/F, Wu Chang House (open Monday to Friday from 9:00 to 17:45) was re-opened. The IPD had deferred deadlines falling on any date from 23 March to 24 April for filing any document with the Registries to 27 April. The IPD have confirmed that there are no further planned deadline extensions.

Hong Kong Courts:

The Magistrates' Courts will re-open on 19 May 2020, and the Small Claims Tribunal on 21 May 2020. Parties and legal representatives are urged not to do filing and other business immediately after re-opening unless urgent, as it is anticipated that there will be a significant number of users simultaneously attempting to file documents with the courts after the date of re-opening.

Hungary – Hungarian Intellectual Property Office (HIPO)

The HIPO visitors offices (at 1054 Budapest, Akadémia u. 21.) have been closed to the public since 18 March 2020, and will remain closed indefinitely. Inspection of documents will not be available during this period. In-person consultations with case administrators are also suspended indefinitely.

In person filing of applications is only available at the central HIPO office (1081 Budapest, II. János Pál pápa tér 7.) on business days between 10.00AM – 12.00PM. The automatic filing terminal in the central HIPO office will continue to be available 24/7. However, the

HIPO is encouraging everyone to use the online filing systems or the postal services. From 10 April onwards the HIPO will no longer be providing information support via telephone. Users requiring information from the registry should instead e-mail info@dsiv.hr. Extension of time limits may be requested by users. As much as possible under applicable legislation, HIPO will take into account the difficulties faced by users when setting the time limits. Time limits set by HIPO to rectify irregularities and/or submit comments, and which expired on 31 March 2020 (or following that date) are automatically extended to 2 June 2020. This measure does not apply to time limits which expire after 2 June 2020.

Hungarian Courts:

All physical hearings until 26 May 2020 are adjourned, unless they are "urgent matters". There will be no automatic extension of deadlines.

Italy – Italian Intellectual Property Office

All terms relating to administrative proceedings that are pending on 23 February 2020 or started after that date, are suspended between 23 February 2020 and 15 May 2020 (at the request of a party or ex officio). This is pursuant to Article 37 of the Italian Decree Law no.23 which was published by the Italian Government in April 2020. Industrial property rights expiring between 31 January and 15 April 2020 will automatically retain their validity until 15 June 2020.

The extension does not relate to terms relating to appeals before the Board of Appeals or the Appeals Commission, as they refer to proceedings of a judicial and non-administrative nature.

Italian Courts:

Pursuant to Law Decree no.23/2020, all IP cases scheduled before the Italian Courts between 9 March to 11 May 2020 were postponed ex officio to a date after 11 May 2020. For cases scheduled between 11 May 2020 to 30 June 2020, judicial authorities will take measures such as holding hearings remotely (by using videoconferencing tools); or postponing the hearings to a date after 30 June 2020.

Poland – Polish Patent Office

The Polish Patent Office cancelled all hearings from 16 March 2020 onwards until further notice. They also have announced that they will only be communicating with parties via e-mail or regular mail – therefore there will be no possibility to review files.

In the period between 8 March 2020 to 30 June 2020, the deadlines for (i) filing an opposition to a trade mark application, or (ii) submitting a translation of the European patent into Polish (or submitting a translation into Polish of a limited or amended European patent) have been delayed to 1 July 2020.

Polish Courts:

In Poland several Acts have been adopted in response to the ongoing pandemic. The first Act was published on 2 March 2020 and the most recent one on 14 May 2020.

To the extent that the clock for calculation of court deadlines had not started ticking due to suspension of deadlines under the Act published on 2 March, the clock will resume from 24 May onwards.

Where the Act of 2 March 2020 has suspended an already ticking clock, from 24 May 2020 onwards, the clock will continue from the point in time that it previously stopped.

Romania – the Romanian State Office for Inventions and Trademarks (OSIM)
OSIM was closed for quarantine from 10 March until 22 March 2020 and reopened on 23 March. Deadlines completed during the closure were automatically extended for close of business 23 March. It remains unclear if the suspension for this period has extended the other terms.

As of 23 March 2020, all activities involving public attendance (including hearings or meetings) were suspended until the termination of the emergency state (declared for 30 days starting with 16 March 2020 under the President Decree no. 195/20202). Any information or registration requests shall be submitted through the authority's website, email, mail, fax or telephone. It remains unclear if and how the challenges in front of the authority are also suspended and if positive, what would be the procedure for them.

Romanian Courts:
During the state of emergency, the activity of the national courts will continue for "cases of special urgency". For such cases, the courts will take the necessary measures to conduct the case remotely, and will use fax, e-mail or other means to transmit the relevant documents. The judgement of non-urgent civil cases will be suspended during the period. After the end of the state of emergency, the judgement of non-urgent civil cases will resume ex officio. The courts will take measures to set up new hearing terms and summon the parties. Some national courts dealing with non-urgent civil cases have already extended hearing terms previously allocated to the cases.

Spain – Spanish Patent and Trademark Office
All administrative terms in proceedings managed by the Spanish Patent and Trademark Office have been suspended. The prescription period of rights and actions enforceable before the Office will be also deemed suspended. The Office has announced that, given the high volume of automated administrative processes, it is possible that some automatic notifications with references to deadlines will be generated, but that such references should be disregarded. The SPTO premises are also closed but the Office can be reached by telematic means.

Spanish Courts:
While the state of alarm continues, all court activity has been suspended, and all court deadlines have been automatically extended to the end of the state of alarm. According to the most recent statements made by the Spanish government, the state of alarm will be extended until at least 23 May 2020.

United Kingdom – Intellectual Property Office (UKIPO)
On 27 March 2020, the UKIPO declared 24 March 2020 and subsequent days until further notice to be «interrupted days». The declaration of interrupted days means that any deadlines for patents, supplementary protection certificates, trademarks, designs, and applications for these rights which fall on an interrupted day will be extended to the next non-interrupted day. This extension applies to all non-statutory periods that have been specified by staff. However the extension does not apply to time periods

that are set out under various international IP treaties such as the Patent Cooperation Treaty, European Patent Convention or the Madrid system, where the UKIPO may be acting as a Receiving Office. The period of interruption does not affect filing dates of IP applications which are filed at the Office and do not claim priority from a previous application. However, the UKIPO has advised users not to wait for the end of the period of interruption, and to meet original deadlines where possible to avoid a surge of work once the interruption period ends.

United Kingdom Courts:
Hearings are continuing via telephone, Skype, or other virtual methods where possible. No further physical hearings will be booked to take place until 1 June 2020, but this date will be kept under review. To support this, a new Civil Procedure Rule Practice Direction 51Y has been introduced to give further guidance on conducting audio hearings.

United States – the United States Patent and Trademark Office (USPTO)
On 16 March 2020, all USTPO offices were closed to the public "until further notice", but remain open for the filing of documents and fees via (i) the USPTO electronic filing system, (ii) the United States Postal Service, (iii) hand-delivery to the Customer Service Window, or (iv) facsimile transmission.

All deadlines related to patent or trademark applications due to fall between 27 March and 31 May (inclusive) have now been extended to 1 June. To be eligible for an extension, filings must be accompanied by a statement explaining that the delay in filing or payment is due to the COVID-19 outbreak.

The USPTO have also waived the requirement for original handwritten signatures signed in permanent dark ink or equivalent for certain correspondence, and are now accepting copies of handwritten signatures as an alternative.

United States Courts:
The US Supreme Court will hear oral arguments virtually in May in relation to cases postponed in March and April. Courts in the majority of states have suspended or cancelled trials.

World Intellectual Property Organisation (WIPO)
An announcement made by WIPO on 16 March explained that their business continuity plans have allowed them to continue to process applications filed through WIPO's Global IP Services. The WIPO Arbitration and Mediation Centre also continues to receive and administer cases submitted under the WIPO Mediation, Arbitration, Expediated Arbitration and Expert Determination Rules. Under the WIPO Rules, parties and neutrals will benefit from considerable procedural flexibility. This will allow for a range of procedural adjustments as may be necessary. The WIPO Arbitration and Mediation Center is also offering a variety of online case administration tools, for example online docket and videoconferencing facilities.

The Madrid System
The World Intellectual Property Organization (WIPO) is continuing operations under the Madrid System.

Under the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (*the Regulations*), applicants, holders and IP offices who have failed to meet a time limit for a communication addressed to WIPO may be excused if they send that communication within five days after regaining access to mail, delivery services or electronic communication.

WIPO have also applied a period of grace for the payment of fees for the renewal of an international registration under Rule 5 of the Regulations. In any event, WIPO must receive communication, instruction or payment no later than six months from the date on which the time limit concerned expired.

The Patent Cooperation Treaty (PCT) System

The International Bureau of WIPO (including in its role as receiving Office) remains open for the filing and processing of PCT applications. The Bureau has suspended the transmittal of paper PCT documents and notifications, and will instead only transmit documents and notifications electronically.

PCT Rule 82*quater*.1 allows for the delay in meeting PCT time limits in certain scenarios. This includes delays caused by the pandemic – including delays in the submission of documents, and/or the payment of fees. To benefit from this Rule, the applicant would usually be required to present evidence to the relevant Office no later than six months after the expiration of the applicable time limit (in addition to having taken the relevant action as soon as reasonably possible).

In situations where the international application has lost legal effect as a result of having been declared considered 'withdrawn' due to failure to complete required acts within a prescribed time limit, the receiving Office of the International Bureau of WIPO will delay the issuance of such notification until 31 May 2020.

The Hague System

WIPO is continuing operations under the Hague System for the International Registration of Industrial Designs. Users of the Hague System who fail to meet a prescribed time limit for a communication addressed to WIPO may be excused if they send that communication within five days after regaining access to mail, delivery services or electronic communication. The International Bureau must receive the communication concerned no later than six months from the date on which the time limit concerned expired.

PARIS

Loïc Lemercier / Tom Blanchet

COMPULSORY LICENSING AND NEW PROVISIONS AFFECTING IP HOLDERS DURING THE CORONAVIRUS CRISIS IN FRANCE AND GLOBALLY

Pharmaceutical companies and screening test manufacturers are facing new major challenges due to the global health crisis relating to the coronavirus (COVID-19). To strike the right balance between the interests of rights holders, third parties and the public, exceptions and limitations to patent rights have been promulgated in France and abroad

Key issues

- Exceptional times, exceptional measures:

  COVID-19 clearly presents an imminent threat to public health which, in some jurisdictions, is likely to justify the grant of compulsory licences and more, such as seizures of medicines or screening tests and/or the launch of generic products before the expiry of patents/SPCs.

Patent rights as an incentive for investment in innovative activities and the production of knowledge

Patent law rewards the respective inventor with an exclusive right to his or her invention for a maximum of 20 years. Patent holders generally have the exclusive right to manufacture, use, offer for sale, sell, import, export, tranship or hold an invention. Thus, any other person who wishes to operate that invention will ordinarily need to enter into a licence agreement, or else be exposed to a legal liability.

Exception to the exclusive right: compulsory licences

From a French legal perspective, an exception occurs when patents are subject to a compulsory license where the interests of public health require it and there is no amicable agreement between the parties.

This exception is of interest to pharmaceutical companies and medical device manufacturers during the COVID-19-crisis.

Specificities of compulsory licences

Compulsory licences differ from ordinary licences in two important respects:

- First, the person seeking to use the invention need not obtain permission from the patent holder, which is not needed for compulsory licenses in some emergency situations;
- Second, the compensation to be paid to the patent holder is an adequate remuneration commensurate with the economic value of the invention and is not determined by private contractual negotiations.

Scope of compulsory licences

Under Article L. 613-16 of the French intellectual property code, the French government is entitled to be granted a compulsory license for patents relating to:

(a) ***a medicinal product, a medical device, an in vitro diagnostic medical device or a related therapeutic product***;

(b) ***a process for obtaining them***, a product necessary for obtaining them, or ***a process for manufacturing such a product***;

(c) an ex vivo diagnostic method.

Patents for such diagnostic products, processes or methods may be subject to the ex officio licence regime in the interest of public health only when such products, or products resulting from such processes or methods are made available to the public "in insufficient quantity or quality" or at abnormally high prices, or ***when the patent is exploited under conditions contrary to the interest of public health*** or constitute practices declared to be anti-competitive following an administrative or judicial decision that has become final.

Where the purpose of the licence is to remedy a practice that has been declared anti-competitive ***or in cases of urgency, the Minister responsible for industrial property shall not be required to seek an amicable agreement***.

In light of the foregoing, the application of compulsory licences is allowed for medicines but also in the field of "process for manufacturing such a product (i.e. a medical device such as [a] diagnostic test)".

Recent compulsory licence case-law in the pharmaceutical industry

Recently[1], the Administrative Supreme Court (Conseil *d'Etat*) dismissed a request in summary proceedings ("*référé liberté*"), for the continued manufacturing and marketing in France of the former "Levothyrox" medicine formula operated by Merck, considering that **the requirement of urgency is not met**.

According to the reasoning of the judge, Merck had undertaken to manufacture, import and make available the "Euthyrox" medicine in France until the end of 2018, and that it has not been established that the new imports, together with existing stocks from previous imports, would not be sufficient to avoid a shortage in the short term.

In the context of COVID-19, it would be very likely that in a similar case, the Administrative Supreme Court would consider that the condition of urgency is met.

Seizure of medicines or screening tests and request to launch generic products before the expiry of patents/ spcs during the state of health emergency

Due to the COVID-19 crisis, the French government has taken a step further than the use of compulsory licenses for inventions in areas of public health interest. Law No. 2020-290 of 23 March 2020 in response to the COVID-19 epidemic, introduced a new Article L.3131-15 in the French Public Health Code (CSP), that allows the Prime Minister to:

7° ***order the seizure ("requisition") of all goods and services necessary for the fight against the sanitary disaster as well as any person necessary for the operation of these services or the use of these goods***. The compensation of these seizures is governed by the code of defence;

1 Administrative Supreme Court (*Conseil d'État*), Summary proceedings, Collegial formation, 26 July 2018, No. 422237.

8° to take temporary measures to control the prices of certain products made necessary to prevent or correct the tensions observed in the market of certain products; the National Consumer Council is informed of the measures taken in this regard;

9° ***if necessary, take any measures to make available to patients appropriate medicines for the eradication of the health disaster***.

As of today, the State of Health Emergency has been extended in France for a further two-month period due to COVID-19. Assuming that new epidemics appear in the future, the same provisions may apply. Consequently, pharmaceutical companies and screening test manufacturers should keep those provisions in mind.

The current context raises important issues about the balance between patent/SPC protection and public interest with that of direct access to specific medicines and COVID-19 screening tests.

Data exclusivity considerations

Further to the above comments regarding compulsory licensing, we would point out that a data exclusivity regime could be an obstacle for the execution of a compulsory licence or government use of a patent. Hence, it may be necessary to waive the rights conferred under data exclusivity in order to allow a compulsory licensee to obtain marketing approval of the licensed product. It is therefore appropriate to check if national regulations may provide that data exclusivity shall have no effects against a compulsory licensee granted for any of the grounds established under the applicable patent law, or against persons authorised to undertake a governmental non-commercial use of the patented product.

In all cases, as in the case of patents, exceptions may be provided for data exclusivity protection, such as for cases of emergency, and public health reasons. As mentioned earlier, COVID-19 clearly presents an imminent threat to public health which is likely to justify the voluntary waiver of or exception to data exclusivity protection. For instance, Mylan has announced additional efforts to support response to the COVID-19 pandemic by voluntarily waiving its marketing exclusivity in the U.S. for Lopinavir/Ritonavir, so as to help ensure wider availability to meet the potential needs of COVID-19 patients.

Comparison with other jurisdictions

The delicate balance between the rights held by patent owners and compulsory licensing has been highlighted in numerous countries due to COVID-19:

Europe

- In Germany, the Bundestag passed an amendment to the Protection against Infection Act, which gives the Federal Minister of Health far-reaching powers in the fight against the corona virus. To ensure that the population has access to medicines against the corona virus, the Federal Health Minister is now authorised to oblige research institutes and pharmaceutical companies to make patented vaccines or medicines available to the general public in return for appropriate compensation. Contrary to what might be assumed at first sight, the legal

regulation is not aimed at vaccines that are currently being developed and are not yet patented, but rather at known and already patented active substances that were developed in the past for other diseases and are now being tested for their effect on corona viruses. The prerequisite for this access to the exclusive right of the patent holder, which, incidentally, is based on Section 13 of the German Patent Act (PatG), is that the Bundestag has previously identified an epidemic situation of national importance. In addition, the patent court can grant a compulsory licence according to section 24 of the Patent Act if previous licence negotiations have failed and there is a particular public interest. This is provided that – as is currently the case – the protection of public health is at issue and there is a significant public interest in access to and the affordability of medicines, then a compulsory licence might also be considered. However, a court procedure is likely to take longer than an order by the Federal Minister of Health in accordance with the IfSG. The new regulation came into force on 28 March 2020.

- In Italy, the Italian government has not implemented special provisions to or the derogation of patent law (including the current regulation of compulsory licene) so far. The intervention in healthcare has been mainly focused on staff, organisation and sanitarian protocols; the supplies of drugs and medical devices have been made mainly through contracts. However, in recent weeks an interesting case appeared in the media some: to remedy a the lack of respirators (which would have been supplied late, also due to lockdown restrictions), a joint partnership between a 3D printing start-up and the Hospital of Chiari (near Brescia, Lombardy, one of the areas in northern Italy most affected by COVID-19) produced with a 3D printer a key device (the valve) for respirators, then applied it to a snorkelling mask supplied by Decathlon, the sports goods retailer: this creative solution has been shown to be effective. The original device is already patented but, due to the emergency, the Hospital did not seek to obtain the authorization from the patent holder. There is no public information regarding the original manufacturer's formal claim, but it seems that there is no legal exception that quite fits this case. The main conclusion appears to be that, if eventually the infringement will be proved, the patent holder will be entitled to an indemnification (rather than a proper compensation of monetary damages), since the infringer would have acted in a state of necessity caused by the emergency.
- In Spain, the Spanish government has not implemented emergency regulations specifically to broaden the compulsory licensing regime in its response to COVID-19. Thus, the regime contained in the Spanish Patent Law applies, which, apart from the compulsory licensing when reasons of public interest exist, provide for another mechanism that the State can use to alleviate the effects of the health crisis caused by COVID-19: the expropriation of patents. This mechanism, more aggressive and extraordinary than compulsory licences, allows the State to take ownership of patents by means of "fair compensation" and if there is a "cause of public utility or social interest". However, Royal Decree 463/2020 of 14 March declaring in Spain the state of emergency of the health crisis situation caused by COVID-19, empowered the Spanish Minister of Health to "intervene and temporarily occupy industries, factories, workshops, holdings or premises of any kind, including privately owned health centres, services and establishments, as well as those

operating in the pharmaceutical industry", and "carry out temporary requisitions of all types of goods and impose mandatory personal services" that contribute to the adequate protection of public health (Article 13). This Royal Decree has been developed, amongst others, by Order SND/276/2020 of 23 March which imposes information, supply and manufacturing obligations on manufacturers and marketing authorisation holders of medicinal products classified as essential for the management of the health crisis (these are included in its Annex I). These manufacturers and marketing authorisation holders must establish the necessary measures to guarantee the supply of such medicinal products to health services and centres, which may be required to be supplied daily.

- In the UK, the existing legislation already provides the right *for* the Government to use patented inventions for the Crown, without requiring the patentee's consent ("Crown use"). The legislation specifically identifies the Government's right to manufacture and supply drugs and medicines. In most circumstances compensation will be payable by the Government to the patentee (or its exclusive licensee) for such use. Such compensation is to be agreed by reference to the loss suffered; based on what *actual* manufacturing could have been undertaken and having regard to the lost profit. In the absence of agreement, the Court will determine the award on those same principles. The legislation also includes special enhanced provisions during a "*period of emergency*" where declared by an Order in Council of the Government. Crown use has been invoked previously by the UK's Minister of Health for a limited period, to import a drug from Italy for the UK's National Health Service because there were no supplies in the UK (*Pfizer v. Ministry of Health*).[2] However, its use has been rare. By contrast, in 2019, the deadlock in access and pricing negotiations between NICE and Vertex Pharmaceuticals over its *Orkambi* drug (a drug to relieve certain symptoms in children with cystic fibrosis) led to campaigners calling for the Government to invoke Crown use to resolve the issue. No such use was invoked, and at the time the (then relevant) Government Minister (Steve Brine) said that Crown use was only "*really intended to deal with emergency use*". Although the current pandemic state of COVID-19 may justify "emergency use", it is unlikely the Government will invoke Crown use unless patent rights are blocking access to essential medicines or pricing is abusive. Instead, recognising the adverse publicity fallout of such behaviours, we anticipate seeing a more conciliatory approach, at least during the pandemic, with voluntary licences offered on free or commercially favourable terms where supply is otherwise restricted, or there is inactivity in research or exploitation.

Americas

- In the US:
  - the government has "march-in" rights under the Bayh-Dole Act to force the funded company to license its rights to a third party to bring the patented invention to market "*upon terms that are reasonable under the circumstances*".[3] This "march-in"

2 More recently, Crown use was successfully established in *IPCom v. Vodafone* relating to the Government's emergency access to the mobile telecommunications network.

3 35 U.S.C. § 203(a)

procedure has until now never been used in the pharmaceutical industry. The government's position in the past has been that this right may only be used where a company does not bring the product to market, not to lower prices;

- the federal government could exercise its eminent domain rights under the US constitution, which gives it the right to force a compulsory licence in the face of a public health threat. This is the case even if the R&D was funded privately. The government's rights, and the patent owner's remedy against this governmental "taking," is reflected in the US federal code 28 USC Sec. 1498.

- In Canada, Bill C-13, the COVID-19 Emergency Response Act passed into law on 25 March 2020. It specifies that if the Federal Minister of Health considers there to be a public health emergency, the Commissioner of Patents may allow the Canadian state to produce, sell and use a patented invention. Unlike existing compulsory licensing provisions, the new law allows the government to issue a licence without first negotiating with the rights holder or establishing its own ability to supply a product. Patentees must be compensated, but the law states only that they should receive "*any amount the Commissioner considers to be adequate remuneration in the circumstances*", considering the economic value of the permit. Licences issued under the new legislation are non-transferable and will be cancelled if the state of national emergency comes to an end. The provision expires at the end of September 2020, after which no patent permit can be granted.
- In Australia, no concrete steps have been taken, but recent reports state that the opposition Labour Party has asked the government to make use of Crown use provisions as part of its response to the pandemic. Shadow industry minister Brendan O'Connor asked the government: "*To detail how Crown use of patents may be invoked, particularly for use for repurposed manufacturing businesses, to address shortages of essential goods impacted by disrupted supply chains*."
- In Chile, Chile's Chamber of Deputies passed a resolution calling on the country's government to declare its support for issuing compulsory licences on patented products that can be used to help treat coronavirus sufferers. On 17 March 2020, the lower legislative assembly voted a resolution which requests the Minister of Health to instruct government departments to report on the vaccines, medicines, tests and equipment that should be considered essential for purposes of issuing patent licences. Furthermore, the document calls on the Chilean government to ask the World Health Organization to collect information on the R&D costs associated with relevant treatments.
- In Ecuador, a commission of the Ecuadorian National Assembly passed a resolution on 20 March 2020 asking the country's health minister to issue compulsory licences on products whose availability is important to the public health response to COVID-19. The Education, Culture, Science and Technology Commission also asks the minister to make use of article 501 of the Código Ingenios, which authorises third parties to access and use a patentee's data, including clinical test data.

Asia

- In mainland China, the Chinese government has not implemented any emergency regulations to broaden the compulsory licensing regime in response to COVID-19. There are existing compulsory licensing provisions under Chapter VI of the Patent Law, but these have not been invoked. However, BrightGene has copied Gilead's "*remdesivir*", the most promising candidate against the deadly pathogen. BrightGene, however, made clear that the generic version is still in an R&D phase, and that its final marketing requires permission from the patent holder, Gilead. In parallel, Gilead is providing the medicine for free for studies to test *remdesivir* in adult patients with mild-to-moderate or severe respiratory disease caused by the novel coronavirus.
- In Hong Kong, there are no new emergency regulations to broaden the government's power to use patented inventions in response to COVID-19. The Hong Kong Patent Order (Cap 514) already contains provisions for (i) compulsory licensing (Part 8) and (ii) government usage of patents in a period of extreme urgency (Part 9), but neither of these has been invoked.
- In Israel, the Minister of Health issued a precedential permit for the use of three Israeli patents covering the anti-retrovirus medicine "*Kaletra*" (Abbvie) in order to import quantities of a generic version of the medicine for use in the treatment of patients suffering from the COVID-19 virus. Kaletra, which is generally used for the treatment of HIV, has been found useful in the treatment of some patients suffering from the virus.

Practical considerations

According to the new Article L.3131-15 in the French Public Health Code (CSP) cited above, during the State of Health Emergency it would be allowed in France (i) to seize medicines ("*requisition of all goods*") and/or (ii) to ask for the launch of generic products on French territory before the expiry of patents/SPCs ("*take any measures to make available to patients appropriate medicines*").

Importantly, it should be noted that the seizures provided in this new article could be compensated by the code of defence, but which would not be at the upper end of the scale. However, it seems that a patentee is not entitled to claim damages or to obtain compensation if an early launch of the generic medicine is requested by the French government.

Likewise, although Article L.3131-15 CSP has been introduced by Law No. 2020-290 relating only to COVID-19, the provisions are included in a broader section entitled: "State of Health Emergency" ("*Etat d'urgence sanitaire*"), that could be ordered only in the event of "*a health disaster endangering, by its nature and severity, the health of the population*" (Article L.3131-12 CSP).

Regarding the grant of compulsory licences, as it stands under French law, an important limitation should be also considered by public authorities. That is, the above French provisions to grant compulsory licences (Article L. 613-16 of the French intellectual property code) cannot impose obligations to disclose trade secrets. However, the question of sharing know-how or trade secrets for the manufacture of medicines already arises before a patented medicine is offered for sale.

For those countries that have used them, compulsory licences have made it possible to obtain significant price reductions or to obtain supplies of generic medicines; this generates savings necessary to substantially improve access to vital therapies for HIV (Brazil, Thailand, Indonesia, etc.) or more recently for certain cancers (India). Paradoxically, the US government itself used the threat of compulsory licensing in 2001 to obtain a significant reduction in the price of ciprofloxacin (in order to stockpile this anthrax antidote for a possible attack).

The COVID-19 crisis affects not only patent law. However, COVID-19 clearly presents an imminent threat to public health which, in most jurisdictions, is likely to justify the grant of compulsory licences and more.

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DÜSSELDORF

Dr. Claudia Milbradt / Dr. Florian Reiling[1]

PATENT LAW: APPROPRIATE BALANCE BETWEEN PRIVATE AND PUBLIC HEALTH INTERESTS IN TIMES OF CORONAVIRUS CRISIS

Patent protection in pharma and healthcare has always been a matter of intense debate. In the context of coronavirus (COVID-19), the debate about the right balance between justified exclusivity and the public interest in any progress in scientific (pharmaceutical) research becomes even more urgent. Here, patent law must reconcile different interests: On the one hand, it must reward inventors in order to encourage them to make new innovations, while ensuring on the other hand that the general public and not only a few privileged individuals benefit from the inventions. Outside times of crisis, the patent system has proved its worth and has always provided for an appropriate balance between the various interests. However, will this assessment also hold true for the coronavirus crisis or will adjustments be required?

Introduction

Due to the massive spread of *COVID-19* and the daily increasing number of new infections, many pharmaceutical companies intensified their researches to develop and market a vaccine as soon as possible. For the individual governments the protection of public health is a top priority. Along with the *Coalition for Epidemic Preparedness Innovations* (*CEPI*), an international foundation in public-private partnership, they invest large sums of money in the development of a vaccine.

Generally, the company can expect to realize an appropriate return on invest with the development of a vaccine or any potent anti-viral drug, given that patent protection grants the owner of an invention an exclusive right for its use and commercialisation.

However, provided that – as is currently the case – the protection of public health is at issue and that there is a significant public interest in access to and the affordability of drugs, exceptions to the exclusive protection of the patent holder might be necessary. In such cases, the German Patent Act ("**GPA**") provides for a compulsory licence regime under which access to a specific patent may exceptionally be granted in accordance with the requirements of section 24 GPA.

Claudia Milbradt
IP Stars: Patent star 2020

IP Stars: Trade mark star 2020

Key issues

- In principle, patent protection grants the owner of an invention an exclusive right for its use and commercialisation.
- However, the coronavirus crisis could lead to restrictions of patent rights.
- Recently, the Bundestag passed an amendment to the Protection against Infection Act which empowers the Federal Health Minister to oblige research institutes and pharmaceutical companies to make patented drugs available to the general public in return for appropriate compensation.
- Besides, the German Patent Act ("**GPA**") provides for a compulsory licence regime under which access to a specific patent may exceptionally be granted under certain conditions.

1 The authors would like to thank Annika Drabinski and Nico Schur, research assistants at Clifford Chance, Düsseldorf, for their help in preparing this manuscript and their contributions to this article.

In addition, section 13 GPA provides for the possibility to suspend the exclusive right in so far as the Federal Government orders that the invention shall be used in the interest of public welfare or federal security. In this case, the patent holder must tolerate the usage of the patent but receives a certain remuneration in turn.

Based on this regulation, on 28 March the Bundestag passed an amendment to the Protection against Infection Act (*Infektionsschutzgesetz*), which gives the Federal Minister of Health far-reaching powers in the fight against the coronavirus. To ensure that the population has access to medicines against the coronavirus, the Federal Health Minister is from now on authorized to oblige research institutes and pharmaceutical companies to make patented vaccines or medicines available to the general public in return for an appropriate compensation. Prerequisite is that the Bundestag has previously identified an epidemic situation of national importance. Therewith, the German government ensures that in the event of a crisis the population is provided with the necessary vaccines and medicines.

This article intends to provide an overview of the interplay and the implications between the patent as an exclusive right and the compulsory licence and further access rights according to the Protection against Infection Act as restriction for the patent holder. Moreover, it raises the question of whether the current patent system can sufficiently satisfy the different interests against the background of the current coronavirus crisis.

Patent as an exclusive right

Patent law rewards the respective inventor with an exclusive right to his invention for a maximum of 20 years. On the one hand, such an exclusive right provides an incentive for private companies to create further innovations. On the other hand, it causes a monopoly on the invention which – as critics of the patent system usually argue – can limit competition and the free use of innovations.

Patent law has succeeded in striking an appropriate balance between those private and public interests by granting an exclusive right to the patent holder, but at the same time imposing on him an obligation to disclose his invention and limiting the protection in terms of time, scope and territory. This mechanism has so far ensured an appropriate balance between the multiple interests, which in turn encourages inventors to do research and invest.

Exception of exclusivity: compulsory licences

Since absolute protection of the patent, however limited in the aforementioned sense, may not prove to be in the interest of the public in any and all situations, the German legislator created the compulsory licensing regime in section 24 GPA.

At international level, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-Agreement), which applies to all member states of the *World Trade Organisation* (*WTO*), provides for the possibility of granting a compulsory licence in Article 31.

Character of compulsory licences

Compulsory licences are non-exclusive licences that allow third parties to use the patent against the will of the patent holder. They can be requested at the Federal Patent Court, but only under strict conditions in very limited exceptional cases, as they substantially encroach on the property right of the patent holder. In the past, there seems to be only one single case[2] in the pharmaceutical sector in which both the Federal Patent Court[3] and the Federal Court of Justice[4] have so far granted a compulsory license for reasons of public health protection.

A pandemic such as the coronavirus could give cause to examine the conditions and consequences of compulsory licences.

When is a compulsory licence granted and what are the consequences?

According to section 24(1) GPA a compulsory license may be granted if (i) the patent applicant has tried without success for a reasonable period of time to obtain a permission from the patent holder to use his invention under reasonable conditions and (ii) there is a special public interest for the grant of the licence.

The first condition for a compulsory licence is thus that the patent holder refuses to grant a licence to the licence applicant although the latter has previously offered him an adequate compensation. The offer made by the applicant must be reasonable. In this respect, the Federal Court of Justice stated that the perspective of the licence applicant is decisive.[5] He is required to make efforts to obtain a licence on terms which a reasonable and economically acting third party would be prepared to bear in his place.

Secondly, a public interest must require the grant of a compulsory licence. The Federal Supreme Court emphasised that this requirement cannot be generally defined. Rather, all circumstances of the individual case have to be taken into account. When weighing up the different interests, however, it must be considered that the legal system in principle grants the patent holder an exclusive right. Therefore, the Federal Court of Justice held that a compulsory licence can only be granted if there are special circumstances in which the public interest prevails. In the specific case, the Court of Justice affirmed a public interest for the grounds that – without the licence – a drug with a comparable therapeutic effect would no longer be available for the treatment of the serious illness HIV.[6]

2 The Federal Patent Court had granted a compulsory licence also in another case, but its decision was reversed by the Federal Court of Justice in the second instance on the reason that there was a lack of public interest [see Federal Court of Justice, decision of 5 December 1995 – X ZR 26/92 (*Polyferon*)].

3 Federal Patent Court, Decision of 31 August 2016 – 3 LiQ 1/16 (EP).

4 Federal Court of Justice, Decision of 11 July 2017 – X ZB 2/17 (*Isentress/Raltegravir*).

5 Ibid, recital 29 ff.

6 Ibid. recital 38 ff.

If the requirements for the grant of a compulsory licence are met, the Federal Patent Court grants the applicant a non-exclusive licence. At the same time, it determines a license fee of an appropriate amount. Thus, in addition to the patent holder, a third party can use the patent for a fee that is usually lower than the fee requested by the patent holder.

Immediate but temporarily suspension of patent rights according to Protection against Infection Act

However, even in the field of medical and vaccine research, where the health of the population as a particularly sensitive asset is at stake, compulsory licences have so far been the absolute exception. This indicates that exclusive protection of the patent holder has in principle proven to be appropriate in this area as well, whereas the compulsory licence has only the function of a last means in licence negotiations which – as we have seen – has only been used under very narrow circumstances.

This applies at least outside times of crisis. The actual significance of the compulsory license regime might now be tested in the context of the current coronavirus crisis. With the Amendment to the Protection against Infection Act, the parliament declared the coronavirus crisis as an epidemic situation of national importance. Regarding patents, as said, the amendment empowers the Ministry of Health to issue that an invention can be used in the interest of public welfare or in the interest of federal security.[7]

Although section 13 GPA does not affect the validity of the patent, it is one of the provisions that set limits to the exclusive right of the patent holder in the interest of the public. It remains to be seen whether this means will be used. However, the current legislative clearly highlight that the government is more than willing to make use of its powers.

Contrary to what might be assumed at first sight, the Protection against Infection Act is not aimed at vaccines that are currently being developed and are not yet patented, but rather at known and already patented active substances that were developed in the past for other diseases and are now being tested for their effect on coronaviruses.

Why became this additional Protection against Infection Act necessary? A court procedure according to section 24 GPA is likely to take longer than an order by the Federal Minister of Health in accordance with the Protection against Infection Act. In case of a threat to the public health, time is of outmost importance and thus the preliminary suspension of patent rights may be justified under the narrow prerequisites: pandemic situation, temporarily and compensation for the patent holder.

7 See Article 1 section 5 para 2 no 5 of the Act for the protection of the population in the event of an epidemic situation of national importance, 27 March 2020, see BGBl. 2020 I Nr. 14, p. 587 ff.

Closing remarks

In principle, the interests of the patent holder are comprehensively protected by an exclusive right to the patent and are brought into an appropriate balance with public interests – at least in 'regular times'.

Yet, in the context of the current coronavirus crisis, patent holders must be aware of the outlined restrictions, such as compulsory licenses, if they do not agree to market a vaccine or medicine at reasonable prices or grant a respective licence.

It is essential that the involved stakeholders try to achieve an appropriate balance in order to ensure the affordability of adequate health care for the general public and allow the development of urgently needed drugs and, at the same time, uphold an adequate patent protection level.

MILAN

Andrea Tuninetti Ferrari / Andrea Andolina

"MADE-IN ITALY" AND COVID-19: ANY DEMAND FOR A "VIRUS FREE" CERTIFICATION FOR FOOD PRODUCTS IS UNLAWFUL

Italy is dealing with the COVID-19 pandemic and will soon face the economic implications of the lockdown over the entire Italian territory.

In the meantime, Italian producers and manufacturers are facing unfair commercial practices which, if not addressed, may result in unjustified tarnishing of the Italian brands.

Over the past few weeks, fake news and theories, which are not backed by any scientific evidence, have surfaced among the social media, suggesting that as a result of COVID-19 having spread in the Italian territory, "*Made-in*" and Italian-sounding products may not be safe for consumers. These allegations have been associated, in particular, with the food sector – one for which the Italian "*Made-in*" stands out worldwide – as a result of certain Italian products having been blocked at customs due to the outset of the pandemic crisis and where certain buyers of Italian products have reportedly sought "virus free" certifications (which, as of today, no authority can grant).

The competent European and Italian bodies have recently clarified that any expectations of a "virus free" certification is unsupported by any provision of law and ultimately misconceived, as follows:

- The recent Italian Government's Law Decree no. 9 of 2 March 2020 Italian Government qualifies as **unfair commercial practice** in the food supply chain under Dir. (EU) 2019/633 any act or demand to subordinate the purchase of products to the adoption of a non-mandatory virus free certification related to the COVID-19 (Art. 33, par. 4);
- On 9 March 2020, The EFSA (European Food Safety Authority) took a firm stand in the debate, stating that "*there is currently no evidence that food is a likely source or route of transmission of the virus*"; and
- The European Union Commission, in the "*Guidelines for border management measures to protect health and ensure the availability of goods and essential services*" issued on 16 March 2020, tackles the issue, affirming that "*Member States should preserve the free circulation of all goods*" and that "*no restriction should be imposed on the circulation of goods in the Single Market, especially (but not limited to) essential, health-related and perishable goods, notably foodstuffs, unless duly justified*". It has been also clarified that "***no additional certifications should be imposed on goods legally circulating within the EU single market***".

Key issues

- The Law Decree no. 9 of 2 March 2020 qualifies as **unfair commercial practice** in the food supply chain any act or demand to subordinate the purchase of products to the adoption of a non-mandatory virus free certification related to the COVID-19;
- The EFSA stated that "*there is currently no evidence that food is a likely source or route of transmission of the virus*";
- According to the EU Commission "*no additional certifications should be imposed on goods legally circulating within the EU single market*".

Links

- **EFSA** press release (https://www.efsa.europa.eu/en/news/coronavirus-no-evidence-food-source-or-transmission-route);
- **EU Commission** guidelines (https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/european-agenda-migration/20200316_covid-19-guidelines-for-border-management.pdf).

MILAN

Andrea Andolina / Iolanda D'Anselmo

AI AND BIG DATA IN THE FIGHT AGAINST CORONAVIRUS

Humanity is using technology and data to conduct its global fight against the realistic enemy that is known as Coronavirus. It goes without saying that our post-lockdown world will be very different: scenarios that just weeks ago would have been appropriate only for dystopic fiction, are now realistic.

As the lockdown restrictions are going to be gradually relaxed, governments are turning to structure "Phase 2", where society must find "new" normalcy: various technologies are often mentioned among the measures and tools that will enable us to push the restart button safely, by helping to contain the COVID-19 virus and to prevent a second wave of propagation.

Technology as a "Phase 2" driver

China, South Korea, Singapore, Israel and Italy have already implemented new technology, based on artificial intelligence (AI), to collect and analyse data. These include: apps and algorithms to monitor Coronavirus positive or potentially positive persons, mapping their social interactions; GPS, video surveillance data and drones, to track the general movements of the population; and devices which measure body temperature and help prevent access to public places by individuals with fever and other symptoms.

These measures – some of which have already been experimented in the context of military operations and the fight against terrorism – are likely to be effective as countries seek to limit the spread of the contagion, but bring to light very complex legal and political issues.

Telecommunication companies, social media and other private companies that store crucial data, such as geolocalisation data and payment and transactions data, could be forced or incentivised to share the data with public authorities, at least in an aggregated and anonymised form.

The Global System for Mobile Communications

The idea to exploit personal data held by telecommunication companies' (tel.cos) is also currently under the watchful eye of the Global System for Mobile Communications ("**GSMC**"), the widely-used digital mobile network that represents the interests of 750 mobile phone operators and vendors across the world. The English newspaper, "*The Guardian",* reported that the GSMC's current director, Mats Granryd, is exploring the creation of a **global data-sharing system** that could track individuals around the world, as part of an effort to curb the spread of Coronavirus. Against this backdrop, he has also said that the GSMC "*is engaging with operators, policymakers and*

Key issues

- Technology can play a crucial role in providing collective safety and economic growth.
- The GSMC is currently exploring the creation of a global data-sharing system that could track individuals around the world.
- The EDPB calls for lawful processing of personal data even in the unprecedented challenge of Coronavirus.
- The IDPA declares that new legislative provisions, which have not yet been adopted, are necessary to allow massive sharing of non-anonymised personal data.
- Tech start-up grants to the Italian government, which will help with licensing its newly-developed contact tracing software.

international organisations around the world to explore viable mobile big data and AI solutions to fight this COVID-19 pandemic ***while adhering to principles of privacy and ethics.***"

The view of the Data Protection Authorities

At European level, on 19 March 2020, the European Data Protection Board ("**EDPB**") published a statement (the "**EDPB Guidelines**") whereby it called upon data controllers and processors to ensure protection of the personal data of their data subjects and to guarantee lawful processing of personal data **even in the face of this unprecedented challenge represented by Coronavirus**.

The EDPB has made clear that Directive 2002/58/CE (the "**e-Privacy Directive**"), as transposed and implemented by the respective domestic national legislative frameworks, continues to apply to the processing of telecom data, such as an individual's location data.

In principle, the e-Privacy Directive and the Italian Data Protection Code (mainly in Article 126) allow data controllers to disclose location data to third parties provided that: (i) the data is made **anonymous**, or, if anonymisation is not possible; (ii) the data subjects express their **consent** to the disclosure.

Accordingly, sharing **aggregated data** to monitor lockdown restrictions, or to track the movements of individuals who have tested positive for Coronavirus, does not in principle appear to undermine individual privacy, provided that the data which is disclosed by the authorities is in **anonymised and aggregated form**.

The EDPB Guidelines also address the processing of location data **without the data subject's consent**, driven by the concerns raised by the World Health Organisation (WHO): article 15 of the e-Privacy Directive enables Member States to introduce legislative measures for the safeguard of public safety that will allow processing of location data in emergency situations, like the Coronavirus pandemic, **without seeking the data subjects' consent**.

In a recent interview published on 18 March 2020 in the Italian newspaper *Il Corriere della Sera*, the Italian Data Protection authority (the "**IDPA**") invited Italian public authorities to encourage an approach based on the principles enumerated in the EU's General Data Protection Regulation ("**GDPR**"): (i) **necessity**; (ii) **minimisation**; and (iii) **proportionality** of the data processing.

Nevertheless, the IDPA also stated that if Italian public authorities wish to obtain non-anonymised personal data from data controllers **the Italian legislature will be required to enact legislative provisions** that specify, *inter alia*; (i) the type of personal data that tel.cos must disclose to public authorities; (ii) the security measures to be implemented to protect the data subjects' rights and interests; (iii) the modalities of the data processing; (iv) the legal grounds for the processing; and (v) the temporary nature of the provisions, which must be strictly limited to the current emergency scenario. In this case, data controllers must provide to data subjects specific notice in accordance with Article 13 of the GDPR.

Therefore, data controllers could lawfully communicate non-anonymised location data to public authorities if it is so required by the law (Article 6(1)(c) of the GDPR) to the extent that this communication is **expressly authorised by Italian law**. So far, the Italian legislature has not yet authorised this type of disclosure.

Preliminary measures adopted in Italy by the Extraordinary Commissioner for the Coronavirus emergency

On 16 April 2020, the Italian Extraordinary Commissioner, who was appointed to manage efforts during the coronavirus emergency, provided for a tech start-up company to grant the Italian government a licence to use its newly-developed contract tracing software.

According to current press reports, the software application uses Bluetooth wireless technology to record when users are in close proximity with each other. When someone tests positive for the coronavirus, the app would be able to send an alert to users who have been in physical proximity with the newly-diagnosed person, and recommend actions such as self-quarantine and testing, while preserving anonymity.

Compared to location-tracking based on networks or satellites, Bluetooth wireless technology could more accurately and less intrusively log proximity between individuals and the duration of such proximity. The app would be downloaded and used on a voluntary basis. Nevertheless, to be effective, it should be used by at least 60% of the population, citizens: for this reason, download the app could be tied to incentives (or penalties); however, such a system could collide with the “voluntary” nature of the technology. A harsh political debate is currently in progress in Italy on this issue, and could undermine the very implementation of this technology.

The underlying trade-off: collective safety v. individual rights?

Allowing the intensive use of personal data – irrespective of whether the data subjects have given their consent – will likely improve the effectiveness of how a nation protects its population, by limiting contagion, and provide prosperity, by avoiding further restrictions. On the other hand, the very notion of data protection would be attacked, starting from the key element of data subject consent, and may open the door to a new world, where both private companies and public authorities will have access to much more of our information and to a far clearer picture of our habits and actions.

In essence, we would be moving closer to what is currently already happening in the digital world – albeit in a more fragmented fashion – where huge volumes of data are held by various private entities and are subject to multiple legal requirements and cautions from several and sometimes conflicting sources of law, such as data protection, antitrust, and civil rights.

Technology makes this scenario possible, and the legal context offers ways to implement it lawfully. It is merely a matter of making a political and cultural choice. Are we ready to trade some individual rights for increased collective safety?

Links

- The Guardian on GSMC: https://www.theguardian.com/world/2020/mar/25/mobile-phone-industry-explores-worldwide-tracking-of-users-coronavirus
- EDPB Guidelines of 19 March 2020: https://edpb.europa.eu/news/news/2020/statement-edpb-chair-processing-personal-data-context-covid-19-outbreak_it.
- IDPA interview in *Il Corriere della Sera* of 18 March 2020: https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/9294705.
- Order no. 10 of 16 April 2020 adopted by the Italian Extraordinary Commissioner for the Coronavirus emergency: http://www.governo.it/it/dipartimenti/commissario-straordinario-lemergenza-covid-19/14483

DÜSSELDORF

Dr. Claudia Milbradt / Nicolas Hohn-Hein[1]

3D PRINTING IN TIMES OF CRISIS FROM A GERMAN IP LAW PERSPECTIVE

The COVID crisis, which accelerated around the world in March, dramatically increased the global demand for medical supplies. Media reports soon emerged about private individuals creating certain medical items, such as ventilator parts and protective visors, using their 3D printers at home and delivering them to local hospitals and physicians. While clearly demonstrating human ingenuity and compassion in times of crisis, it can be expected that 3D printing technology will further develop in the 2020s. The extensive copying and use of certain commodities cannot go unnoticed from a German IP law perspective, and provides an excellent occasion to shed some light on the IP implications that come with 3D printing, a technology that has become more and more important and sophisticated in recent years. We discuss in this article the basic legal principles of IP protection, and pose the question if, and to what extent, 3D printing of objects without the consent of the IP rights holder may be permissible under exceptional circumstances, such as the ongoing COVID pandemic.

Key issues

- 3D printing relates to a set of technologies used to build three-dimensional objects (3D Object) from a digital file (3D Model File).
- The 3D Model File as well as the 3D Object may be subject to IP protection.
- Notwithstanding the event of a pandemic, the public interest does not generally prevail over the protection of IP.
- However, the public interest must be considered when interpreting the law, in particular the scope of limitations, and may lead to the application of specific provisions that readjust the balance between protection of one's property and public welfare.

Technical background

The term "3D printing" or "additive manufacturing" relates to a set of technologies used to build three-dimensional objects from a digital file. Typically, a 3D printing process is performed in two stages. The first stage involves either the creation of a 3D scan of an actual object, or a digital representation of such an object using specialised software (so-called "computer-aided design" or "CAD" software). At the second stage, specialised software transforms the representation into sliced instructions for a 3D printer, which then creates a three-dimensional reproduction of the original object. The beginnings of 3D printing date back to the 1980s, when the American engineer Chuck Hull invented the first commercial 3D printer. Currently, the automotive, medical and aerospace industries especially use the technology to manufacture certain parts. In the mid- and long-term, the technology is believed to become an important corner-stone of space exploration.

1 The authors would like to thank Annika Drabinski and Nico Schur, research assistants at Clifford Chance, for their help in preparing this article.

Subject matter and IP protection regimes

Subject Matter

It is important to note that we have to distinguish between the 3D Model File and the 3D Object itself when discussing IP protection.

3D Model File

Three-dimensional printouts are usually based on an electronic file which contains, as with a blueprint or – to stick with the idea of "printing" – a Word file, the software code commands required for the printer to print out the desired object ("**3D Model File**"). The 3D Model File therefore needs to be created by a designer (via a CAD software application), stored on a storage device (e.g. a hard drive) and finally loaded to the printer's memory for printing.

3D Object

The result of the print job is the actual physical representation of the object recorded in the 3D Model File ("**3D Object**"). The 3D Object can be any object of any quality and shape, depending on the information stored in the particular 3D Model File and the capabilities of the particular printer, e.g., with respect to the printing method applied, the material used (e.g. plastics, metal filaments), the printer's print resolution &c.

3D printing method

A third, potentially protectable, subject matter could be the applied printing method (and/or the underlying technology) as these methods become increasingly sophisticated over time.

IP protection regimes

Without doubt, both the 3D Model File as well as the 3D Object may enjoy IP protection to some extent. The sole – but considerable – challenge is to determine which IP protection regime (copyright, trade secret, patent, trademark, design etc.) shall be applicable in the respective case, acknowledging that the protection regimes often even overlap and may even apply cumulatively or consecutively.

That said, copyright protection will likely offer some degree of protection in most cases as the 3D Model File and the 3D Object often constitute "original works of authorship". As German copyright law applies a relatively low threshold for copyright protection, the electronic 3D Model File will likely be protectable as copyright even if the design of the 3D Object itself – regardless of whether it still in digital form or already printed – does not qualify for copyright protection (e.g. due to a lack of originality). Other viable protection regimes, covering in particular the "look and feel" of a 3D Object, may be trademark law and/or design law.

In view of the recent coming into effect of the European Trade Secret Directive and its transposition into German law under the German Trade Secret Act, trade secret protection becomes increasingly important for the protection of the economic value of assets developed by companies in order that they shall not become part of the public domain but rather are kept secret. In particular, the 3D Model File may be protected as

a trade secret if the requirements of section 2 no. 1 of the German Trade Secret Act are met. In that context, it is always critical for the rights holder to take appropriate security measures (e.g. conclusion of non-disclosure agreements, secure server infrastructure etc.) at all times in order to prevent the 3D Model File from being obtained by third parties (e.g. via cyber-attacks). Remedies available for unauthorised use of a 3D Model File which is a trade secret may also extend to the creation and marketing of the 3D Object and/or the infringing product.

In case the 3D Object itself already enjoys patent protection, making a copy of it by means of 3D printing may already constitute a direct patent infringement. In contrast, if a 3D Object is part of a patent-protected object or process, the creation of the 3D Model leading to the aforementioned 3D Object may only qualify as a mere preparatory act for the subsequent 3D printing. However, the creation and distribution of the 3D Model may be considered as an "indirect patent infringement" according to Section 10 of the Patent Act. Eventually, the aforementioned cases need to be distinguished from a situation where the method and/or technology applied for the 3D printing itself might enjoy patent protection.

Relevant stakeholders

Due to the spread of 3D printers for home use as well as the existence of 3D printing as a service, the circle of relevant stakeholders has greatly expanded. Simply put, anyone can create 3D Model Files that could be used by anyone. Stakeholders can therefore range from **private individuals**, design or manufacturing **companies**, 3D **print service providers** to **online platforms** and **marketplaces** for the **sharing** of 3D Model Files.

Of particular interest are operators of 3D printing marketplaces as these stakeholders tend to facilitate the dissemination and execution of the 3D Model Files. Under current case law, marketplaces can usually only be held liable if they are aware of the legal infringement or if such infringement is evident. Since platform operators are, without further investigations, usually unable to recognise whether 3D Model Files uploaded by users infringe third-party IP, rights holders must inform the operator of any infringement in order to achieve deletion of the 3D Model Files from the platform.

However, that will likely change under the new Copyright Directive (expected to be implemented into national law by the Member States by 7 May 2021) and under the upcoming Digital Services Act. Article 17 of the Copyright Directive reinforces the liability of online content-sharing service providers, the main purpose of which is to store and enable users to upload and share copyright protected content in order to generate profit therefrom (which could apply, e.g., to 3D printing sharing platforms). According to the Directive, service providers must **actively** check uploaded content for copyright infringements before its publication (which will in many cases only be possible through technical means such as specialised automatic upload filters). If the content is protected by copyrights, an authorisation from the rights holder (via licence agreement) needs to be obtained, otherwise access shall be disabled or the content be removed. In future, the Commission's recently initiated legislative procedure for a Digital Services Act, intended to replace the E-Commerce Directive and to regulate the liability regime for illegal online content, could further increase the obligations for service providers.

Similarly, with respect to 3D print shops, German case law considers them only liable if they are aware or grossly negligent of the infringement, therefore requiring them to take appropriate measures to prevent illegal copying. However, in that case, no general obligation to verify the 3D Model File's compliance with applicable law exists. Rather, it is sufficient for 3D print shops to publish a notice on their websites prohibiting the 3D printing of protected works or to obtain written assurance from their customers that the 3D Model File is free from third-party IP rights.

In view of the above, and given how easy it is to generate, store and disseminate and print out 3D Model Files of, in some cases, valuable technology parts, the question is how a mechanism could be implemented to prevent unauthorised copies. A possible way could be to implement a central database where the 3D Model File (or at least an electronic "fingerprint" of the respective 3D Model File) would be stored, and which would need to be checked by operators of 3D printers prior to starting the printing process. Such a centralised database may even be established on the basis of blockchain technology.

Remedies in case of infringements

Rights holders will usually first want to send a warning letter to the infringer before taking further action. Regardless of the IP protection regime, rights holders are entitled to injunctive relief, information about revenue generated by the infringing good, as well as damages and further measures (e.g. market recall). In urgent cases a rights holder may file and obtain a preliminary injunction. Some 3D printing platforms also have takedown procedures under which the copyright owner may send a takedown notice to a service provider, requesting the provider to remove copyright infringing material.

Justification of unauthorised use of 3D printing data in times of (COVID) crisis?

The question arises as to whether a lack of supply of medical devices or protective equipment in public emergencies allows further use of IP rights and thus justifies 3D printing as an exception.

3D printing as "private use"?

If the 3D print is made for private purposes, this may not be covered by the scope of protection of the respective IP right. The scope of patent and trademark protection, for instance, in principle sanctions unauthorised **commercial use** of the 3D Model Files and 3D Objects. Copyright protection is not limited to commercial use but contains a limitation of protection regarding private use in Section 53(1) Copyright Act.

However, private use can always only be considered for such actions that do not have a commercial purpose whatsoever. Thus, only the printout of the 3D Object for private use itself is allowed, but not the prior upload of the 3D Model File on a commercial marketplace. Moreover, since few consumers are likely to own a 3D printer as yet, they will often need to use a printer of a commercial service provider. Depending on the circumstances of the individual case, the act of printing out by the print shop may already constitute an infringement regardless of whether or not the costumer intends to use the printout for private purposes.

Note that the limitation for private use in Copyright Law contains further (and rather strict) requirements. That is, private copies are not allowed if a 3D Model File is used that is obviously unlawfully produced or made publicly available unlawfully. Moreover, only a few individual reproductions are permitted, so that products for private use may be printed only in small numbers.

The Order of Use according to section 13 Patent Act

Regarding Patent Law, the public interest may lead to further restrictions on protection. The German parliament recently declared the corona crisis as an epidemic situation of national importance (due to the Act for the Protection of the Population in the Event of an Epidemic Situation of National Importance of 27 March 2020, which amended the Infection Protection Act), authorising the German Ministry of Health to order that an invention can be used in the interest of public welfare or in the interest of federal security.

According to that Act, such order can be issued for medical devices and articles of personal protective equipment. If issued accordingly, the patent owner's exclusive rights in the patent are suspended for the scope of the order under section 13 of the German Patent Act ("**GPA**"). That statutory "override" of patent rights could enable 3D printouts of these products, as the patent owner must accept the use of the patent (although he, she or it in turn receives appropriate renumeration by the Federal Republic of Germany).

Compulsory Licences

In case a patent owner refuses to grant a licence concerning a patent for 3D printing, so-called compulsory licences provide the means to force the patent owner to authorise the use of the patent under section 24 GPA. Compulsory licences may be requested before the Federal Patent Court, but only under exceptional conditions in very limited cases due to their substantial impact on the patent owner's proprietary rights.

Section 24(1) of the German Patent Act has two requirements. First, a compulsory licence may only be granted if the applicant has tried without success to obtain permission from the patent owner to use the invention under reasonable licence conditions. Secondly, a special public interest for the grant of a licence must exist; for example, when a drug with a comparable therapeutic effect would no longer be available for the treatment of a serious illness. If these requirements are met, the Federal Patent Court orders the grant of a non-exclusive licence to the applicant and determines an appropriate licence fee.

The criteria of "public interest" entails in particular a strict legal requirement which can usually only be met in exceptional cases; for example, where people's lives or public order are immediately and clearly at stake (while any less severe remedies or means are not available). Against this background, the use of compulsory licences in the COVID pandemic seems not unlikely.

Use as a justified emergency measure according to section 34 of the German Criminal Code?

According to section 34 of the German Criminal Code, a person who commits an action in order to prevent a present danger to, *inter alia*, life or physical integrity from himself or another does not act unlawfully. The provision is only applicable if the danger cannot be

prevented in any other way and requires that the protected interest substantially outweighs the impaired interest of the other person when weighing the different interests.

Although this section originates in criminal law, it also is potentially applicable in civil law. While this might justify the infringement of IP rights theoretically, it has not yet been applied in IP law. In view of the very strict requirements, these are likely to be fulfilled only exceptionally. With respect to COVID, there could be good arguments in some exceptional cases that this section applies when a vital medical device is urgently needed to treat a life-threatening condition of a patient and the device cannot be acquired elsewhere.

The potential Impacts of Fundamental Rights

Ultimately, fundamental rights can also have an impact on IP protection. Generally, fundamental rights are not directly applicable between private individuals, but only between private individuals and the state. However, they influence IP rights as they are binding for the courts, since fundamental rights must be considered when interpreting the law, especially the scope of limitations. Sometimes their weight can – exceptionally – justify IP infringements.

For example, if urgently needed (but unfortunately IP-protected) medical ventilators, or parts thereof, are printed via 3D printing, the influence of basic rights may overcome the illegitimacy of the infringing act, as here the right to life and the right of physical integrity of patients is at stake (Article 2(2) of the German Constitution and Articles 2(1), 3(1) of the Charter of Fundamental Rights of the European Union).

However, these rights have to be weighed against the fundamental ownership rights of the rights holder (Article 14(1) of the German Constitution and Article 17(2) of the Charter of Fundamental Rights of the European Union). A general justification of infringements would be comparable to an expropriation of the respective IP rights and, therefore, not be proportional, as milder means exist (e.g. the conclusion of licence agreements or, as mentioned earlier, compulsory licences). Thus, justification is only permissible in individual cases under special circumstances and if the action is strictly necessary to save lives.

Conclusion

Both the 3D Model File as well as the 3D Object can each be subjects of IP protection. The risk of infringement of IP rights is particularly high due to the many different parties involved and the fact that 3D Model Files are easy to generate, store and disseminate.

The public interest in the use of IP-protected medical devices and related products does not generally lead to an exclusion of protection. However, limitations (e.g. section 53(1) German Copyright Act) or special provisions regarding the public interest (e.g. sections 13, 24 GPA) may apply. The latter can be seen as a means to readjust the balance between IP protection and public interest. In this context, fundamental rights must be considered when determining the scope of these exceptions. That aside, the public interest justifies the infringement of IP rights only in very exceptional circumstances of individual cases, albeit in connection with a global pandemic such as the ongoing COVID pandemic.

DÜSSELDORF

Fabian Wild / Annika Drabinski

FEDERAL CONSTITUTIONAL COURT ON UPC: GERMAN LEGISLATION FOUND VOID

On 20 Mach 2020, the German Federal Constitutional Court's second senate published its decision of 13 February 2020 on the constitutionality of the German legislation which sought to approve the agreement to establish a Unified Patent Court ("**UPC-Agreement**"). The German legislation has been found void.

Key issues

- Constitutional Court found German legislation on UPC void.
- Court required a two-thirds majority of all members of parliament which had not been obtained in the German *Bundestag*.
- UPC's future unclear: implementation of UPC at least further delayed.

Background

The UPC-Agreement signed as an international treaty by a large majority of the EU Member States in February 2013 marked – together with a number of corresponding EU regulations – the preliminary highlight of the EU's striving for a major patent law reform and the implementation of a patent with unitary effect across (most of) Europe.

The pre-existing system of European patents granted by the European Patent Office which are, in fact, a bundle of applications for patents with national effect centrally filed, was largely seen as too lavish and costly: the validation into national patents often requires a translation of the patent, renewal fees become due on a country-by-country basis, and a nullity suit filed against a national patent derived from a European Patent has only national effect. Thus, the UPC-Agreement was meant to reduce those inefficiencies and to further strengthen the enforcement of patents across the EU by establishing a Unified Patent Court having jurisdiction with regard to European patents with unitary effect that are to be registered with the European Patent Office.

The legal framework provides three conditions for the UPC-Agreement's entry into force: entry into force of the amendments to the Brussels I Regulation; ratification or accession by at least 13 Member States; ratification by three Member States with most European Patents in effect in 2012 (France, Germany, United Kingdom). While the first two conditions could have been satisfied in recent years, the third condition turned out to be the trouble spot.

Despite Brexit, ratification in the United Kingdom was completed in April 2018, although the United Kingdom announced some weeks ago that it will not seek involvement in the UPC in future. In Germany, however, a constitutional complaint was submitted in June 2017 by a German lawyer arguing that the German legislation regarding the UPC-Agreement (i.e. the act of approval) was unconstitutional, *inter alia*, due to "democratic deficits" of the UPC organs. In view of this constitutional complaint, the Federal Constitutional Court preliminarily stopped the legislative procedure by requesting the Federal President to refrain from promulgating the act.

Decision

The long-awaited decision of 13 February 2020 by the Federal Constitutional Court's second senate has now been published (2 BvR 739/17). It holds that the German act of approval is unconstitutional on formal grounds and, therefore, void.

Under German constitutional law, any act that amends or supplements the content of the *Grundgesetz*, i.e. the German constitution, or makes such amendments or supplements possible, requires a two-thirds majority of all members of the legislative bodies, including the *Bundestag*.

The Federal Constitutional Court found that the adoption of the German act of approval in relation to the UPC-Agreement would have required such two-thirds majority. It transfers sovereign rights to the Unified Patent Court, a supranational body, that would – exclusively – exercise jurisdiction to a certain extent. German courts which generally exercise judicial power under the German constitution, would be substituted to the same extent. Basically, the UPC-Agreement is found to constitute a "functional equivalent" to the amendment of the fundamental treaties of the European Union.

The law was ultimately passed with only 35 members of the Bundestag being present. Therefore, despite the unanimity of the vote in the *Bundestag*, it clearly failed to reach the two-thirds majority of all members of the *Bundestag* that the Federal Constitutional Court found to be applicable. The act that passed parliament was therefore declared void.

According to the Federal Constitutional Court, an act of approval to an international treaty that has been adopted in violation of the *Grundgesetz* cannot provide democratic legitimation for any measure subsequently adopted by the EU or a supranational organisation. Thus, the fundamental right of citizens to participate in the democratic decision-making process is violated

Three of the eight judges comprising the second senate expressed a dissenting opinion – an unusual outcome at the Federal Constitutional Court. According to the dissenting judges, the aforementioned fundamental right of citizens to participate in the democratic decision-making process cannot be violated by neglecting the formal requirements of legislature transferring sovereign powers. If that would be the case, further steps towards European integration could be considerably delayed.

Prospects

This decision will at least further delay the implementation of the UPC and the unitary patent since the required ratification by Germany – the last country to ratify the UPC-Agreement – has been stopped by the Federal Constitutional Court – at least for the time being.

To adopt a new act and thereby ratify the UPC-Agreement, Germany would need to initiate a new legislative procedure taking into account the formal requirements stipulated by the Federal Constitutional Court. This may take months. Further, it is unclear whether this new act would remain unchallenged, bearing in mind that several aspects had been

raised in the original complaint which allegedly could lead to the act being void from a constitutional perspective. In its decision, the Federal Constitutional Court did not finally decide on these other aspects of the German legislation but rather dismissed the plaintiff's further allegations as inadmissible. For the reform's proponents, this is equally good and bad news: the Federal Constitutional Court still leaves the door open for such new approach, provided, however, that the two-thirds majority has been obtained. Nevertheless, its ultimate constitutionality can hardly be read between the lines.

Two other recent developments may cast doubts on the implementation of the UPC, at least in the near future. The first is the spread of the coronavirus which will certainly keep German legislative busy in the upcoming months.

Further, the UK's role may cause additional problems: notwithstanding its ratification of the UPC-Agreement in 2018, the UK decided at the end of February 2020 that it will withdraw from the UPC system. This would trigger further delay as the legal framework would need to be adjusted, e.g. regarding the seats of the central divisions of the Court of First Instance, which is, besides Munich and Paris, also London.

More importantly, the UK's withdrawal from the UPC system might also affect the political will in Germany. Without one of the main players being part of the unitary system, it is not clear whether the two-thirds majority of all the members of the German *Bundestag* as required by the Federal Constitutional Court could be obtained. The actual advantages of the UPC system are certainly reduced without the UK sitting at the table.

The future of the UPC remains therefore open. The recent decision by the German Federal Constitutional Court is, however, a huge setback for all proponents of the reform. We will keep you updated on any new developments in the future.

BARCELONA

Josep Montefusco

THE COURT OF JUSTICE OF THE EUROPEAN UNION'S MOST RECENT JUDGMENT INTERPRETING ARTICLE 3(A) OF THE REGULATION CONCERNING SUPPLEMENTARY PROTECTION CERTIFICATES FOR MEDICINAL PRODUCTS: THE TWO-STEP TEST IS HERE TO STAY, BUT AT WHAT COST?

Council Regulation 1768/92/EC of 18 June 1992, concerning the supplementary protection certificates for medicinal products ("**SPC**"), codified as European Parliament and Council Regulation 469/2009/EC of 6 May 2009 (the "**SPC Regulation**"), was enacted almost 30 years ago with the intention of providing a clear and uniform framework for the homogeneous grant of SPC across the European Economic Community. In spite of this good intention, the IP authorities and the Courts of the different Member States have been, and are still today, applying the SPC Regulation in a heterogeneous fashion. It is therefore not surprising that the SPC Regulation continues to be a regular source of referrals of questions from national Courts to the Court of Justice of the European Union ("**CJEU**").

We will briefly review below the most recent episode of this saga, the judgment handed down by the CJEU on 30 April 2020 in the *Royalty Pharma* case (C-650/17).

Article 3(a) SPC Regulation

Doubtlessly, the interpretation of Article 3(a) of the SPC Regulation has been at the fore of these referrals. Article 3 sets the requirements for the grant of an SPC. In particular, Article 3(a) determines that the "product" for which an SPC is being applied must be *"protected by a basic patent in force"*. According to Article 1(b), "product" is the active ingredient or combination of active ingredients of a medicinal product.

The meaning of "*protected by a basic patent in force*" within Article 3(a) has been the subject matter of several referrals to and decisions from the CJEU, particularly in cases where applicants had applied for SPCs for "products" consisting of combinations of two or more active ingredients, relying on basic patents, the claims of which referred to one only of said active ingredients. In its controversial judgment in the *Medeva* case (C-322/10), the CJEU disregarded the so-called "infringement test" and took the view that Article 3(a) was not satisfied in cases where the combination of active ingredients was not "specified" in the wording of the claims of the basic patent. In *Actavis vs Sanofi* (C-443/12), the CJEU drew a line between active ingredients which represent *"the core inventive advance that is the subject of the basic patent"* and *"other active ingredients, not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in general terms"*. In *Actavis vs Boehringer*

Josep Montefusco
Legal 500 EMEA – Patents – Tier 1: Next Generation Partner

IP Stars: Patent star 2020

IP Stars: Trade mark star 2020

Legal 500 EMEA – Copyright – Tier 1: Next Generation Partner

Miquel Montañá
Legal 500 EMEA – Patents – Tier 1: Hall of Fame

IP Stars: Patent star 2020

IP Stars: Trade mark star 2020

Isabel Carulla
Legal 500 EMEA – Patents – Tier 1: Next Generation Partner

Key issues

- The requirement set in Article 3(a) of the SPC Regulation (what is meant by "*a product must be protected by a patent in force*") has been a regular source of requests for preliminary rulings from national Courts to the CJEU since the enactment of the Regulation almost 30 years ago.
- In *Royalty Pharma*, the CJEU has clarified that the "*core inventive advance*" test is irrelevant for the purpose of ascertaining if a product is protected by a basic patent in force in the sense of Article 3(a).
- The CJEU backs the application of the two-step test adopted in *Gilead vs Teva* also to patents including functional claims.
- In a finding with far-reaching consequences, the CJEU held that a product falling within a functional definition included in the claims of a basic patent, but which has been developed after the priority date of said patent as a result of an autonomous inventive step, is not protected by said patent within the meaning of Article 3(a).

(C-577/13), the CJEU found that in order for a basic patent to protect "as such" an active ingredient "as such" within the meaning of Article 3(a), that active ingredient should constitute *"the subject-matter of the invention covered by the patent"*.

Finally, in view of the unsatisfaction produced by its previous decisions, in *Teva vs Gilead* (C- 121/17) the Grand Chamber of the CJEU attempted to offer a definitive answer to the ever controversial interpretation of Article 3(a), by establishing a two-step test. Pursuant to this test, a product not explicitly recited in the claims of the basic patent would nevertheless satisfy Article 3(a) if the claims of the patent relate to the product (1) **necessarily** and (2) **specifically**, as follows:

(1) The product must, from the point of view of a person skilled in the art and in light of the description and drawings of the basic patent, **necessarily** fall under the invention covered by the basic patent.

(2) The person skilled in the art must be able to identify the product **specifically** in light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned.

The *"Royalty Pharma"* referral

This case concerns the degree of "specification" required for a product to satisfy Article 3(a). The facts of the case under review are as follows. Royalty Pharma Collection Trust ("**Royalty Pharma**") owned a patent which claimed dipeptidylpeptidase IV (DPP-IV) inhibitors by means of a functional definition. The claims of this patent did not define any compound structurally. After the filing date of Royalty Pharma's patent, Merck, Sharp & Dohme ("**MSD**"), a licensee of Royalty Pharma, developed the DPP-IV inhibitor sitagliptin on its own, for which MSD obtained a patent, a market authorisation for the medicinal product Januvia and, on the basis of said patent and market authorisation, an SPC for sitagliptin.

Royalty Pharma also requested an SPC for sitagliptin on the basis of its patent and MSD's market authorisation for Januvia. The German Patent Office rejected the application on the grounds that, although sitagliptin satisfied the functional definition of the basic patent as a DPP-IV inhibitor, it did not fulfil Article 3(a) as sitagliptin was not disclosed (specified) in Royalty Pharma's basic patent. Royalty Pharma appealed this decision before the Bundespatentgericht (German Federal Patent Court). Royalty Pharma claimed that the Patent Office's contested decision had overlooked that the contribution and the core of the patented invention did not consist in the use of specific compounds, but in the utilisation of DPP-IV inhibitors (e.g. sitagliptin) to treat diseases such as *diabetes mellitus*.

Considering the doubts it had about the role of the "*core inventive advance*" test in the interpretation of Article 3(a), the Bundespatentgericht referred the following questions to the CJEU:

'1. Is a product protected by a basic patent in force pursuant to Article 3(a) of Regulation (EC) No 469/2009 only if it forms part of the subject matter of protection defined by the claims and is thus provided to the expert as a specific embodiment?

2. Is it not therefore sufficient for the requirements of Article 3(a) of Regulation (EC) No 469/2009 if the product in question satisfies the general functional definition of a class

of active ingredients in the claims, but is not otherwise indicated in individualised form as a specific embodiment of the method protected by the basic patent?

3. Is a product not protected by a basic patent in force under Article 3(a) of Regulation (EC) No 469/2009 if it is covered by the functional definition in the claims, but was developed only after the filing date of the basic patent as a result of an independent inventive step?'

After the referral, the CJEU rendered its judgment in *Teva vs Gilead* embracing the two-step test. However, the German Court did not wish to withdraw its request for a preliminary ruling because it understood that the CJEU had not expressly endorsed the General Advocate's opinion that the "*core inventive advance*" test was irrelevant for the purposes of Article 3(a), and therefore reasonable doubts remained about the role of this test in the examination of Article 3(a) that the CJEU should further clarify.

The judgment

The CJEU first clarified that the relevant test for the purposes of Article 3(a) was the two-step test it had adopted in *Teva vs Gilead*, making it clear that the focus of the analysis should be put on the interpretation of the claims and not in what constitutes the inventive concept of the patent.

Then, the CJEU replied to the first two questions together. In essence, the CJEU ratified the applicability of the two-step test also to patents comprising functional claims. The CJEU held that the fact that a product is not expressly disclosed in the basic patent does not preclude *per se* the grant of an SPC for said product, if the claims of the patent relate "**necessarily**" and "**specifically**" to it. Although the CJEU stated that it was for the national Court to assess if both conditions were met in the case at stake, the CJEU expressed its opinion that the functional claims of the basic patent necessarily included sitagliptin (as this was a DPP-IV inhibitor), but it was less clear if an expert would be in a position to identify sitagliptin specifically. For this purpose, the judgment indicated that the expert should be able to objectively deduce "*directly and ambiguously*" from the specification of the patent at its priority date that sitagliptin fell within the scope of the invention.

Turning to the third question, the CJEU concluded that a product which, despite falling within the scope of a functional definition included in a claim, has been developed after the priority date of the patent as a result of an autonomous inventive step, is not "*protected by a basic patent in force*". The CJEU held that the relevant date for considering the scope of protection of a patent is its priority date. It followed that granting an SPC for a product that had only been developed after the priority date would allow its owner to "*unduly*" benefit from the results of research carried out after the priority date, when said results were not yet known. Likewise, the CJEU affirmed that it would not be in accordance with the objectives of the SPC Regulation, i.e., incentivising research and allowing patent owners to amortise their investment, to grant an SPC for a product which is not protected by the basic patent, in so far as the object of said SPC would not be the result of the research claimed by the basic patent.

Implications

While the most recent judgment issued by the CJEU in the SPC saga appears to have clarified some important aspects, such as the irrelevance of the "*core inventive*

advance" and the prevalence of the two-step test for the purposes of Article 3(a) of the SPC Regulation, the question is, as often happens when the CJEU steps into the SPC field, if this judgment has opened as many questions as it has settled.

First, to satisfy the second step of the test ("***specifically***"), the CJEU found that a product should be within the limits of what an expert could deduce "*directly and ambiguously*" from the specification of the patent at its priority date. Perhaps unconsciously, the CJEU used words having a clear meaning in patent law (novelty, added matter). But did the CJEU really intend to instruct the national Patent Offices and Courts to apply novelty or added matter tests to verify if a claim relates specifically to a product not expressly recited in the claims? Or should "*directly and ambiguously*" be deemed to have a different, less strict, meaning for the purposes of Article 3(a)?

Secondly, the CJEU clarified that a product developed after the priority date of the basic patent by means of an autonomous inventive step cannot be regarded as being protected by said basic patent. Again, the words "developed", "autonomous" and "inventive step" may be interpreted very differently. What is the degree of product development required to preclude the grant of an SPC? Is "developed" the equivalent of "invented", or is it meant to refer to some preclinical or clinical development only? Did the CJEU refer to "inventive step" as the patentability requirement? Is it therefore necessary to reject an SPC application if the product is, or could have been, the subject matter of a separate patent? And what is the meaning of "autonomous" in this context? May a product developed by the same patent owner be the result of an "autonomous" inventive step, or is this condition applicable to research carried out by third parties only? What is the maximum degree of reliance on the teachings of the basic patent required to regard a product as the result of an "autonomous" inventive step?

Conclusion: will *Royalty Pharma* be a painkiller or a headache for Patent Offices and national Courts?

Whilst a lot of questions may arise from *Royalty Pharma*, it is clear that the CJEU appears to have endorsed a tougher approach to the definition of *"protected by a patent in force"* that may raise the bar for SPC applicants. In particular, this judgment may be detrimental for the owners of patents protecting the results of valuable early-stage research ("proof of concept") and benefit patents protecting the fruits of late-stage research (i.e., clinical development). This is indeed tricky, as the SPC Regulation was not intended to favour one type of research over others.

On a different note, *Royalty Pharma* may become a new source of headaches for national Patent Offices, as they may need to start assessing applications not only in view of the classical requirements of Article 3, but also bearing in mind other concepts falling within the realms of the patentability requirements. This will probably make the administrative processes more complex and burdensome and, quite likely, increase the level of litigation before the national Courts.

It would therefore not be surprising in the next few years that national Courts continue to feed the CJEU with further requests for preliminary rulings about the interpretation of Article 3(a). What remains to be seen is if the numbers of referrals will slow down after Brexit, as it is the British Courts which have historically taken the lead in questioning the CJEU on the interpretation of this provision.

BARCELONA

Juan Cuerva de Cañas

LAW 2/2019, DATED 1 MARCH: AMENDMENT OF THE SPANISH COPYRIGHT ACT TO ALIGN IT WITH EUROPEAN LAW (IN ADDITION TO OTHER COPYRIGHT MATTERS)

Spanish Law 2/2019, dated 1 March 2020, entered into force on 2 March. Its purpose is essentially to modify the Spanish Copyright Act[1] by transposing to Spanish law Directive 2014/26/EU of 26 February 2014, and Directive (EU) 2017/1564 of 13 September 2017 ("**Law 2/2019**"). The Spanish legislator, however, has also taken advantage of this Law to supplement or clarify other issues of interest with regard to copyright.

This article contains a brief review of some of the main changes introduced by Law 2/2019 to the Spanish Copyright Act, leaving aside all new provisions in relation to collecting entities which, because of their relevance and extension, will be the subject of more specific analysis in the next edition.

Blocking websites that infringe copyright

Undoubtedly, one of the principal and most important changes introduced by Law 2/2019 is the authority it grants, when the circumstances established by law exist, to the Second Section of the Spanish Copyright Commission to order – *with no requirement for judicial authorisation* – that those websites through which copyrights are infringed be blocked.

As a reminder for readers not familiar with the Spanish Copyright Act, the Spanish Copyright Commission[2] acts through its two Sections. The First Section performs mediation and arbitration functions and supervises the collecting entities, whereas the Second Section is responsible for safeguarding copyrights against their possible breach by the parties responsible for information society services (online infringements).

Should the Second Section of the Spanish Copyright Commission consider that a certain information society service infringes a copyright, it can take measures to (i) interrupt (i.e. suspend) the provision of the infringing service, or (ii) have the infringing content withdrawn. Before adopting such measures, however, the infringing information society service provider must be called on to voluntarily withdraw the alleged infringing content within forty-eight (48) hours.

Juan Cuerva de Cañas
Legal 500 EMEA – Copyright – Tier 1: Rising star

Rais Amils
Legal 500 EMEA – Patents – Tier 1: Rising star

Key findings

- Under the new provisions of the Spanish Copyright Act introduced by the Law 2/2019, the Spanish Copyright Commission is entitled to order, *with no requirement for judicial authorisation*, that those websites through which copyrights are infringed be blocked.
- Law 2/2019 has introduced a new regulation of the author's resale royalty right (*droit de suite*).
- Law 2/2019 transposing to Spanish law Directive (EU) 2017/1564, completes the former regulation of the legal exception in favour of persons with disabilities.
- The Spanish legislator has also taken advantage of Law 2/2019 to amend the current regulation of certain limitations or exceptions, particularly, the fair remuneration for private copying and the limitation applicable to press clippings.

1 Royal Decree 1/1996, dated 12 April 1996.

2 Official body national in scope, dependent on the Spanish Ministry of Culture.

Until now, non-fulfilment of the voluntary withdrawal of infringing content, or of a withdrawal order contained in a final decision of the Second Section of the Spanish Copyright Commission, constituted, on second offence, a very serious administrative offence, sanctioned with a fine of EUR 150,001 to EUR 600,000.

This fine is maintained in the reform instituted by Law 2/2019. However, the fine (primary measure) can now be supplemented by an ancillary measure: when the seriousness and social impact of the infringing conduct so justifies, the Spanish Copyright Commission is authorised to order the cessation of the infringer's activities for up to one (1) year. To render such cessation effective, the Commission may order – *with no requirement for judicial authorisation* – that the providers of intermediary services (such as internet access), electronic payment and advertising services suspend the service that they provide to the infringer.

Regulation of the author's resale royalty right (*droit de suite*)

Another aspect to point out in relation to the amendment of the Spanish Copyright Act by Law 2/2019 is the inclusion in the Spanish Copyright Act of the new regulation of the author's resale royalty right (droit de suite). According to this resale royalty right, the authors of graphic or plastic works –such as paintings, drawings, sculptures, tapestries, ceramics, photographs and video art– are entitled to receive, from the seller, a share of the price obtained for the resale of his or her works, following the first sale by the author.

The resale royalty right is recognised to (i) Spanish authors; (ii) authors who are citizens of other Member States of the European Union; and (iii) authors who are citizens of third countries but who normally reside in Spain.[3] This right is transmitted to the rightfully entitled successors following the death (or declaration of death) of the author and terminates after seventy (70) years have elapsed as from 1 January of the year following the date on which such death (or declaration of death) occurred.

The aforementioned resale royalty right:

a) Applies, in general, to all resales in which the following take part, as sellers, buyers or brokers: art market professionals such as sales rooms (showrooms), auction houses, art galleries, art dealers and, in general, any individual or legal entity that habitually performs brokering activities in this market, and also when any of these activities are carried out online.[4]

b) Arises when the resale price per work of art sold is equal to or greater than EUR 800 (not including taxes).

3 For authors who are citizens of third countries who do not normally reside in Spain, the resale royalty right is recognised only when the legislation of the author's country of citizenship recognises the resale royalty right to authors of EU Member States (principle of reciprocity).

4 Except for acts of resale of the work purchased by an art gallery directly from the author, provided that (i) the resale price does not exceed EUR 10,000 (not including taxes) and (ii) the time elapsed between the first acquisition and the resale does not exceed three (3) years.

c) Can be calculated as an amount, by applying the following scale:

Resale price (in euros; not including taxes)	Percentage
Up to 50,000	4%
From 50,000.01 to 200,000	3%
From 200,000.01 to 350,000	1%
From 350,000.01 to 500,000	0.5%
Over 500,000.01	0.25%

The total maximum amount of the resale royalty right will be 12,500 euros.

Lastly, please note that the resale royalty right is a collective management right held by collecting entities, who are entrusted by law to inform the rights holder and to collect and distribute the amount owing to the authors.

The statute of limitations on the rights holder's action to exercise their resale royalty right before art market professionals expires three (3) years after that resale was notified.

Modification of the regulation of certain limitations or exceptions

Exception in favour of persons with disabilities

Furthermore, Spanish Law 2/2019 harmonises, in the internal market, certain uses of works and other subject matter without the authorisation of the copyright holder in favour of certain persons with disabilities. In particular, Law 2/2019 transposes to Spanish law Directive (EU) 2017/1564[5], despite the fact that the core of this Directive was already contained in the Spanish Copyright Act which, as of 1996 established an exception in favour of persons with disabilities. Thus, new Article 31 ter of the Spanish Copyright Act, as it is currently worded, establishes that:

a) It is possible to reproduce, distribute and communicate to the public works already accessible to the public without authorisation from the copyright holder when such acts (i) are for the benefit of persons with disabilities; (ii) are carried out on a non-profit basis; (iii) are directly related to the disability in question; and (iv) are effected using a procedure or means adapted to the disability and are limited to what the latter requires.

b) In those special cases which do not conflict with the normal exploitation of the work and which are not excessively detrimental to the legitimate interests of the copyright holder, the authorised entities established in Spain which produce accessible format copies of works for exclusive use by persons who are blind, visually impaired or otherwise print-disabled, may carry out the acts indicated in the

5 Directive (EU) 2017/1564 of the European Parliament and of the Council of 13 September 2017 on certain permitted uses of certain works and other subject matter protected by copyright and related rights for the benefit of persons who are blind, visually impaired or otherwise print-disabled, and amending Directive 2001/29/EC on the harmonisation of certain aspects of copyright and related rights in the information society, approved by the European Union to fulfil the international obligations it must assume by virtue of the Marrakesh Treaty of 27 June 2013.

preceding section for exclusive use by such beneficiaries or by an authorised entity established in any Member State of the European Union.

c) For the purpose of this law:

   1. Visual impairment and difficulties accessing printed material, including materials in audio and digital formats, in order to determine the beneficiaries of this section, are understood to be those of persons who:

      a. are blind;

      b. have a visual impairment which cannot be corrected/improved so as to give them visual function substantially equivalent to that of a person who has no such impairment, and who are consequently unable to read printed works to substantially the same degree as persons without such impairment;

      c. have a perceptual or reading disability/difficulties preventing them from reading printed works to substantially the same degree as persons without such disability/impairment, or

      d. are unable, due to a physical disability, to hold or manipulate a book or to focus or move their eyes to the extent that would be normally acceptable for reading.

   2. Authorised entities will mean those non-profit entities which provide education, instructional training, adaptive reading or information access to persons who are blind, visually impaired or who face other barriers to accessing printed material, or which, as public institutions or non-profit organisations, provide these same services as one of their primary activities, institutional obligations or as part of their public interest missions.

These authorised entities have certain legal obligations, in particular to:

a) Distribute, communicate and make available accessible format copies of works exclusively for use by the aforementioned persons with disabilities mentioned above (or by other authorised entities).

b) Take the appropriate steps to discourage the unauthorised reproduction, distribution or communication to the public or making available to the public of accessible format copies.

c) Demonstrate due care in handling the works and the accessible format copies thereof, and maintain a record of such handling.

d) Publish information on the updates made under this exception, with it being sufficient for this purpose to provide an update on its website, with a list of such information to be provided to Spain's Ministry of Culture every six (6) months.

e) Provide the beneficiaries of the exception, the holders of the rights and other authorised entities, on request, with the list of works and formats available and details of the authorised entities with which accessible format copies have been exchanged.

Fair remuneration for private copying

Another relevant legislative change introduced by Spanish Law 2/2019 concerns fair remuneration for private copying. Law 2/2019 establishes that persons (natural or legal) who are not exempt from paying the fair remuneration may request a reimbursement in two (2) specific circumstances:

a) If these persons act as end consumers, justifying the solely professional purpose of the reproduction equipment, apparatus or device, provided that such equipment, apparatus or device (i) is not made available to private users; and (ii) is designed to be used for purposes other than making private copies; or

b) When the material reproduction equipment, apparatus or devices acquired are designated for export or delivery to another country within the European Community.

According to this new regulation, in general, requests for reimbursement cannot be made for amounts below twenty-five (25) euros and the party seeking reimbursement will have one (1) year in which to exercise the corresponding reimbursement action.

Press clippings

Prior to Law 2/2019, the Spanish Copyright Act had already established a limitation applicable to press clippings. According to that limitation, periodic compilations in the form of reviews or press reviews are considered quotations and, when such compilations consist basically of the mere reproduction of newspaper articles for commercial purposes, the copyright holder is entitled to receive equitable remuneration.

Now, by means of Law 2/2019, the Spanish legislator has specified in relation to this limitation that the reproduction, distribution or communication to the public (whether in full or in part) of isolated newspaper articles in a press dossier that takes place within any organisation (whether public or private) will require the authorisation – a licence – of the copyright holders.

In that way, there is currently no longer any doubt that an authorisation (a licence) will be needed not only for (i) preparing/compiling a press review, but also for (ii) its internal distribution; for example, amongst the employees of a company.

MILAN

Andrea Tuninetti Ferrari / Andrea Andolina

AN EMPLOYEE'S INVENTIVE ACTIVITY: THE ITALIAN SUPREME COURT CLARIFIES HOW TO ASSESS EQUITABLE REMUNERATION (IF DUE)

The issue of remuneration for the inventive activity performed by an employee has always been a serious head-scratcher for those Italian companies with an R&D team. Attempts have been made to make it easier for employers and employees to tackle equitable remuneration by amending the relevant pieces of legislation at least a couple of times over the past ten years, but – even though the current version of article 64 of the Italian Industrial Property Code ("**IP Code**") provides a detailed outline of the regulation – there is still a lot of uncertainty, which requires stakeholders to periodically carry out due diligence of the employment agreements (and any other IP-related arrangements with employees) and make adjustments. Negotiating equitable remuneration is never easy.

Case law has contributed to defining the subject-matter, and identifying the practicalities one must be aware of. The latest contribution comes from the Italian Supreme Court of Cassation, which recently ruled on the criteria for the quantification of the remuneration. The Supreme Court's findings partially deviate from the previously established principles.

The remuneration of an employee's inventive activity

Under Italian law, the employer has a right to patent any inventions created by an employee during the performance of their employment agreement; the employee nevertheless maintains the moral right to be considered as the inventor. Any inventive activity must be remunerated.

Remuneration is set out either in:

a) the employment agreement, if the inventive activity expressly falls within the ordinary tasks of the employee; in this case, remuneration for the inventive task is a portion of the salary (article 64(1) of the IP Code);

b) a separate *ad hoc* agreement, if inventing is not one of the regular tasks given to the employee pursuant to their employment agreement (article 64(2) of the IP Code).

Lacking any of the above remunerations, the employee has the right to claim an equitable remuneration (in Italian: *equo premio*) if the inventive activity results in the employer having the right to patent an invention (even if the employer elects not to

Key issues

- The employee's inventive activity must be remunerated by the employer in the employment agreement or in a separate arrangement with the employee.
- Lacking an express remuneration of their inventive activity, the employee has the right to be awarded an equitable remuneration (*equo premio*) if the invention is patented (or even if it is eligible for patent grant).
- The equitable remuneration is generally quantified by using the "German formula", which usually results in heavily relying on the royalties obtained by the employer.
- However, the Italian Supreme Court warns that the above formula should not be interpreted narrowly. There are cases where additional variables, that are beyond the mere amount of the royalties obtained by the employer, may become of relevance in order to assess the importance of the invention. Although these additional variables may not lend themselves to a specific quantification, they nonetheless must be factored into the calculation process.

patent it, exploiting the invention under the trade secret *regime*). This right (i) expires after ten years of the patent grant (or the moment when the invention could have been applied for patent – a moment in time that is difficult to precisely determine), and (ii) can be waived by the employee (if the requirements set out in articles 2113 of the Italian Civil Code and 410 of the Italian Civil Procedure Code are met).

Quantification of the equitable remuneration: the *German formula*…

Italian Courts have generally used the following *formula* (usually referred to as the "German formula") to quantify equitable remunerations:

ER = V * P

(**E**quitable **R**emuneration) = (**V**alue of the invention) * (**P**ercentage)

The value "V" of the invention is determined based on the royalties that have (or would have) been paid for the invention, actually or potentially (assuming a fictitious scenario where an employer has to obtain a licence to use the invention in the workplace).

The percentage "P" is determined as a result of a combination of the following *criteria*: (i) the employee-inventor's contribution in determining the technical problem to be solved; (ii) the employee-inventor's contribution in proposing the solution to the technical problem; and (iii) the ordinary tasks of the employee-inventor.

Sometimes the *formula* is adjusted by referring to other variables, if applicable or relevant, such as: (iv) the compensation already received by the inventor; and (v) the contribution that the inventor has received from the employer's organisation.

… and the "equitable corrections" to the equitable remuneration according to the Italian Supreme Court

The Italian Supreme Court notes that the problem with the *German formula* is that, when rigidly applied, that *formula* may deceive the appraiser into missing certain material variables which normally affect the commercial exploitation of an invention. These variables must also be factored into the *formula*.

The case that was recently considered by the Supreme Court shows the importance of correctly factoring the commercial exploitation of the invention for the purposes of quantifying the equitable remuneration:

- the case concerns the remuneration of an inventor in the steel manufacturing business;
- the employee challenged the employer's quantification based on a strict application of the *German formula:* the employee argued that calculating a simple total based on the royalties actually paid to the employer by the licensees was not fully representative of the commercial value of the invention; and

- the employee claimed that – especially in highly specialised and complex businesses such as steel manufacturing – a patented invention is never a stand-alone asset, but it is part of a bigger inventive idea, eventually covered by multiple patents. In the case at issue, for instance, the patented invention was the logical and technological premise for subsequent inventions patented by the employer (and exploited in the market).

The Supreme Court granted the employee's argument, recognising an "*equitable correction*" (of the *German formula*) as legitimate, thereby allowing the introduction of new variables.

Although these additional variables may be *per se* difficult or impossible to quantify at times, they are capable of playing an essential role in the determination of the overall importance of the invention, beyond simply the total amount of royalties generated by licensing the very invention under discussion out to the market.

MILAN

Andrea Tuninetti Ferrari / Filippo Maria Volpini

THE SURVIVAL OF DIGITAL DATA

A few years ago, news was reported about Bruce Willis having complained about Apple's company policy, which prevented him from "bequeathing his digital music collection, held on his 'many, many iPods', to his children when he dies."[1] So, what about his social media accounts, chat conversations or email accounts? 2020 may be the right time to answer. Or not?

Key issues:

- In the online world, people generally leave behind countless traces, such as purchasing preferences, images, passwords; this myriad of information gives shape to the digital identity;
- the Recital 27 of GDPR expressly excludes from its scope the data regulation of deceased persons while acknowledging the possibility for Member States to regulate the matter autonomously;
- the Italian Privacy Code recognises the possibility for the data subject to dispose in relation to his or her digital inheritance, specifying, however, that the possible prohibition cannot cause prejudice "*to the exercise by third parties of the patrimonial rights deriving from the death of the data subject as well as the right to defend their interests in court*";
- some social networks, such as Facebook and Instagram, offer the possibility to convert the profiles of deceased people into commemorative pages;
- the National Council of Notaries has reconstructed the issue and seems to have found a solution to regulate the digital inheritance through the so-called *post-mortem* mandate.

In the digital world, death is not such a simple and intuitive concept; indeed, one could provocatively say that, perhaps, it represents nothing more than a mere utopia.

When an individual walks through the online world, he/she leaves behind countless traces, such as: documents, images, videos and conversations. This myriad of information, often contained in password-protected accounts, shapes his/her so-called 'digital identity.'

Digital identities do not merely dissolve following the death of the natural person to whom they belong, but potentially remains on the net forever. Therefore, from the very beginning we see the importance of acquiring greater awareness, taking care of our digital heritage and clearly establishing its fate for when we will no longer be in this 'offline' world.

If one thinks for a minute, the fact is, he/she would realise that our digital heritage, in addition to physical devices such as hard drives and USB keys, involves a considerable amount of heterogeneous personal data, including social network profiles, online banking, email accounts, cloud storage spaces, chats, multimedia files, software licences and cryptocurrencies (this is certainly not exhaustive).

The management of all this personal data involves not only the legal issues of inheritance law but also ethical issues, which become even more complicated when the deceased person formerly earned money via the Internet. A clear example of such a case is provided by YouTubers, Switch gamers, Instagram's Influencers or, more generally, by all those who generate online content.

Regulatory scenario of deceased persons' data

In Italy, as in many other countries, there is no specific legislation on succession in digital heritage.

The personal data of deceased persons are excluded (in recital 27) from the scope of the GDPR, which acknowledges the possibility for Member States to regulate the matter autonomously, with clear implications for the harmonisation of the single digital market;

1 https://www.theguardian.com/technology/shortcuts/2012/sep/03/bruce-willis-v-apple-owns-music-ipod.

even in cases of processing for the purpose of archiving (recital 158) or historical research (recital 160), the applicability of the GDPR to deceased persons is excluded.

The Italian Privacy Code (Legislative Decree 196/2003, hereinafter, the "***Code***") in its pre-GDPR version, article 9 (now repealed), provided that, in the event of the death of the person concerned, his/her rights could be exercised "*by those who have a personal interest or act to protect the person concerned or for family reasons worthy of protection.*"

Legislative Decree 101/2018, which amended the Code to ensure its consistency with GDPR, came into force on 19 September 2018 and introduced article 2-*terdecies* of the Code. This new provision takes over the diktats of the repealed article 9, providing that "*the rights referred to in Articles 15 to 22 of the Regulation referring to personal data concerning deceased persons may be exercised by those who have an interest of their own, or act to protect the data subject, as his representative, or for family reasons worthy of protection.*"

In the new normative formulation, therefore, the rights that can be exercised after the death of the data subject have explicitly been identified in those "*referred to in Articles 15 to 22 of the Regulation,*" i.e. the so-called data subject's rights (right of access, right to rectification, right to be forgotten etc.), while in the previous version the formulation was broader.

The main innovation of the new piece of legislation, however, is to be found in paragraph 2 of article 2-*terdecies* of the Code, where, in relation to the "*information society services*", the interested party now has the right to prevent third parties, by means of an express declaration of will (presented to the data controller or communicated to the same), from exercising the data subject's rights on behalf of the deceased data subject.

The new Code, therefore, recognises the possibility for the data subject to dispose in relation to his or her digital inheritance, i.e. the rights of his or her digital identities, specifying, however, that the possible prohibition cannot cause prejudice "*to the exercise by third parties of the patrimonial rights deriving from the death of the data subject as well as the right to defend their interests in court*" (see paragraph 5, article 2 *terdecies*).

Rather than a digital will, this seems to be more of a right of veto, whereby the data subject may arrange the *post mortem* disposal of his or her digital data during his or her lifetime, provided that "*the will of the data subject to prohibit the exercise of the rights referred to in paragraph 1 must be unambiguous and must be specific, free and informed*" (paragraph 3).

Information is unclear on the limitation to the right of the data subject contained in the second part of the paragraph 3, whereby "*the prohibition may concern the exercise of only some of the rights referred to in that paragraph.*" Reference is made to the rights of the data subject referred to in paragraph 1 (Articles 15 to 22 of the GDPR), although it is not clear why the prohibition may concern only 'some' of those rights, or which it applies to.

This is an unfortunate legislative formulation, which will undoubtedly lead to serious interpretative doubts in the foreseeable future, when the exercise of the rights inherent in one's digital heritage will become increasingly widespread.

The digital will document and other precautions

Odd as it may seem, the best solution to protect one's digital assets may seem to remain an old-school, offline will, whereby one expressly outlines how he/she wants the digital heritage to be managed.

The National Council of Notaries has been dealing with this issue since 2007 and has also adopted a catalogue of warnings (such as: "*entrusting someone with the password of an online bank account does not mean leaving them the resource*") and suggestions (such as: "*social networks, email, remote disks, in short, all the online services that you use are based in Italy? If the answer is no, remember that if you do not do it on time, recovering your data could lead to expensive disputes with international elements*")[2].

The National Council of Notaries has reconstructed the issue through the general categories of law and have found a solution to regulate their digital inheritance through the so-called *post-mortem* mandate. This kind of mandate is allowed in our legal system and can be used to give a trusted person credentials for access and specific instructions on what to do in case of death. The fact that the activity, which is the subject of the mandate, does not have a patrimonial character, prevents the mandate being considered contrary to the prohibition of agreements as to succession. The National Council of Notaries also specifies in its study that "*Passwords, credentials and mortis causa succession*", "*this seems to be exactly the case since, as has already been observed, allowing access to a physical or online resource is not equivalent to intervening on the legal relations, dominical or otherwise, of which the materials that the resource itself holds are the object.*"

On the contrary, a traditional will document is not considered, at the moment, a viable method for the transmission of access keys to one's own digital heritage. In addition, because of the peculiar characteristics that it has in our system (think, above all, of advertising) that makes it unsuitable for the transfer of data that by their nature should remain confidential (access credentials, usernames and passwords).

It would be desirable for each of us to "clean up" our online presence and remove unnecessary accounts and profiles and finally, when choosing a service, for example, a mailbox, to read the conditions of the service so as to avoid, where possible, entering into contracts with complex cancellation conditions.

A few practical examples: the Google and Facebook policies

It is not always easy for heirs to be able to interact with providers when trying to secure the deceased person's oblivious account details.

2 https://www.notariato.it/sites/default/files/Ereditx_Digitale.pdf

Email service providers have very different policies. For instance, Yahoo requires the non-transferability of the account whose content is completely deleted upon notification of the death of the account holder. Google, on the other hand, offers its users the possibility to predetermine who will have access to their account and whether it should be deleted through the 'Inactive Account Management' function.

However, if the user has not availed of this option, Google's policy requires the account holder to co-operate with close relatives, considering the possibility of closing the account or obtaining some of its content, but without ever providing access data, which shall remain subject to protection in accordance with the confidentiality of the user, even after his or her death.

Some social networks, such as Facebook and Instagram, offer the possibility to convert the profiles of deceased people into commemorative pages. Leaving aside the ethical issues related to mourning (and the good taste of such a choice), it should be noted that the policy of Facebook has changed following a ruling of the German Federal Court of Justice (in Karlsruhe on 12 July 2018). That obliged Facebook to provide parents with access to the profile of their daughter as a result of her death having occurred in uncertain circumstances. The court's reasoning was to assimilate Facebook as a 'paper' diary that can undoubtedly be "inherited", especially when there are particular and significant interests as in the present case.

Facebook, therefore, today allows users to identify an 'heir contact' who will be allowed to access and manage the account of the deceased, with some limitations.

If that 'heir contact' does not opt to delete the profile, the account will then be transformed into a commemorative account, whereby the heir(s) may write posts and edit the profile image, but has no power of interaction with respect to chats, posts and activities undertaken in the past by the *de cuius*, for which it considered the prevailing interest to be that of protecting the confidentiality of the original user.

Conclusion no. 1: As of today, the matter of post mortem digital heritage, in fact, continues to be governed by the terms and condition of Internet service providers

In light of the abovementioned arguments, the issues related to digital identity and digital heritage are topical but still lack coherent and efficient (EU or state) regulation, resulting in a situation where, once again, it is the service providers (and their users), who have address these issues by creating a 'best' practice.

In this situation, we can only that the popular adage "*prevention is better than cure*" be followed. Therefore, initially, ensure that people are aware of their digital identities and everything that comprises those (a search of their accounts, elimination of unused or superfluous profiles, and choosing services with more flexible cancellation conditions). Secondly, to ask them what fate they want for their digital heritage, providing a detailed guide to their heirs (the writers and/or custodians of the so-called digital will document, drawing up a list of passwords and access data).

Remember, digital personal data does not die with the person concerned; indeed, it is potentially eternal.

Conclusion no. 2: What should drive digital heritage regulation?

From a *de jure condendo* perspective, legislators' attention must be drawn to such vital issues, given the importance (including economic) of the underlying interests, where there is a risk of frustrating digital assets of great value, without any possibility of transmitting them to their heirs.

From a subjective point of view, discussions regarding a subject's digital inheritance requires: (i) identifying the user and the jurisdiction where he/she constructs his/her digital identity; then (ii) tracing him/her back to a unique heritage; from an objective viewpoint. On the other hand, it is possible to distinguish between: (i) online digital heritage; and (ii) offline digital heritage, which can and must be the subject matters of different regulations.

Another interesting prompt concerns the notion of 'digital asset.' Italian jurists tend to consider digital assets as any other " *tangible or intangible entity, legally relevant*" contemplated under article 810 of the Italian Civil Code, and to be "*suitable to satisfy interests worthy of protection*". If one agrees with this thesis, it follows that digital data are part of an individual's assets.

If one looks in general at the system of succession law in Europe, it can be seen that it differs considerably in each Member State, so much so that it to attempt a comparison between different legal systems would be complex.

It is precisely for this reason that it is considered that regulatory intervention in the succession of digital assets should not come from the national legislator but rather from the European legislator, in order to avoid other legal conflicts. Thus, rather than waiting for each Member State to issue its own law regulating the digital inheritance, and then intervening with a uniform approach, the European legislator could use the form of a Regulation (as already in place for the protection of personal data) in an area of law where most Member States yet to adopt any regulation. This could be a potent tool both when attempting to avoid further fragmentation in the field of inheritance and to complete the standardisation work started with Regulation (EU) 650/2012.

Pending regulatory intervention, it is up to legal practitioners, in particular notaries and lawyers, to create a good enforcement practice.

In the *interim*, these practitioners may advise their clients that it is best to: (i) reconstruct a digital identity (by deleting unused or superfluous profiles and giving preference to online platforms with more flexible cancellation conditions); and to (ii) ask them what fate they want for their digital assets, providing detailed guidance to their heirs (drafting of the so-called "digital will document", drafting the list of passwords and access data &c.).

The practicable way at the moment is to draw up a *post-mortem* warrant. Clearly, this instrument remains valid and usable as long as, following the death of the principal, it does not lead to a mandate being given to the agent undertake acts which would require the attribution of inheritance rights in contempt of the prohibition of agreements as to succession.

On the other hand, as far as property rights are concerned, and pending legislative reform, it may be useful to use the provisions of the traditional will, although possible contradictions with the limitations laid down in the contract with the provider may be expected.

Currently, most service providers have partially modified their general terms and conditions by providing that, where the user is resident in one of the Member Countries/States, the applicable law and the competent court will be those of his/her habitual place of residence.

In the case of an Italian deceased person who has also drawn up a digital will document, the platform may not refuse to communicate to the heirs or legatees the credentials to access the user's profiles and take possession of data or content of patrimonial value (given the invalidity in our legal system of any clause limiting the succession in the assets, including digital). Therefore, contractual access restrictions would not be valid, where there is a valid testamentary provision that the provider cannot fail to comply with.

However, it will be necessary for users to make a survey of their digital identities i.e. of their presence on the web and, consequently, of the existing contracts with the various service providers. Even the acceptance of the conditions of use of a social network that provides for the deletion of one's data after death could be considered a valid clause, which also takes the form of a *post-mortem* mandate having as its object the destruction of digital content or correspondence and in which the mandated representative is itself the provider. Although the average user may be unaware of the general terms and conditions of the contracts he or she enters into with the various services available to the digital society, it is advisable for legal practitioners to ensure that the user is aware of the consequences of his or her actions, which without the necessary precautions could lead to such definitive consequences as the irreversible loss of his or her digital data.

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Florian Reiling[1]

LEGAL OBSTACLES TO THE EXPLOITATION OF GERMAN IP RIGHTS IN THE AFTERMATH OF AN M&A TRANSACTION

Foreign direct investment from China has been an essential part of the Chinese Government's reform agenda since 2000. Whereas the Chinese Government previously focused on attracting foreign direct investment and promoting growth and employment in its own country, its "Going Global" strategy has been encouraging Chinese companies to undertake direct investments in other industrialised countries for almost 20 years now.

Due to the establishment of subsidiaries, company takeovers and mergers abroad, Chinese companies strengthen their market position and competitiveness in the international market. An increasing number of Chinese investors are very interested in mergers and acquisitions ("**M&A**") in Germany, not only to gain access to the German market, but especially to obtain valuable technologies, the corresponding intellectual property rights ("**IPR**") and know-how of German companies.

However, Chinese investors must also be aware of the legal obstacles they may encounter in the course of an M&A transaction. According to German law, foreign bidders are not always allowed to acquire German companies and to exploit the technologies back in their home countries without restrictions.

The purpose of this paper is to point out which legal restrictions Chinese investors should consider during the acquisition of a German company, in particular with regard to the Foreign Trade and Payments Ordinance (*Außenwirtschaftsverordnung*), the Act on Employee Inventions (*Arbeitnehmererfindungsgesetz*) and research and development contracts ("**R&D contracts**"), and how they can best ensure the acquisition of all the IPR of the German target.

Restrictions imposed by the Foreign Trade and Payments Ordinance

Chinese investors may be prohibited from acquiring a German company by the Federal Ministry for Economic Affairs and Energy on the basis of the Foreign Trade and Payments Ordinance. In principle, the Federal Ministry for Economic Affairs and Energy is authorised to examine any acquisition by purchasers established outside the territory of the EU and EFTA (Iceland, Liechtenstein, Norway and Switzerland), provided that the transaction results in the foreign purchaser obtaining at least 25 percent of the voting rights in the domestic target. For critical infrastructure (energy, water, healthcare, media, etc.) as well as for certain defence-related sectors, the threshold value which

Key issues

- Investors from outside the territory of the EU and EFTA can be prohibited from entering the German market or be subject to restrictions under the Foreign Trade and Payment Ordinance.
- A respective evaluation takes place if the foreign purchaser intends to obtain at least 25 percent of the voting rights in the target company (if the target is part of the critical infrastructure the applicable threshold value is at 10 percent). A certificate of non-objection issued by the Federal Ministry for Economic Affairs and Energy can grant legal certainty to the purchaser.
- The exploitation of acquired IPR back in China may entail unexpected financial consequences, if the implications relating to publicly funded research projects are not adequately taken into account (e.g. potential repayment obligation of received funding or restrictions regarding the use of generated IPR).
- Further implications may result from the application of the German Act on Employee Inventions, the adherence to which is an essential part of any due diligence process, in particular with regard to the claiming of employee inventions and the payment of an appropriate employee invention remuneration.

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makes the investment examination mandatory was lowered from 25 to 10 percent at the end of 2018 by an amendment to the law.

If the acquisition of a domestic company or a stake in a domestic company by a non-EU/EFTA resident poses a threat to the public order or security of the Federal Republic of Germany, i.e. affects fundamental interests of the public (under the current draft legislation the material threshold will be lowered to a mere "probable adverse effect"), a prohibition order can be issued pursuant to Section 59 of the Foreign Trade and Payments Ordinance which prevents the transaction. The Federal Government also has the power to impose remedies on the parties. These provisions are intended to protect the German economy against the outflow of knowhow and technologies to countries outside the territory of the EU and EFTA.

In order to avoid the risk of a subsequent prohibition of the M&A transaction and to obtain some legal certainty, Chinese purchasers are advised to request a certificate of non-objection from the Federal Ministry for Economic Affairs and Energy (*Unbedenklichkeitsbescheinigung*) prior to closing the acquisition.

R&D contracts

Chinese purchasers should pay special attention to possible R&D contracts involving the target company.

R&D contracts are typically concluded between companies or between companies and nonuniversity/university research institutions in order to research and develop new technologies. Over recent years, the number of such contracts has increased significantly. Generally, the following types of contracts can be distinguished: contract research and research cooperation contracts. Whereas in the case of contract research, a company outsources its research activities to a university or nonuniversity research institution, in the case of a research cooperation contract, both partners contribute to the success of the project through participation in certain activities. Research cooperation contracts are not only concluded between science and industry, but in many cases also between companies that are active at different stages of production and manufacturing (vertical cooperation) or that are actually competitors and want to reduce their own expenses for research and development work by means of cooperation (horizontal cooperation).

In the context of an M&A transaction, Chinese investors must pay particular attention to R&D contracts between companies and research institutions that involve publicly funded projects, as financial support for these kinds of projects is frequently linked to certain funding conditions set by the Federal Government (so-called "Auxiliary Terms and Conditions for Funds Provided by the Federal Ministry of Education and Research to Commercial Companies for Research and Development Projects on a Cost Basis" – "**NKBF 2017**"). These funding conditions are an integral part of every notification of a grant, unless expressly stated otherwise therein.

They provide, inter alia, that the recipient of a grant may, in principle, exploit the results obtained from the project, such as know-how, industrial property rights and copyrights, outside the European Economic Area (EEA) and Switzerland only with the prior written consent of the Federal Ministry of Education and Research. The Federal Ministry of Education and Research is entitled to make its approval conditional on the payment of appropriate remuneration up to the amount of the grant. Exploitation without prior consent may result in repayment of the entire grant amount. Against the background of

this regulation, which is intended to ensure that projects funded by the Federal Government primarily benefit the domestic market, Chinese purchasers must thus, in the case of the acquisition of a target company that is involved in a publicly funded project, usually take into account the payment of appropriate remuneration or even the repayment of the entire funding amount to the Federal Government. As both can result in high costs, it is essential for the Chinese purchaser to carefully examine the origin and the funding of the IPR of the target during the IP due diligence process.

The German Act on Employee Inventions

Finally, the provisions of the German Act on Employee Inventions play an important role in the course of M&A transactions. The purpose of the Act is to create an appropriate balance of interests between the employee making an invention in the course of his or her work and the employer for whose account and with whose resources the invention has been made. Since most German patents and utility models are based on employee inventions, Chinese purchasers need to be aware of the particulars of the German Act on Employee Inventions when acquiring a German target in order to avoid unexpected recovery or compensation claims by employees with regard to their inventions.

According to the Act on Employee Inventions, the inventor initially owns the rights in an invention. However, the employer can claim the right to an employee's invention in return for appropriate compensation. Whereas before 2009 the employer had to claim the invention in writing, now the employer's claim to the invention is deemed to be declared if he does not expressly release the invention to the employee within four months from receiving the invention report. Thus, if an employee's invention was not properly claimed by the employer (until 2009) or subsequently released (since 2009) and furthermore not transferred in any other form to the employer at a later time, all rights to the invention remain with the employee. In such a case, the latter may request the transfer of the patent right and/or claim compensation from the employer due to previous exploitation.

The amount of the inventor's compensation is calculated in accordance with Section 9 of the German Act on Employee Inventions on the basis of the economic exploitability of the invention, the employee's role and position in the company and the company's share in the development of the invention. As remuneration, a one-off lump-sum payment or an ongoing payment to the employee can be agreed. Since, depending on the importance of the invention, the employee's claims to compensation can be quite high, Chinese purchasers must assess, before acquiring the target company, whether and to what extent one-off or ongoing compensation claims of employees must still be fulfilled. They are recommended to counter such risks in advance of the transaction, for example by means of appropriate agreements with the relevant employees or through contractual guarantees and indemnification obligations of the seller.

Conclusions

Since industrial property rights and know-how constitute an essential factor in the value of a company, the origin and ownership of these rights should be carefully examined in advance of the M&A transaction. Chinese investors seeking to acquire a target in Germany must be aware of the restrictions imposed by the Foreign Trade and Payments Ordinance, which may prevent their entry into the German market. In addition, the exploitation of the acquired IP rights in China may be more expensive for the Chinese purchaser than assumed. Two (out of several other) reasons for this assessment are represented by (i) the German provisions for publicly funded research and development projects and (ii) the German Act on Employee Inventions.

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We would like to thank the following people for their contributions to this publication:

Tom Blanchet
Associate
Paris
T: +33 1 4405 5209
E: tom.blanchet@cliffordchance.com

Andrea Andolina
Associate
Milan
T: +39 02 8063 4240
E: andrea.andolina@cliffordchance.com

Iolanda D'Anselmo
Lawyer
Milan
T: +39 02 8063 4294
E: iolanda.danselmo@cliffordchance.com

Nicolas Hohn-Hein
Senior Associate
Dusseldorf
T: +49 211 4355 5664
E: nicolas.hohn-hein@cliffordchance.com

Fabian Wild
Associate
Dusseldorf
T: +49 211 4355 5967
E: fabian.wild@cliffordchance.com

Juan Cuerva de Cañas
Abogado
Barcelona
T: +34 93 344 2279
E: juan.cuerva@cliffordchance.com

FURTHER CONTRIBUTORS

Alejandro Acosta Rodriguez	Nico Schur
Annika Drabinski	Luca Anna Topp
Uche Eseonu	Filippo Maria Volpini
Sarah Kleinschumacher	

CONTACTS

Australia

Tim Grave
Partner
Sydney
T: +61 28922 8028
E: tim.grave@cliffordchance.com

Sam Luttrell
Partner
Perth
T: +61 892625 564
E: sam.luttrell@cliffordchance.com

Belgium

Thomas Vinje
Partner
Brussels
T: +32 2 533 5929
E: thomas.vinje@cliffordchance.com

Dieter Paemen
Partner
Brussels
T: +32 2533 5012
E: dieter.paemen@cliffordchance.com

China

Ling Ho
Partner
Hong Kong
T: +852 2826 3479
E: ling.ho@cliffordchance.com

France

Diego de Lammerville
Partner
Paris
T: +33 1 4405 2448
E: diego.delammerville@cliffordchance.com

Loïc Lemercier
Counsel
Paris
T: +33 1 4405 5916
E: loic.lemercier@cliffordchance.com

Germany

Claudia Milbradt
Partner
Düsseldorf
T: +49 211 4355 5962
E: claudia.milbradt@cliffordchance.com

Italy

Florian Reiling
Counsel
Düsseldorf
T: +49 211 4355 5964
E: florian.reiling@cliffordchance.com

Luciano Di Via
Partner
Rome
T: +39 064229 1265
E: luciano.divia@cliffordchance.com

Andrea Tuninetti Ferrari
Senior Associate
Milan
T: +39 02 8063 4435
E: andrea.tuninettiferrari@cliffordchance.com

Poland

Krzysztof Hajdamowicz
Counsel
Warsaw
T: +48 22 429 9620
E: krzysztof.hajdamowicz@cliffordchance.com

CONTACTS

Russia

Torsten Syrbe
Partner
Moscow
T: +7 49 5725 6400
E: torsten.syrbe@cliffordchance.com

Singapore

Nish Shetty
Partner
Singapore
T: +65 6410 2285
E: nish.shetty@cliffordchance.com

Spain

Miquel Montañá
Partner
Barcelona
T: +34 93 344 2223
E: miquel.montana@cliffordchance.com

Josep Montefusco
Partner
Barcelona
T: +34 93 344 2225
E: josep.montefusco@cliffordchance.com

The Netherlands

Jaap Tempelman
Counsel
Amsterdam
T: +31 20 711 3192
E: jaap.tempelman@cliffordchance.com

United Kingdom

Vanessa Marsland
Partner
London
T: +44 20 7006 4503
E: vanessa.marsland@cliffordchance.com

Stephen Reese
Partner
London
T: +44 20 7006 2810
E: stephen.reese@cliffordchance.com

United States

Daryl Fairbairn
Counsel
New York
T: +1 212 878 4960
E: daryl.fairbairn@cliffordchance.com

Steve Nickelsburg
Partner
Washington
T: +1 202 912 5108
E: steve.nickelsburg@cliffordchance.com

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www.cliffordchance.com

Clifford Chance, Königsallee 59,
40215 Düsseldorf, Germany

2005-000383