Legal & Regulatory Update

EU Legal & regulatory update – June 2014

ABSTRACT

UK and European content is compiled and written by Bird & Bird LLP, an international law firm which advises Life Sciences clients on:

- licensing intellectual property and know-how
- R&D agreements and other commercial contracts
- clinical trials
- regulatory issues
- risk management
- private equity, venture capital, joint ventures, strategic alliances, mergers & acquisitions and stock exchange listings
- patent & trade mark litigation
- data protection
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- product liability

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This section is intended to be a synopsis of recent legal developments and is not intended to be exhaustive. If any issue referred to in this section is to be relied on, specific advice should be sought.

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GENERAL COURT OVERRULES EUROPEAN COMMISSION ON ORPHACOL MARKETING AUTHORISATION

Facts

Article 10a of EU Directive 2001/83/EC, as amended, provides a route by which an applicant seeking marketing authorisation for a medicinal product can secure such an authorisation without the need to submit pre-clinical data and clinical trial data as to safety and efficacy, or to cross reference (after expiry of the period of regulatory data protection) an existing marketing authorisation for the same active substance based on such data. Article 10a requires that the applicant:

> *"demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the [EU] for at least 10 years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I".*

It goes on to provide that "[in] that event, the test and trial results are to be replaced by appropriate scientific literature".

Laboratoires CTRS had sought a centralised marketing authorisation under the Article 10a route for its medicinal product Orphacol (cholic acid), used to treat two rare, but serious liver disorders. Cholic acid had not previously received a marketing authorisation in the

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European Union. Despite a recommendation from the relevant standing committee of the European Medicines Agency that a marketing authorisation be granted in respect of Orphacol, after seeking unsuccessfully to pressure the standing committee into changing its opinion, the European Commission eventually adopted an implementing decision refusing a marketing authorisation, as it took the view that there was no legal basis for granting such an authorisation in this case.

Decision

On July 4 2013 the General Court upheld an appeal by Laboratoires CTRS seeking to annul the European Commission's decision. In so doing, the court rejected all three reasons advanced by the European Commission in reaching its decision.

First, the European Commission asserted that the well-established medicinal use of cholic acid had not been proved, arguing that its use as a hospital preparation between 1993 and 2007 was insufficiently systematic and well documented to prove well-established medicinal use over a period exceeding 10 years. In support of this, it argued that "hospital preparations" are not covered by Directive 2001/83/EC. However, the court held that these are covered by Article 5(1), which subsequently relieves certain medicinal products from the provisions of the directive, such as the need to secure a marketing authorisation, where these are:

> *"supplied in response to a bona fide unsolicited order, formulated in accordance with the specification of an authorised health care professional and for use by an individual patient under his direct personal responsibility".*

The European Commission's second argument was that it was inconsistent with the well-established medicinal use route for Laboratoires CTRS to have been able to rely on "exceptional circumstances" as a reason for not providing comprehensive data on safety and efficacy, as is allowed by Article 22 of Directive 2001/83/EC where the applicant can show that it is unable to do so for "objective, verifiable reasons". The court also rejected this argument, noting that nothing in the legislation precludes the simultaneous application of the concepts of "well-established medicinal use" and "exceptional circumstances"; the court observed that Laboratoires CTRS had "objective, verifiable reasons" in the rareness of the disorders in question and in ethical considerations. Indeed, the conditions that Orphacol was used to treat were sufficiently rare for it to have secured designation as an orphan medical product.

Finally, the European Commission argued that the grant of such a marketing authorisation would undermine the objectives of the EU Paediatric Regulation (1901/2206) and the protection of innovation. As to the second point, the court held that this had not been presented in the European Commission's decision as a free-standing ground for refusing to grant the marketing authorisation, but merely as a remark. As to the first point, the court noted that Article 9 of the Paediatric Regulation specifically excludes applications under the well-established medicinal use route from the relevant requirements of the regulation. Thus, the court also rejected this third line of argument.

Comment

This decision represents a setback for the European Commission in its attempts to limit the scope of the well-established medicinal use route for securing marketing authorisation for a medicinal product. The European Commission has in the past successfully sought to limit reliance on the well-established medicinal use route in cases where it has been used in an attempt to circumvent the regulatory data protection afforded to new active substances which have already received marketing authorisation. An example of this is the Plavix case in Germany, as a result of which the European Commission threatened proceedings against Germany for allowing such circumvention to take place; however, the European Commission did not then proceed, presumably because it received satisfactory assurances from the German authorities that their practice had changed. However, the Orphacol case is different and concerns an active substance that had not previously received a marketing authorisation in the European Union. It is clear that by extending its hostility to the well-established medicinal use route to this different situation, the European Commission has overreached itself.

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PROMOTING EARLY ACCESS TO NEW MEDICINES — BUILDING AN "ADAPTIVE LICENSING" FRAMEWORK

Adaptive licensing

Referred to by various terms (staggered approval, managed entry, progressive authorisation), "adaptive

licensing" is a departure from the traditional approach to authorising new medicinal products. Under the current system, the initial grant of a marketing authorisation (MA) tends to be regarded as a "magic moment", at which point the medicine is suddenly held to be safe and efficacious. The "adaptive licensing" (AL) approach embraces the reality that, due to restricted patient exposure during clinical trials, it is often not until the post-marketing phase that information on the benefit-risk profile of the product as used "in real life" is obtained, and that there are certain situations in which a degree of acknowledged uncertainty over the benefit-risk profile of a product at the time of initial MA may be acceptable to regulators, patients and payers alike. Given this, medicines regulators have been discussing developing the concept of AL, namely, a prospectively planned, flexible approach to licensing whereby an initial, limited MA is granted (often for a "niche" indication/restricted patient population) based on limited data. Prospectively planned extensions of the MA, following iterative phases of data gathering and regulatory evaluation, follow. The hope is that, as well as providing patients with timely access to new medicines for treating serious conditions with unmet medical needs, AL will also help to address the fact that the number of newly approved drugs per year has remained flat in recent years (as increasing demands in terms of the amount of up-front data required to bring a new drug to market necessitates increased investment to match the scale, duration and complexity of clinical trials required). The AL approach will allow products onto the market based on smaller scale trials in limited indication(s)/patient population(s).

For now, the AL approach is founded on various existing mechanisms (discussed below) which are already in place to ensure that the regulatory framework is able to promote the assessment and approval of medicines to treat currently unmet medicinal needs, making them available to patients as soon as possible. AL seeks to balance timely access to new authorised treatments with the need to have enough data for a robust risk/benefit profile assessment. In the European Medicine Agency's "Road Map to 2015", it is emphasised that "AL should not lead to reducing evidentiary requirements for first-time marketing authorisation".

The European Medicines Agency (EMA) has now announced that it is seeking candidate medicines to enter a pilot scheme to investigate the application of the AL approach in the context of medicines currently in development. Although already much debated, this is the first formal step by EU regulators towards introducing a specific AL approach to getting selected products onto the market.

From the current licensing framework to AL

The current medicines regulatory framework does recognise that MA applicants will not always be able to produce full dossiers of robust clinical data at the time of MA application. In the interests of making authorised products available to patients in need, the legislation already provides for mechanisms to address this issue, allowing authorisation in a variety of special circumstances where there is sufficient justification. For example, a "conditional" MA (valid for one year and renewable) may be granted where there is scientific data to demonstrate a positive benefit-risk profile for the medicinal product (pending confirmation) but the clinical part of the dossier is incomplete. The product must meet certain criteria. Specific obligations (with a timetable for completion of further studies) are attached to the MA and the aim is to convert the authorisation to a "normal" MA in due course, depending on the outcome of those studies. An "exceptional circumstances" authorisation also provides a route to MA (again with specific obligations attached and based on annual reassessment of the benefit-risk profile), but in situations where it is unlikely that a full data package will ever be obtained (where the indication is very rare, where comprehensive information cannot be provided "in the present state of scientific knowledge" or where it is contrary to generally accepted principles of medical ethics to collect such information).

Pre-authorisation "compassionate use" schemes and the increasing emphasis on post-authorisation pharmacovigilance through follow-on trials, patient registries, risk minimisation plans and other schemes, also illustrate a shift in thinking away from the traditional binary unapproved/approved paradigm towards viewing the initial authorisation of a product more as just a formal step in a progressively managed product development and monitoring programme.

For the time being, AL will use the regulatory approaches available within the existing framework (including scientific advice, centralised compassionate use and the other mechanisms described above, particularly conditional marketing authorisation and risk management plans). However, some stakeholders see this new approach as possibly transforming the licensing landscape to become the standard approach to authorising new medicines; it may well be that legislative changes (strengthening these existing mechanisms and addressing other issues) will be required for full implementation to succeed.

The EMA's AL pilot scheme and beyond

In seeking candidates for its pilot scheme, the EMA has asked industry to identify suitable experimental medicines currently in the early stages of clinical development (normally prior to the initiation of confirmatory studies i.e. during or prior to phase II, although this can be considered case-by-case). Significant coordination and buy-in among all stakeholders will be needed to make AL work well, so the pilot scheme will involve all those with a role in determining patient access, including health technology assessment bodies, organisations issuing clinical treatment guidelines and patient organisations. The informal discussions will take place in a "safe harbour" environment to allow for open discussion of the pros and cons of all options in confidence, without commitment from either side; the rules of engagement are currently being developed.

Under AL, the aim is to adapt the MA as information on the benefits and risks of the product evolves and undergoes regulatory assessment. AL may not be applied to all drugs in the same manner; a product for use in treating a serious or life-threatening illness where there is an unmet medical need and promise of high added clinical value for patients may require considerably less data for an initial authorisation than would be required for a new product to treat a disease for which there is already a range of treatments. The specifics of the pathway are likely to vary on a case-by-case basis and to differ from one product to another and from one therapeutic area to another. This pilot scheme aims to assess how future AL pathways might be designed for different products and indications, as well as highlighting any potential problems that might arise. For a fully developed AL framework to succeed, regulators may need new authorities to allow them to implement wide use of restrictions on the terms of the MA and prescribing surveillance.

The possibility of a means of reducing the overall costs of developing new products, by allowing better informed decisions on product viability to be made earlier in the development process, should be attractive to industry, although it is likely that a number of issues will need to be addressed if AL is to succeed; for example, the current reward and incentive structures are designed to work in the context of the traditional "all-population" authorisation and promotion approach and these may need to be re-examined. The EMA notes that the European Commission will examine the legal and policy aspects of AL as the scheme progresses.

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ARE MY TECHNOLOGY TRANSFERS READY FOR THE NEW TTBER AND THE UPC?

In this contribution, we highlight two developments that shall impact technology transfers:

1. On May 1, 2014, the revised EU block exemption regulation for technology transfer agreements, the so-called *TTBER*, entered into force,[1] together with the new guidelines for technology transfer agreements (*TT-Guidelines*).[2] They bring important changes for future and existing technology license agreements.[3]
2. As matters stand, it may be expected that by the end of 2015, the Unitary Patent Package will take effect. This package will bring a Unitary Patent and a Unified Patent Court, with new challenges and opportunities, which one should consider when conducting technology transfers that comprise patent (application(s)), including future and existing patent license agreements.

Both developments may warrant that parties adapt their policies concerning technology transfers and that they review their existing licensing agreements.

The revised TTBER and TT-Guidelines

Introduction

Together with Article 101 of the Treaty on the Functioning of the European Union ("*TFEU*"), the TTBER in combination with the TT-Guidelines provide the core competition law framework for licensing agreements relating to

1 Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements (OJ L93, 28.3.2014, p. 17-23).

2 Communication from the Commission 2014/C89/03, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (OJ C89, 28.3.2014, p. 3-51).

3 New TTBER: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.093.01.0017.01.ENG; new TT-Guidelines: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2014:089:TOC#C_2014089EN.01000301.doc; press-release: http://europa.eu/rapid/press-release_IP-14-299_en.htm

technology and is therefore of particular importance for companies in technology driven sectors like life sciences.

Article 101(1) TFEU prohibits as incompatible with the internal market "[..] *all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market* [..]". Pursuant to Article 101(2) TFEU, such agreements shall be automatically void, and also competition authorities such as the European Commission, the Dutch Authority for Consumers and Markets and the Bundeskartellamt can decide to investigate the contracts and impose fines if the contracts show a consistent violation of the TTBER without there being an objective justification.

However, Article 101(3) TFEU allows that the rule of Article 101(1) is declared inapplicable in the case of any such agreement, decision and concerted practice, or categories thereof,

> *"which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives; (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question."*

This is where, for technology licensing agreements,[4] the TTBER and TT-Guidelines come into play. In accordance with Article 101(3) TFEU, the TTBER provides that the prohibition of Article 101(1) TFEU shall not apply to technology transfer agreements. After all, such agreements will normally improve economic efficiency and be pro-competitive as they can reduce duplication of R&D, strengthen the incentive for the initial R&D, spur incremental innovation, facilitate diffusion and generate product market competition.[5] However, this is not a general exemption. Supplemented by the TT-Guidelines, the TTBER formulates a series of criteria for, and limitations to the "safe harbour" that the TTBER provides.

4 The TTBER does not apply to licensing in the context of R&D agreements. For this, a separate EU block exemption regulation is in place. Same goes for licensing in the context of specialisation agreements. Also excluded from the scope are agreements that merely have the purpose of reproducing and distributing software copyright protected products, and agreements to set up technology pools.

5 See Recital 4 of the new TTBER.

The previous TTBER[6] and TT-Guidelines[7] have been in place since 2004, and they were due to expire on 30 April 2014. Therefore, preparations were commenced for a revision of both instruments. This comprised two public consultation rounds issues by the European Commission. The first consultation was started in 2011, and invited interested parties to communicate their experiences with the existing framework.[8] The second was held in 2013, and served to obtain comments concerning a proposal by the Commission for a revised package comprising a new TTBER and new TT-Guidelines.[9] On 21 March 2014, the Commission adopted the new TTBER and new TT-Guidelines, and per 1 May 2014, they have replaced the old TTBER and TT-Guidelines.

The new TTBER and TT-Guidelines contains some important changes, deviating from the former framework. The most significant changes relate to the following:

- Passive sales restriction;
- Grant back obligations;
- Non-challenge clauses.

Passive sales restriction

Under the new TTBER, the restriction on passive sales will only be allowed when the licensor grants an exclusive license. Absent such exclusivity, each passive sales restriction is considered to be a so-called "hard core restriction", and hence will not be allowed. Under the old TTBER, there was an exemption which allowed a licensor to restrict passive sales for a period of two years for those situations where a licensee was offered a new and exclusive territory or customer group (in license agreements concluded between non-competitors). Please note that the new TT-Guidelines provide for a further explanation to this restriction by considering the fact that a passive sales restriction can be justified if the licensee needs to do significant investments in marketing, promotion and/or production (TT-Guidelines, § 126).

> *"Where substantial investments by the licensee are necessary to start up and develop a new market,*

6 Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (OJ L 123, 27.4.2004, p. 11).

7 Commission Notice 2004/C 101/02, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (OJ C101, 27.4.2004, p. 2-42)

8 http://ec.europa.eu/competition/consultations/2012_technology_transfer/index_en.html

9 http://ec.europa.eu/competition/consultations/2013_technology_transfer/index_en.html. Bird & Bird LLP has filed a submission in the public consultation.

restrictions of passive sales by other licensees into such a territory or to such a customer group fall outside Article 101(1) for the period necessary for the licensee to recoup those investments. In most cases a period of up to two years from the date on which the contract product was first put on the market in the exclusive territory by the licensee in question or sold to its exclusive customer group would be considered sufficient for the licensee to recoup the investments made. However, in an individual case a longer period of protection for the licensee might be necessary in order for the licensee to recoup the costs incurred."

Restriction of automatic grant back obligation

Another topic that has been subject to changes concerns clauses obligating the licensee to transfer to the licensor ownership or grant to him an exclusive license for any improvements to the licensed technology. Whereas the former TTBER exempted contractual obligations for grant back of rights concerning improvements that are *non-severable* from the licensed technology (i.e. improvements that cannot be exploited without infringing the licensed technology), under the new regulation even this exception shall be waived. The European Commission explains in the new TT Guidelines (para. 129) why this further restriction would be necessary.

> *"An exclusive grant back is defined as a grant back which prevents the licensee (which is the innovator and licensor of the improvement in this case) from exploiting the improvement (either for its own production or for licensing out to third parties). This is the case both where the improvement concerns the same application as the licensed technology and where the licensee develops new applications of the licensed technology. According to Article 5(1)(a) such obligations are not covered by the block exemption."*

A result of this limitation on imposing automatic grant backs is that the licensor will be linked to the licensee for the duration of the licensed technology, and that he will be restricted in the possibility to exploit its own technology to the fullest. This threat may have the counter-productive adverse effect that the licensor will keep his technology to himself in order to avoid the licensee making improvements to it, as these will not be automatically transferred or exclusively licensed back to the licensor.

What remains allowed under the new TTBER is a contractual obligation for the licensee to grant back to the licensor on a *non-exclusive* basis.

Non-challenge clause

Another important change of approach relates to termination clauses in the event of validity attacks. Under the old TTBER it was allowed to terminate the license agreement if the licensee challenged the validity of one or more of the licensed IP-rights. The block exemption for this type of termination clause in the current TTBER will be waived and replaced by a more strict case-by-case approach for termination clauses in non-exclusive license agreements. Only termination clauses in exclusive licenses will remain under the automatic block exemption; specific rules apply to know-how licenses.

The rationale of this change has been laid down in paragraph 134 of the new TT-Guidelines:

> *"The reason for excluding non-challenge clauses from the scope of the block exemption is the fact that licensees are normally in the best position to determine whether or not an intellectual property right is invalid. In the interest of undistorted competition and in accordance with the principles underlying the protection of intellectual property, invalid intellectual property rights should be eliminated. Invalid intellectual property stifles innovation rather than promoting it."*

Safe harbour for patent pools

The Commission acknowledges the pro-competitive effects of patent pools, in particular in the context of standardization, and providing "safe harbour" rules for patent pools in the revised section of the TT Guidelines. This chapter in the new TT-Guidelines is very helpful, but should be read in combination with the chapter on Standardisation in the Guidelines for horizontal cooperation agreements.[10]

Settlement agreements

The Commission's experience in the effects of settlement agreements on competition is reflected in a revised chapter in the TT-Guidelines.

Effect

The new TTBER and TT-Guidelines took effect on 1 May 2014, and they will have to be applied in respect of any technology transfer agreement concluded as from that date. Further, technology transfer agreements that have been concluded up until 30 April 2014, and that are in

10 Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ, C11/1, 14.2011.

compliance with the old TTBER, will remain exempted under that until 30 April 2015. However, this is only a one year transitional period. As from 1 May 2015, they must also comply with the new framework provided by the new TTBER and new TT-Guidelines.

It may be added hereto that the (new) framework will only apply if it concerns licensing agreements which are not intra-group, i.e., with a third party outside the group structure. This means that if a holding company licenses its technology to one of its subsidiaries in which it exercises sole control, or if subsidiaries conclude license agreements with each other, this is considered as an intra-group license agreement. The competition rules only apply on agreements or concerted practices outside the group structure and hence, if intra-group license agreements are concluded these will not be covered by the new (and old!) TTBER.

The unitary patent package

As matters stand, it may be expected that by the end of 2015, the Unitary Patent Package will take effect. This will be the biggest change in the last 40 years of patent law in Europe, i.e. since the introduction of the European patent. Briefly put, the Unitary Patent Package consists of:

a. the creation of a European patent with unitary effect ("*Unitary Patent*") by way of an enhanced cooperation of all EU Member States except for Spain, Italy and Croatia.[11] For this, two EU regulations have been adopted on 17 December 2012: EU Regulation No. 1257/2012, which serves to create the unitary patent protection system as such, and Council Regulation No. 1260/2012, which sets out the legal framework for the applicable translation arrangement.
b. the creation of a Unified Patent Court ("*UPC*"). For this, an intergovernmental Agreement on a Unified Patent Court ("*UPC Agreement*"), which also sets out the (basic) rules for the UPC, has been signed by 25 EU Member States (i.e. all EU Member States except for Spain, Poland and Croatia).[12]

The above mentioned date of entry into effect of the Unitary Patent Package is not carved in stone, if only because many practical preparations still need to be completed, but there is little doubt that the new system will become a reality in the not too distant future. In this context, it is noted that the system will come into force as soon as *thirteen* Contracting EU Member States, including the United Kingdom, Germany and France, have ratified the UPC Agreement[13]. So far, Austria and France have ratified, and Belgium and Malta have completed the ratification procedure.

The Unitary Patent

The Unitary Patent will come as an alternative to already existing forms of patent protection, i.e. the traditional European patent, which is (argued to form) a bundle of national patent rights, and national patents[14]. Note, however, that the Unitary Patent will only be available in part of the jurisdictions where one can obtain a traditional European patent. For the other jurisdictions protection through a traditional European patent (or national patents) will still be necessary.

The Unitary Patent will undergo the same examination procedure as traditional European patents, be it that *ultimo* one month after the date of publication of the mention of the grant of the patent, the patentee can "upgrade" the European patent to a Unitary Patent by requesting the unitary effect to be registered in the register for unitary patent protection. As a consequence, the patent will — with retroactive effect — have unitary effect in all participating EU Member States where it has unitary effect, i.e. in those which have at the date of registration ratified the UPC Agreement. This means that in those EU Member States it shall provide uniform protection and that it shall have equal effect.[15] It shall confer on the patentee the right to prevent any third party from infringing his exclusive rights throughout the territories of these EU Member States,[16] and the scope of that right and its limitations shall therefore be uniform.[17] Further, in these EU Member States the patent may only be limited, transferred or revoked, or lapse, in respect of

11 Croatia has entered the EU after the adoption of the two regulations. Spain, Italy and Croatia are free to participate in the cooperation if/when they deem fit.

12 The UPC's Rules of Procedure, which finely detail the procedural rules to be applied by the court, are still in draft form (16th), but adoption thereof is expected within relatively soon.

13 See Article 18(2) of EU regulation 1257/2012, as well as Article 89 UPC Agreement.

14 A requirement for Unitary Patents is, however, that it has been granted with the same set of claims in respect of all participating EU Member States (Art. 3(1) of EU regulation 1257/2012).

15 Article 3(2), first para of EU regulation 1257/2012.

16 Article 5(1) of EU regulation 1257/2012.

17 Article 5(2) of EU regulation 1257/2012.

all of them[18]. (Licenses may of course be concluded in respect of the whole or part of the territories of the participating Member States.[19])

The maintenance fees of a Unitary Patent are still to be determined, but it is expected that they will be as high as the fees of a traditional European patent designating 4-5 contracting states.

The Unified Patent Court

The UPC will be a specialized patent court, composed of specialized patent judges. It will consist of a court in the first instance, made up of three types of divisions (Central, Regional and Local), hosted by a variety of contracting EU Member States,[20] and a court of appeal with seat in Luxembourg. It will serve as the exclusive *"one stop shop"* for a variety of actions concerning Unitary Patents, including infringement, declaration of non-infringement, and revocation actions. Given the UPC's exclusive jurisdiction, such actions cannot be instituted with national courts.

It is noted that the UPC's exclusive jurisdiction is not limited to Unitary Patents: in as far as it concerns the territories of the contracting EU Member States, this will also count for any traditional European patent, unless it is *opted-out* from the UPC's jurisdiction, as well as for any Supplementary Protection Certificate (SPC) that is based on a Unitary Patent or on a European patent that has not been opted out. Unitary Patents (and SPCs based thereon) cannot be opted out.

Traditional European patents and European patent applications can — at least for a transitional period of 7 years — be opted out from the jurisdiction of the UPC, unless an action concerning the patent has already been brought before the UPC.[21] The opt out shall be for the life of the European patent or application, including the time after expiry, lapse or withdrawal, and it shall cover all designations owned by the proprietor(s) in question.[22] Interestingly, an opt-out can also be *withdrawn* by the patentee, unless an action has already been brought before a national court.[23]

Judgments of the UPC will have effect in all contracting EU Member States, and shall have effect regarding the patent as a whole. The advantage hereof is obvious: one will only need a single decision from the UPC, to put an end to pan-European infringements, contrary to the current situation where patentees have to seek injunctive relief before a multitude of national courts. However, the flipside of the coin is that the patentee can lose big: he may also lose its infringement case, or even its patent for all contracting EU Member States.

Technology transfers that comprise patent (application(s))

European patent portfolio management and enforcement strategies will have to be reviewed in the wake of the new system. However, also in technology transfers involving patents, patent applications or SPCs, whether by assignment, acquisition or licensing, one will have to take due account hereof, for instance when doing the due diligence.

Particularly in sectors like the life sciences, the value of a transaction is dependent on the value of the know-how and IP that goes with it. For the value of the IP, it is not only important that the patent portfolio covers the (to be) exploited technology and potential competitive technologies, and so for a sufficiently remaining period to recoup the investments and make a decent profit, but also that it is suitably strong to deter, and if necessary to successfully litigate against competitors. Having a

18 Article 3(2), second para of EU regulation 1257/2012.

19 Article 3(2), third para of EU regulation 1257/2012.

20 The Central Division will have branches in London, Paris and Munich (case-distribution depending on type of technology). Regional Divisions can be set up in cooperation by at least two contracting EU Member States, and Local Divisions can be set up by single Member States. As matters stand — this is still in progress — there will be a Nordic-Baltic Regional Division, formed by Estonia, Latvia, Lithuania and Sweden, and perhaps one or two additional Regional Divisions (including a South-Eastern Regional Division), but the majority of those contracting EU Member State with an interest in forming a division will most likely decide to host a Local Division.

21 Article 83(3) UPC Agreement.

22 See the Note to Rule 5 of the *draft* Rules of Procedure (16th). Further, it is noted that Article 83 of the UPC Agreement is not entirely clear on the opt-out arrangement, and even open for multiple interpretations. For this reason, the Preparatory Committee of the UPC has on 29 January 2014 adopted its (first) Interpretative Note, i.e. on the consequences of the interpretation of Article 83. Herein, the Preparatory Committee concludes "[..] *that if an application for a European patent, a European patent or a Supplementary Protection Certificate that has been issued for a product protected by a European Patent is opted out (or during the transitional period the case is brought before a national court), the Agreement no longer applies to the application for a European patent, the European patent or the Supplementary Protection Certificate concerned. As a consequence the competent national court would have to apply the applicable national law.*"

23 Article 83(4) UPC Agreement.

Unitary Patent, or the prospect thereof, may well have an effect on the value. In principle, this could be an upward effect, because of the unitary character and the fact that it can be enforced on a pan-European basis through a single specialized patent court (the UPC). However, having all eggs in one basket also poses the aforementioned risk of losing big, and certainly in respect of patents with a weaker validity or scope, having a Unitary Patent may not impact positively on IP value. The same goes for SPCs based thereon, for European patents that are not opted-out (unless an opt-out is still possible), and for SPCs based on such not opted out European patents. Also, there are various parties in the Life Sciences who at least for the first years of the UPC want to opt-out their European "crown-jewel" patents and SPCs, if only because they first want to see how the UPC will assess patent and SPC cases.

Therefore, also in view of technology transfers involving patents, patent applications or SPCs, proprietors should carefully consider how they should protect their inventions in Europe, through Unitary Patents, traditional European patents (and opt them out) or through national patents. Ideally, this assessment is done on a case-by-case basis, and timely before the system goes live, be it of course whilst taking account of the costs of such an exercise (and those of the Unitary Patent). Those who are interested in obtaining rights through such technology transfers may want to consider all of this when conducting their due diligence.

Another issue to be taken into account is that under Article 47(2) UPC Agreement, the holder of an *exclusive* licence in respect of a patent shall be entitled[24] to bring actions before the UPC under the same circumstances as the patent proprietor, provided that the patent proprietor is given prior notice. Only in cases where the licensing agreement provides otherwise, will this not be the case. Indeed, this corresponds to statutory rules in certain European jurisdictions, but in other European jurisdictions, such as for instance the Netherlands, only the patentee is in principle entitled to seek relief.

Further, pursuant to Article 47(3) UPC Agreement the holder of a *non-exclusive* licence shall not be entitled to bring actions before the Court, unless the patent proprietor is given prior notice and in so far as expressly permitted by the licence agreement.

For the patentee, who wants to be in control of the institution of court proceedings with the UPC, this is something to be taken into account when negotiating future agreements. Also, he may need to review his existing exclusive licensing agreements, and re-negotiate a provision stipulating that only he shall be entitled to bring actions before the UPC.

Also, in view of maintaining a certain degree of control over the institution by third parties of declaration of non-infringement proceedings, he may want to take similar steps in respect of the entitlement to respond to third party applications in writing for a written acknowledgment of non-infringement. After all, a refusal or failure to respond, by the patentee *or* the licensee, is a requirement for the third party to institute a declaration of non-infringement action with the UPC.

The non-exclusive licensee should, on the other hand, be aware that under the UPC Agreement, he shall only be entitled to bring actions before the UPC, if — apart from giving prior notice to the patentee — he is expressly permitted to do so in the licensing agreement.

Moreover in general, professionals who advise their clients in respect of licensing agreements, should always take due account of the above when Unitary Patents or traditional European patents are potentially involved.

In this respect, it is added that in such licensing agreements, whether to be concluded or already in place, parties may also wish to make clear arrangements in respect of decisions concerning the filing of a request for unitary effect (see above), and the filing of opt-out requests and the withdrawal thereof.

Conclusion

Both the new TTBER and the upcoming Unitary Patent Package give good reason to review existing technology transfer policies, and the criteria that are formulated in the relevant agreements; however not only in respect of future deals, but also in respect of existing agreements. Certainly if there is a need to review existing patent licensing agreements on compliance with the new TTBER, and even re-negotiating them, then this would seem a sensible moment to also review (and if necessary re-negotiate) the terms that potentially impact on the position of, and control over court proceedings before the UPC.

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DEVELOPMENTS IN PUBLICATION OF CLINICAL TRIAL DATA BY THE EUROPEAN MEDICINES AGENCY

The EMA has announced a final round of targeted consultations with key stakeholders on its draft policy on proactive publication of clinical trial data. The policy

24 Not exclusively: under the UPC, the patentee remains entitled as well.

seeks to balance the commitment to provide the widest possible access to data with the need to protect personal data and legitimate commercial confidential information. The Agency has been releasing clinical trial reports on request once the decision-making phase of the marketing authorisation process has been completed since November 2010 as part of its access to documents policy. It is now moving towards proactive publication of clinical trial data and has published for consultation a draft policy on proactive publication of clinical trial data in June 2013. The consultation was open for 3 months during which the EMA has received over 1,000 comments. The policy was then discussed at the EMA's Management Meeting in March 2014.

Now the final fine-tuning consultations will take place at the beginning of May 2014 and will focus on the principles for the possible pre-publication redaction of the clinical trial study reports in order to protect data containing commercially confidential information. Another objective is to clarify how the data owners will be consulted before publication of clinical study reports. The policy is expected to be presented to the EMA's Management Board for endorsement in June 2014.

The clinical data policy is part of the EMA's transparency initiative intended to encourage trust and confidence in the system. It runs parallel to other initiatives in the EU to increase transparency of clinical trials, in particular the new Clinical Trials Regulation which received a strong vote in favour in the European Parliament on 2 April 2014 and is expected to come into force in mid-2016.

At the same time, AbbVie has withdrawn both its court cases brought against the Agency concerning access to clinical trial data. The cases concern requests by third parties for access to AbbVie's clinical trial reports submitted to the EMA. The EMA has initially refused access on the grounds that it would undermine AbbVie's commercial interests. However, it decided to release the data following a complaint to the European Ombudsman who concluded that the reports did not contain commercially confidential information and recommended that the information be disclosed. AbbVie applied to the General Court to annul the Agency's decision to release the information. It also made an application for a preliminary injunction to prevent disclosure pending a final decision, which was granted in April 2013. Following the successful appeal to the CJEU by the Agency, the preliminary injunction was set aside and AbbVie has asked the EMA to consider a new set of redacted documents. The EMA considered that the very limited redactions proposed by AbbVie were consistent with the Agency's redaction practices and had no significant impact on the readability of the reports. The EMA has therefore accepted the new documents.

Another court case brought by InterMune against the EMA challenging a decision to grant access to clinical study reports is still ongoing.

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