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Introduction

Welcome to the 19th Edition of the Clifford Chance Global IP Newsletter. This newsletter focuses on patent law and especially on healthcare related patent issues.

We kick off with an update of healthcare related patent case law. Newly issued judgements by Spanish and German Courts will be presented and analyzed in our first two articles.

After that, we will take a look on the relation between manufacturers of generic pharmaceuticals to original manufacturers and regulatory bodies in our next two articles with a view from Italy and Australia.

Subsequently, we will turn our focus on the law of the supplementary protection certificate. After giving you an overview of the latest case law by the European Court of Justice and German courts on issues arising out of the European legal framework, we will provide you with an opinion on the effects of the latest changes to the supplementary protection certificate regulation.

Next on the list, we will be wrapping up the healthcare specific part of this Newsletter with an outlook into the near future. Medical Cannabis in Germany is a rather new factor in the healthcare sector and is in any case an important issue going forward.

This Newsletter will then fade out with two interesting articles in the context of patent nullity in French and European law. Finally, you will find an update to copyright enforcement in Poland.

We hope that you do not just enjoy reading this latest issue of our Global IP Newsletter but also will take away valuable information for your daily work. We look forward to your feedback.

Your Global CC IP Team

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BARCELONA:
THE BARCELONA COURT OF APPEAL CLARIFIES THAT "SWISS CLAIMS" WERE NOT AFFECTED BY THE SPANISH RESERVATION TO THE EPC

On 16 May 2018, Section 15 of the Barcelona Court of Appeal, specialising in patents, issued a ruling by means of which it clarified the legal status of the "Swiss-type claims" and found that they were not affected by the Spanish Reservation to the European Patent Convention ("**EPC**") made under Art. 167.2 a).

Brief summary of the facts

Spain made a Reservation under Art. 167.2 a) EPC, according to which patents claiming protection for chemical or pharmaceutical products "as such" were ineffective in Spain. This Reservation produced effects on all European patents granted on the basis of applications filed prior to 7 October 1992.

This was the case for European patent EP 0.521.471 and its related Supplementary Protection Certificate ("**SPC**") held by AstraZeneca and which referred to the active ingredient Rosuvastatin, since the patent had been applied for on 30 June 1992 (and, thus, when this Reservation was still in force).

This patent protected: in its claims 1 to 4 and 9, the chemical compound of Rosuvastatin; in its claims 5 and 6, the pharmaceutical compound of Rosuvastatin; in its claims 7, 8, and 10 to 14, a process to obtain Rosuvastatin; and in claims 15 and 16, a use of Rosuvastatin. In particular, claim 16 read: "*Use according to claim 15, wherein the pharmaceutical composition is for treating hypercholesterolemia, hyperlipoproteinemia and atherosclerosis*". As can be seen, claim 16 took the form of a "Swiss-type claim", i.e. a claim with the following wording: "*Using compound X in the manufacture of a medicine for the treatment of condition Y*".

Whereas Barcelona Commercial Court No. 5 initially granted an *ex parte* interim injunction in favour of AstraZeneca against Ratiopharm (ruling dated 21 February 2017), the injunction was finally lifted after Ratiopharm was heard (ruling dated 12 July 2017). The main reason for lifting it was that, according to the Court (which upheld the defendant's thesis), all the claims of the patent in question were affected by the Spanish Reservation, including the process and use claims, as the "Swiss-type claim".

The Commercial Court accepted that claim 16 was a Swiss-type claim and, thus, a process claim. However, it considered that the invention should be analysed as a whole, together with all the rest of the claims (i.e. product, use and process claims). In this context, the court considered that if it were concluded that claim 16, merely because it is "formally" a process claim, does not fall within the scope of the Spanish Reservation, this would avoid, *de facto*, the application of this Reservation to the rest

Key Issues

- Types of claims: (i) product claims (which give the product absolute protection), and (ii) activity claims (process or use claims), whose protection is more limited.
- "Swiss-type claims" fall within the category of "activity claims".
- The Spanish Reservation to the EPC made under Art. 167.2.a) only affected chemical and pharmaceutical products as such. Process and use claims were not affected by the Reservation and it is not possible to interpret the scope of this Reservation broadly.

of the claims (including the product claims) and to the invention as such (i.e. the Rosuvastatin). Since the unique use of Rosuvastatin that was known is for "treating hypercholesterolemia, hyperlipoproteinemia and atherosclerosis", as claimed by claim 16, failing to apply the Reservation to this claim would entail a "fraud of law", as the patent holder would be able to impede the use of Rosuvastatin for the unique use for which this compound was known. In practice, according to the court, this would be equivalent to protecting the product Rosuvastatin *"as such".*

In order to justify this interpretation, the court invoked the CJEU judgement dated 18 July 2013 (C-414/11, *Daiichi case*) regarding the TRIPS Agreement, according to which one must distinguish between "claimed inventions" and "protected inventions", and a previous judgement from the Barcelona Court of Appeal dated 19 December 2016, which found that "*purpose-limited product claims*" were indeed affected by the Reservation.

AstraZeneca appealed this ruling before the Barcelona Court of Appeal, which has revoked it by means of its ruling of 16 May 2018. However, despite upholding AstraZeneca's appeal, the interim injunction could not be reinstated because the Barcelona Court of Appeal's ruling was handed down after the Supplementary Protection Certificate expired.

The Barcelona Court of Appeal has clarified that "Swiss-type claims" are not affected by the Spanish Reservation

In its ruling dated 16 May 2018, the Barcelona Court of Appeal clarifies the following about the scope of the Reservation and "Swiss-type claims":

(a) The Reservation to the EPC made by Spain referred to the "*protection on chemical or pharmaceutical products as such*"; that is, those offering absolute protection. The Reservation did not include process claims and, as claims of use are a type of process claim, they also fell beyond its scope.

(b) The EPC accepts European patents that include product claims limited by use, for the first therapeutic use, and "Swiss-type claims" for second or subsequent therapeutic uses. As for "Swiss-type claims", it refers to Decision G 5/83 of the European Patent Office's Enlarged Board of Appeal, which accepted the patentability of those claims of use for the second therapeutic indication, drafted as "*use of a substance X to produce a medicinal product for the treatment of disease Y*". The purpose of "Swiss-type claims" is to overcome the two main objections to the patentability of the second therapeutic indications, i.e. absolute novelty and the prohibition on the patenting of medical or surgical treatment.

(c) Transitional Provision 1 of the former Spanish Patent Act (Act 11/1986, applicable to that case) accepted the patentability of the processes for obtaining chemical or pharmaceutical products or processes for the use of chemical products. According to this provision, only inventions concerning chemical and pharmaceutical products could not be patentable before 7 October 1992, in line with the Reservation made by Spain to the EPC.

Taking the above into account, the Barcelona Court of Appeal concludes that neither the Reservation nor the aforementioned transitional provisions refer expressly to either use claims, or to first or second therapeutic use claims. Thus, it is not possible to conclude that these claims are prohibited, unless one were to broaden the application of the rule prohibiting the patentability of pharmaceutical products, which is not permissible, as this would breach the general principle of law that states that prohibitions must be interpreted restrictively.

Since "Swiss-type claims" are a legitimate means to claim protection for second or subsequent medical uses, the Court of Appeal stated that it is not possible to conclude (as the Commercial Court did) that these claims constituted a "fraud" aimed at circumventing the Reservation.

Lastly, and in order to avoid misunderstandings, the Barcelona Court of Appeal clarified that this finding did not contradict its former judgement dated 19 December 2016, invoked by the Commercial Court. In this respect, the Court of Appeal made the following clarifications: (i) that the judgement referred to "purpose-limited product claims" (different from "Swiss-type claims") and that, although from some of its statements one might construe that the court established a position on whether or not product claims limited by use were affected by the Spanish Reservation, its grounds were insufficient to definitively consider that first therapeutic use claims were affected by the Spanish Reservation; and (ii) in any case, that the former judgement was clear in stating that the position regarding "Swiss-type-Second-Use claims" developed in its previous case law was maintained.

In conclusion, the Barcelona Court of Appeal has clarified that the Reservation made by Spain to the EPC did not cover patents referring to processes for the manufacture or, as in this case, the use of a chemical product.

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DÜSSELDORF: GERMAN COURTS STRENGTHENED PROTECTION OF SECOND-MEDICAL-USE PATENTS

In 2017 and 2018, the Higher Regional Court of Düsseldorf (*Oberlandesgericht Düsseldorf* – "**OLG Düsseldorf**") significantly broadened the principles previously applied regarding the infringement of Second-Medical-Use patents.[1] Most recently those principles were confirmed by a decision rendered by the Regional Court of Düsseldorf (*Landgericht Düsseldorf* – "**LG Düsseldorf**")[2].

Key Issues

- Rights of Second-Medical-Use patent holders were strengthened by the Higher Regional Court of Düsseldorf
- Infringement of such Second-Medical-Use patents no longer requires "purposeful arrangement"; use for patented indication "in some other way" is sufficient
- Former workarounds such as skinny labelling might fall victim to change of stance
- However, new principles are still vague and should be further clarified by upcoming case law

What are Second-Medical-Use patents?

Second-Medical-Use patents relate to known substances, which are used in new therapeutic ways, i.e. in connection with new medical indications. Granting protection of Second-Medical-Use patents is considered to trigger further research with respect to new medical indications of a certain substance and thereby to promote the continuous general innovation process. At present, applicable statutory provisions acknowledge such objectives by conferring so-called purpose-limited substance protection (*zweckgebundener Stoffschutz*) on those types of patents, e.g. Section 3 (4) German Patent Act and Article 54 (5) European Patent Convention. Related patent claims may be structured as follows: "*Substance X for the treatment of condition Y*".

Prior to the implementation of the above-mentioned statutory provisions, patent-seeking entities had helped themselves by formulating manufacturing-use patents, so-called "Swiss-type claims", accepted by the patent offices. Such "Swiss-type claims" had been structured as follows "*Use of substance X in the manufacture of a medicament for the treatment of condition Y*" and had thereby avoided conflicts with the statutory exclusion from patentability of methods for treatment of the human body.

However, as patents in either scenario serve the same purposes and likewise relate to an inherent feature of the substance in question, German courts apply the same principles, in particular with regard to an alleged infringement of both "Swiss-type claims" and such patents claiming purpose-limited substance protection in accordance with Section 3 (4) German Patent Act and Article 54 (5) European Patent Convention.

1. OLG Düsseldorf, decision of 5 May 2017, I-2 W 6/17 ("***Östrogen-Blocker***"); decision of 1 March 2018, I-2 U 30/17 ("***Dexmedetomidin***").
2. LG Düsseldorf, decision of 5 July 2018 – 4c O 46/17 ("***Fulvestrant***").

Recent principles regarding the infringement of Second-Medical-Use patents

Due to their focus on a given purpose, the scope of protection of Second-Medical-Use patents is – compared to patents claiming absolute protection of a substance – limited. To this end, any given act (e.g. manufacturing, offering, marketing, using) can only be considered infringing if such act is aimed at the therapeutic purpose particularly protected by the Second-Medical-Use patent. The purpose orientation with respect to the protection is thus reflected by purpose orientation in terms of infringement.

In light of the above, German courts had applied rather strict principles of direct infringement of Second-Medical-Use patents. Besides the direct application of a substance for a protected purpose, acts were only considered directly infringing if the product in question was "purposefully prepared" for such given purpose (*sinnfälliges Herrichten*). The latter requirement described a connection of a certain quality between the allegedly infringing act and the use for the patented indication and was exemplarily met when the information contained on the package or in the package insert of a product explicitly referred to the use of such product for the purpose of the patented indication. However, by adapting and generalizing the provided information, those principles could be easily evaded, for example by using so-called "skinny labels", which significantly reduced the protection of Second-Medical-Use patents.

Change of stance: Strengthening the protection of Second-Medical-Use patents

What was already indicated by the decision of the Regional Court of Hamburg (*Landgericht Hamburg* – "**LG Hamburg**") on 2 April 2015[3], was recently affirmed and elaborated by the Düsseldorf courts: On 5 May 2017 ("***Oestrogen-Blocker***") and 1 March 2018 ("***Dexmedetomidin***"), the OLG Düsseldorf broadened the requirements of a direct infringement of Second-Medical-Use patents. The court referred to the German Federal Supreme Court's rationale that the substance's objective suitability for a given medical indication is central to Second-Medical-Use patents and crucial for their protection. Thus, a direct infringement of a Second-Medical-Use patent does not necessarily require an action of "purposeful preparation", but may also occur in case the use of the substance for the patented indication in question is prompted "*in some other way*".

Against this background, the OLG Düsseldorf established two requirements:

- Suitability of the allegedly infringing product for the patented indication

  and

- Circumstances causing the use of the alleged product for the patented therapeutic indication comparable to those circumstances underlying the cases of "purposeful preparation".

3. LG Hamburg, decision of 2 April 2015, 327 O 67/15 ("***Pregabalin***").

The latter requires a sufficient scope of product utilisation and knowledge or grossly negligent lack of knowledge of the party allegedly infringing the Second-Medical-Use patent of such circumstances, which might – according to the OLG Düsseldorf – particularly occur in cases of cross-label use.

On 5 July 2018 ("***Fulvestrant***"), the LG Düsseldorf applied those principles to its decision making process. The court examined whether the plaintiff used the generic drug to a certain extent for the patented indication. Even though the patent infringement was ultimately dismissed due to the lack of substantiation of the use for the patented indication, this decision illustrates that the broadened principles previously developed by the OLG Düsseldorf might persist.

What to keep an eye on

The recent decisions of the courts in Düsseldorf reject a formalistic approach towards the infringement of Second-Medical-Use patents. The formerly applied and easily evadable requirement of "purposeful arrangement" is apparently no longer the minimum standard for claiming infringement of a Second-Medical-Use patent and the decisions paved the way for a more flexible approach, which is supposed to close the gaps caused by the rather strict previous approach.

However, the requirements of the direct patent infringement "*in some other way*" as provided by the decisions are still very vague. It remains to be seen whether the courts will come up with more concise requirements. Further, the second requirement as provided above explicitly takes into account the "purposeful arrangement" approach and requires circumstances comparable to such cases. Thus, what appears to be a flexible approach might still turn out to be old wine in new bottles.

MILAN:
PATENT LINKAGE – THE ITALIAN WAY

"**Patent linkage**" consists of the practice of connecting the marketing authorisation and any other approvals related to a generic drug with the status of the patent covering the original drug. Any patent linkage is generally considered contrary to European law as potentially able to create an unjustifiable disadvantage for the manufacturer of generic drugs. Italy has been already sanctioned by the European Commission for a provision set forth in the Italian IP Code containing a clear patent linkage; however, a few months later new legislation providing for another way to patent link came into force and is still applicable law. Furthermore, in a recent decision, the Regional Administrative Court of Rome interpreted extensively the current patent linkage, thus reopening the debate.

Key Issues

- Despite an earlier law being found contrary to EU law in January 2012, later that same year Italy enacted new legislation – still applicable today – that provides for a way to patent link.
- A recent court decision in Italy held that patent linkage would also work in relation to secondary patents, causing broad discontent among manufacturers of generic drugs.
- A set of preliminary remedies set forth in the Italian law is available to both originators and manufacturers of generic drugs.
- The debate remains open in Italy as to the lawfulness of any patent linkage.

Overview of the applicable law

The Italian legal system has included two laws that permitted achievement of patent linkage:

- Article 68 paragraph 1 bis of Law no. 30 of 2005 ("**IP Code**") according to which "*companies that intend to produce generic drugs outside the patent coverage can launch the procedure for the registration of the product containing the active substance* ***one year in advance of the expiry date of the supplementary protection certificate or, in the absence thereof, the patent covering of the active ingredient***". This law prevents manufacturers of generic products from submitting their request for marketing authorisation prior to the penultimate year of the lifetime of the related patent for the original drug. For instance, if the patent for the original drug has a lifetime of 7 years; manufacturers will need to wait at least 6 years prior to being allowed to submit to the Italian Pharmaceutical Agency ("**AIFA**") their request for marketing authorisation in relation to the generic version of the drug.

As a result of this law, and the lengthy procedure to secure the marketing authorisation in Italy, the risk is that generic drugs will be materially delayed in entering the market.

This law was repealed following an infringement procedure against Italy started by the European Commission. This patent linkage was considered contrary to European law. At the EU level, it is indeed undisputed that not only testing, but also the requesting and issuance of marketing authorisations (and any other related approvals) **must be considered to be non-infringing activities**.

In January 2012, Decree Law 1/2012 aligned Italy to the EU legislation, stating that a marketing authorisation application for a generic drug can be filed **more than one year** before the expiry date of the patent or supplementary protection certificate ("**SPC**"), because only the manufacture, import or sale of the product could be considered an infringement.

Just a few months later, Decree Law no. 158 of 2012 ("**Balduzzi Decree**") was issued, and states as follows:

- **Article 11, paragraph 1 *bis* Decree Law no. 158 of 2012 "*the generic drugs cannot be classified as drugs to be reimbursed by the National Healthcare Service with effect prior to the expiry date of the patent and the certificate of supplementary protection*".**

This new provision contains another way to "patent link".

Indeed, even though the generic drug manufacturers may obtain a marketing authorisation for their products even at such time when the referenced pharmaceutical product is still protected by patent, the generic drugs cannot be listed as reimbursable by the Italian National Healthcare System ("**SSN**") until the patent or SPC is expired.

Originators are clearly in favour of this law, and their position is understandable: allowing earlier listing of a generic medicinal product means that the reimbursed price for the original product automatically decreases and cannot be increased again even if an infringement of the related patent is subsequently declared by Italian Courts.

The Italian Competition Authority proposed to delete this provision of the Balduzzi Decree; however, it is still in force and fully applicable in Italy.

Italian case law and recent developments

On the other hand, Italian Courts have consistently interpreted restrictively the provision of the Balduzzi Decree, stating that the linkage is to be meant only to the patent on the active ingredient of the originator (i.e. the primary patent), **and not** to other related patents (the so-called secondary patents).

This approach has given rise to protests from originators, given that they bear high research and development costs to develop the active compound, as well as to improve the drug and possibly to file secondary patents.

The Medac v. Generici case

A recent decision of Regional Administrative Court of Rome on January 2018 sets out a number of interesting findings.

The case was brought against AIFA by Medac Gesellschaft Fuer Klinische Spezialpraeparate mbH, the owner of an EU patent covering a drug called Reumaflex.

After the expiry of that patent on 19 October 2016, AIFA inserted the Reumaflex in the transparency list along with the generic drug having the same active ingredient.

The patent owner challenged AIFA's decision, claiming that Reumaflex was different from the other drugs having the same active ingredient because it would have a specific dosage of the active ingredient, covered by a **secondary patent**, which was still in force and would expire in 2027. Thus, the patent owner argued that Reumaflex should have been reimbursable in full until the expiry of such a secondary patent.

The court clarified that the link set forth in the Balduzzi Decree is to be meant also to the secondary patents concerning a particular formulation of a product using the same active ingredient (whose patent is expired), when there is, *inter alia*, a serious and vigorous demonstration of the effectiveness and therapeutic innovation of the formulation.

Conclusions

The Italian legal framework still includes provisions of law allowing for patent linkage. Yet, given that these provisions may be contrary to EU law, originators should be hesitant to fully rely on them.

What are the available actions?

For originators: the early filing of an application for a marketing authorisation, even if it does not represent a preparatory act aimed at the marketing of an equivalent drug before the expiry of the relevant patent or SPC, could be read as a clue in that direction, particularly if the manufacturer does not reply to a specific request not to manufacture, import and sell the equivalent drug before the expiry of the relevant patent or SPC.

Originators can therefore seek a preliminary injunction or at least a protective measure to verify if the manufacturer has already started manufacturing or importing the generic drug.

For manufacturers of generic drugs: they might commence a preliminary declaration of non-infringement (permitted under Italian law) if there are elements indicating that the originator is going to initiate legal action against it (e.g. warnings or legal actions taken abroad against other manufacturers of the same generic drug).

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SYDNEY: A BITTER PILL TO SWALLOW… COMPENSATION CLAIMS ON BIG PHARMA DAMAGES UNDERTAKINGS

Two judges of the Federal Court of Australia ("**Federal Court**") have each recently reserved judgment in watershed applications brought by the Commonwealth of Australia intervening in two sets of proceedings involving major pharmaceutical corporations. In each set of proceedings, the patentee had an effective monopoly on the use of a pharmaceutical compound to treat certain health defects. Each patentee sought (and was granted) an interlocutory injunction effectively restraining the relevant generic competitor(s) from entering the Australian market with a competing product. However, a condition of the grant of each injunction was each patentee giving the "usual undertaking as to damages", which (in plain terms) is an undertaking to pay whatever compensation (if any) the Court considers just to *any person* affected by the operation of the injunction ("**Usual Undertaking**"). Following years of litigation in each set of proceedings, the end result was revocation of the relevant patents (or critical claims forming part of the relevant patents). Consequently, an avenue was created whereby parties adversely affected by the operation of the interlocutory injunction could make a claim for compensation on the strength of the patentee's Usual Undertaking.

The Commonwealth's applications are somewhat novel because it is relatively uncommon for non-parties to a proceeding to seek compensation on a party's Usual Undertaking. The Commonwealth's claims extend into the tens of millions of dollars in each case and are said to arise from the fact that, but for the unsuccessful opposition to the validity of the patent, the generic competitor would have been able to advertise and sell a cheaper drug to the Australian market, which would have in turn resulted in the Commonwealth contributing significantly less financial support under the Australian Pharmaceutical Benefits Scheme. This article sets out the factual background of the proceedings and considers the potential consequences of a decision favourable to the Commonwealth, including with respect to a pharmaceutical patentee's willingness to provide the Usual Undertaking whilst infringement and/or validity proceedings are contested.

Key Issues

- Pharmaceutical companies will need to seriously evaluate their options when defending litigation seeking revocation of their patents by cheaper competitors trying to enter to the market, as interlocutory injunctive relief designed to maintain their monopolies may end up costing more than they bargained for.
- It remains to be seen whether a court will accept a limited form of undertaking as the 'price to pay' for obtaining interlocutory injunctive relief but it is open to pharmaceutical companies to test the waters with a view to, for example, limiting sources of potential compensation claims to only the parties to the patent litigation.
- Third parties tangentially affected by a party to a court proceeding giving an undertaking as to damages in support of an application of injunctive relief should carefully consider whether there is any scope to make a claim for compensation if the injunction is ultimately dissolved in circumstances adverse to the undertaking party.

Factual Background

The two sets of proceedings concern, respectively:

1. Sanofi-Aventis' (now "**Sanofi**") supply (in Australia) of the drug "Plavix" (containing the pharmaceutical compound clopidogrel), a product designed to prevent thrombus or clot formation. An enantiomer of clopidogrel, a process for its preparation and certain pharmaceutical compositions containing it, were the subject of a patent in respect of which Sanofi was the patentee ("**Sanofi Case**"); and
2. Wyeth's supply (in Australia) of the drug "Efexor-XR" (containing the pharmaceutical compound venlafaxine hydrochloride), a product designed to treat depression. A method of treatment using venlafaxine hydrochloride was the subject of a patent in respect of which Wyeth was the patentee ("**Wyeth Case**").

In the Sanofi Case, two of Sanofi's generic competitors—Apotex Pty Ltd (formerly GenRx Pty Ltd) ("**Apotex**") and Spirit Pharmaceuticals Pty Ltd—sought revocation of Sanofi's patent on various grounds of invalidity. Prior to trial, in September 2007, Sanofi sought and was granted (upon giving the Usual Undertaking) an interlocutory injunction restraining Apotex from taking various actions in respect of its generic products containing clopidogrel ("**Sanofi Injunction**"). At first instance, the trial judge held that certain claims of the patent were invalid but others were valid such that the Sanofi Injunction was issued on a final basis. However, on appeal to the Full Court of the Federal Court ("**Full Court**"), all claims of the patent were held to be invalid and orders were made for the patent's revocation. An application by Sanofi for special leave to appeal to the High Court of Australia ("**High Court**") was dismissed in March 2010. As a consequence, persons adversely affected by the operation of the Sanofi Injunction were entitled to make claims for compensation on the strength of Sanofi's Usual Undertaking. In May 2010, Apotex made an application for compensation and the Commonwealth made a similar application in April 2013. Apotex settled and discontinued its claim in November 2014, leaving the Commonwealth as the sole compensation claimant. A further application for special leave to appeal to the High Court, notwithstanding the earlier refusal, was refused in November 2015. The Commonwealth's compensation claim was heard between August and September 2017 before his Honour Justice Nicholas of the Federal Court, judgment in relation to which is currently reserved.

Similarly, in the Wyeth Case, three of Wyeth's generic competitors—Sigma Pharmaceuticals (Australia) Pty Ltd, Alphapharm Pty Limited and Generic Health Pty Ltd—sought revocation of Wyeth's patent on various grounds of invalidity. Prior to trial, between June and November 2009, Wyeth sought and was granted (upon giving the Usual Undertaking) interlocutory injunctions against each of Sigma, Alphapharm and Generic Health from taking various actions in relation to their respective generic products containing venlafaxine hydrochloride ("**Wyeth Injunctions**"). At first instance, the revocation cases were unsuccessful. Accordingly, the trial judge gave declaratory relief that each of the generic competitors had threatened to infringe various of the claims of Wyeth's patent, and issued the Wyeth Injunctions on a final basis. Each of the generic competitors appealed to the Full Court which overturned the trial judge's decision and revoked key claims of Wyeth's patent which had (in part) been the subject of the Wyeth Injunctions. An application by Wyeth for special leave to appeal to the High Court was dismissed in May 2012. As a consequence, persons adversely

affected by the operation of the Wyeth Injunctions were entitled to make claims for compensation on the strength of Wyeth's Usual Undertaking. Between May and June 2012, each of Sigma and Alphapharm made applications for compensation and the Commonwealth made a similar application in August 2013. Various additional third parties also brought claims for compensation (including Apotex and Pharamthen S.A.). All compensation claims were heard between June and July 2018 before her Honour Justice Jagot of the Federal Court, judgment in relation to which is currently reserved.

A Preliminary Question

Prior to the hearing of the compensation claims in each of the Sanofi Case and the Wyeth Case, Sanofi and Wyeth tried to block the Commonwealth's claims by arguing that it was precluded as a matter of law from making the claims because relevant provisions of the *Therapeutic Goods Act 1989* (Cth) ("**TGA**") acted as a statutory bar. A Full Court was convened to hear and determine the matter as preliminary special question. The Full Court found, in December 2015, that the TGA did not limit the Commonwealth's right to recover pursuant to the Usual Undertaking ("**Full Court TGA Judgment**"). An application jointly made by Sanofi and Wyeth for special leave to appeal the Full Court TGA Judgment to the High Court was refused on the papers in May 2016.

Evidentiary Hiccoughs

A further hurdle placed in the Commonwealth's path to recovery of compensation was Sanofi's attempt to enforce a term of its settlement deed with Apotex, which is set out in full below:

> **6. Assistance to others**
>
> Otherwise than by compulsion of law, the Applicants agree not to voluntarily assist in any way or encourage:
>
> (a) *the Commonwealth in relation to the Commonwealth Compensation Claim by way of waiving any claim for legal professional privilege that any or all of the Applicants may have, or releasing any third person from any obligation of confidence in respect of information relevant to the Commonwealth Compensation Claim or the Apotex Compensation Claim, or by the provision of documents;*
>
> (b) *any third person in a claim against any of the Respondent Parties in connection with the Undertakings as to Damages by way of waiving any claim for legal professional privilege that any or all of the Applicants may have, or releasing any third person from any obligation of confidence in respect of information relevant to the Apotex Compensation Claim, or by the provision of documents.*

Acknowledging that the common law recognises that there is no property in a witness, Justice Nicholas considered that the effect of Clause 6 was to prevent or hinder the Commonwealth's legal representatives' efforts to interview witnesses from Apotex and discuss with them matters relevant to the issues in the Commonwealth's compensation proceeding, prior to them giving their evidence at the relevant hearing. Accordingly, Justice Nicholas gave declaratory relief that Clause 6 was unenforceable, for reasons including that it interfered adversely with the administration of justice.

Alternative Approaches – The AstraZeneca Case

Whilst the Commonwealth's compensation claim in the Sanofi Case was reserved, and prior to the hearing of the various parties' compensation claims in the Wyeth Case, another major pharmaceutical corporation (AstraZeneca AB) took a somewhat unorthodox approach in May 2018 by agreeing to settle a claim by the Commonwealth for compensation in respect of the Usual Undertaking it had previously given (in circumstances similar to the Sanofi Case and the Wyeth Case). AstraZeneca AB had provided the Usual Undertaking in support of interlocutory injunctive relief obtained in a proceeding for revocation of its patents relating to the pharmaceutical compound rosuvastatin (used in its cholesterol-lowering drug, Crestor). As with the Sanofi Case and the Wyeth Case, AstraZeneca AB took the question of validity of the patent all the way to the High Court (passing an enlarged Full Court bench comprising five justices of the Federal Court along the way) with the end result being revocation of relevant claims. The settlement of the Commonwealth's claim by AstraZeneca AB, however, is interesting in circumstances where, notwithstanding the Full Court TGA Judgment dismissing one of its fellow former patentees' arguments, the threshold issue which remains to be determined by either or both of Nicholas and Jagot JJ is whether the Commonwealth is actually entitled to *any* compensation by virtue of the Usual Undertaking.

Future Cases

Commonwealth compensation claims like the Sanofi Case and the Wyeth Case continue to trickle through the court system (see, for example, in connection with the Usual Undertaking given in respect of Otsuka Pharmaceutical Co., Ltd's patent relating to the compound aripiprazole—used in its schizophrenia medication, Abilify—which was ultimately revoked after special leave to appeal the Full Court's affirmation of the trial judge's findings was refused by the High Court).

In the circumstances, the time is right for pharmaceutical companies to consider strategies which may allow them to obtain injunctive relief against their generic competitors, whilst simultaneously limiting the risk of exposure to compensation claims from the Commonwealth and other third parties. In this regard, it is worth noting that, as part of the Full Court TGA Judgment, his Honour Justice Dowsett delivered a separate, concurring judgment to the majority in which his Honour contemplated (at [20]) the possibility of a party approaching the Court with a limited form of undertaking (other than the Usual Undertaking) which might limit claims for compensation to parties to the relevant proceeding. It would then be a matter for the Court to determine whether the limited undertaking (i.e. something less than the Usual Undertaking) is sufficient 'price to pay' to justify the grant of the interlocutory injunctive relief. As far as can be discerned at the time of writing, no patentee has currently taken up Justice Dowsett on his Honour's offer.

Concluding Thoughts

The impending decisions in the Sanofi Case and Wyeth Case will be closely examined by pharmaceutical corporate patentees when considering whether to seek interlocutory injunctive relief at the outset of patent litigation. Relevant to that consideration will be whether they accept the potential financial consequences of offering the Usual Undertaking or whether they perhaps instead experiment with some alternative form of

undertaking, having regard to Dowsett J's observations in the Full Court TGA Judgment. Evidently, certain stakeholders (such as AstraZeneca AB) appear to now be accepting compensation of the Commonwealth as a 'cost of doing business' in prosecuting patent litigation (if their patents are ultimately held to be invalid). An alternative approach would be to proceed without seeking interlocutory injunctive relief, though this course may end up costing companies more financially in terms of the losses they will suffer as a result of increased competition in a marketplace potentially flooded with cheaper generic products, potentially over a number of years whilst the litigation runs its course.

In addition, if the impending decisions are favourable to the Commonwealth, third parties to proceedings will be galvanised in their hitherto hypothetical claims to compensation which could see a steady increase in litigation seeking to enforce the Usual Undertaking (whether in pharmaceutical patent litigation or otherwise). Either way, both the Sanofi Case and Wyeth Case stand as stark reminders to practitioners and litigants alike that the Usual Undertaking is not a mere formality. It carries serious risks and should not be given lightly.

LINK DIRECTORY:

1. Sanofi Case (Interlocutory Injunction Judgment): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2007/2007fca1485
2. Sanofi Case (Trial Judgment): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2008/2008fca1194
3. Sanofi Case (Full Court Appeal Judgment): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2009/2009fcafc0134
4. Sanofi Case (Transcript of High Court Special Leave Application): http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/HCATrans/2010/59.html
5. Sanofi Case (Transcript of Second High Court Special Leave Application): http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/HCATrans/2015/300.html
6. Sanofi Case – Commonwealth Compensation Claim (Access to Apotex Witnesses): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2017/2017fca0382
7. Wyeth Case (Sigma Interlocutory Injunction Judgment): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2009/2009fca0595
8. Wyeth Case (Alphapharm Interlocutory Injunction Judgment): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2009/2009fca0945
9. Wyeth Case (Generic Health Interlocutory Injunction Orders): https://www.comcourts.gov.au/file/Federal/P/NSD1124/2009/3574344/event/26006569/document/176050

10. Wyeth Case (Trial Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2010/2010fca1211
11. Wyeth Case (Post-Trial Orders Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2010/2010fca1212
12. Wyeth Case (Full Court Appeal Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2011/2011fcafc0132
13. Wyeth Case (Post-Appeal Orders Judgment – Part 1):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2011/2011fcafc0143
14. Wyeth Case (Post-Appeal Orders Judgment – Part 2):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2011/2011fcafc0165
15. Wyeth Case (Transcript of High Court Special Leave Application):
http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/HCATrans/2012/116.html
16. TGA Special Question (Full Court Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2015/2015fcafc0172
17. TGA Special Question (High Court Special Leave Disposition):
http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/HCASL/2016/98.html
18. AstraZeneca Case (Interlocutory Injunction Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2011/2011fca1520
19. AstraZeneca Case (Further Interlocutory Injunction Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2012/2012fca0142
20. AstraZeneca Case (Second Further Interlocutory Injunction Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2012/2012fca0200
21. AstraZeneca Case (Third Further Interlocutory Injunction Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2012/2012fca0265
22. AstraZeneca Case (Trial Judgment):
http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2013/2013fca0162

23. AstraZeneca Case (Post-Trial Orders Judgment): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2013/2013fca0560
24. AstraZeneca Case (Full Court Appeal Judgment): http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/full/2014/2014fcafc0099
25. AstraZeneca Case (Transcript of High Court Special Leave Application): http://www.austlii.edu.au/cgi-bin/viewdoc/au/cases/cth/HCATrans/2015/58.html
26. AstraZeneca Case (High Court Appeal Judgment): http://eresources.hcourt.gov.au/downloadPdf/2015/HCA/30
27. AstraZenca Case (Settlement Advice—see page 57 of H1 2018 Results Notification): https://www.astrazeneca.com/content/dam/az/PDF/2018/h1-2018/H1%202018%20Results%20announcement.pdf
28. Otsuka Case (Federal Court Online Portal): https://www.comcourts.gov.au/file/Federal/P/NSD121/2012/actions

DÜSSELDORF:
THE SUPPLEMENTARY PROTECTION CERTIFICATE – OVERVIEW OF THE LATEST CASE LAW BY THE ECJ AND GERMAN COURTS

It is common sense to any person stumbling over patent law in Europe that the term of a patent is 20 years from the application date. This is, however, different for patents in the healthcare or plant protection sector. Since products developed out of inventions in the medicinal or phytosanitary cosmos are under heavy regulatory control and marketing such products generally takes years, the Supplementary Protection Certificate ("**SPC**") provides a compensation in granting up to five additional years of patent protection in certain cases. Due to the enormous economic value of the prolonged market exclusivity, more and more high profile cases related to this issue are brought to national courts and from there to the European Court of Justice ("**ECJ**"). Especially for "blockbuster" human drugs, every single day of keeping generic medicaments off the market means actual revenue for the patent owner. This article intends to outline the main requirements of obtaining an SPC in Europe and links these conditions with the case law milestones by the ECJ and German courts.

What has to be always kept in mind when talking about the legal concept of an SPC is that it is not a simple patent term extension. In fact, the SPC is attached to a basic patent and a market authorization for a specific pharmaceutical product (plant protection products will not be examined further in this article). Therefore, the SPC system is a blend of patent law and healthcare regulatory law, requiring knowledge by the advising lawyers in both areas. The main rules for an SPC are contained in the Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products ("**SPCR**").

Formal and material conditions

An application for an SPC, has to be filed duly and within the statutory deadlines at the respective national IP office (Art. 9 SPCR). There is no central European body responsible for granting an EU-wide SPC. The filing deadline generally is six months after receiving the market authorization for the respective country (which itself may be obtained centrally and EU-wide) or six months after the grant of the basic patent, if this date is later than the grant of the authorization (Art. 7 SPCR).

Key Issues

- Supplementary Protection Certificates ("**SPC**") have enormous economic value. That is why cases are brought to national patent courts and the European Court of Justice ("**ECJ**") frequently.
- The SPC is based on a basic patent and a market authorization for a specific pharmaceutical product, making it necessary to have profound knowledge in both patent law and regulatory law.
- One of the main principles of the European rules on the SPC is that only one Certificate will be issued per marketed product.
- Admissible basic patents are (combinations of) active ingredient(s), process patents and (Second-Medical-) use patents. The German Patent Court recently held that formulation patents are admissible as well.
- The ECJ postulates that the (combination of) active ingredient(s) must be specified in the wording of the claims. Whether the doctrine of equivalents is applicable is not yet decided by the ECJ.
- Due to the restriction of one SPC per product, not every modification to already existing products, e.g. adding a well-known active ingredient to the product that is covered by the basic patent and was already granted an SPC, will be deemed a new product in the meaning of the SPC-Regulation.

Material requirements are:

- a medicinal product that is protected by a valid basic patent (Art. 3 (a) SPCR),
- a valid regulatory authorization to place the product on the market (Art. 3 (b) SPCR),
- the product has not already been the subject of a certificate before (Art. 3 (c)SPCR),
- the market authorization is the first of its kind for the product (Art. 3 (d) SPCR) and
- the applicant is the owner of the basic patent or its successor in title (Art. 6 SPCR).

These conditions may well be translated in two main rules:

(i) No SPC without a patent and a market authorization and

(ii) Only one SPC per product.

Aside from these rules, the interpretation of the stipulations in the SPCR was and still is subject to numerous proceedings. Disputes between pharma companies range from the admissible subject matters of the basic patent over the necessary intersection between basic patent claims and content of the market authorization to the scope of prior certificates in combination products. On several occasions, the ECJ rendered milestone judgements which circulate among experts and will be briefly explained herein.

Admissible subject matters of a basic patent

According to the wording of Art. 3 (a) SPCR, the basic patent must protect a medicinal product. But not every potential subject matter of a patent is suitable to protect a medicinal product. Art. 1 SPCR contains fundamental definitions of the terms "medicinal product", "product" and "basic patent". Applying these definitions, the obvious case for an applicable subject matter is an *active ingredient or a combination of active ingredients*. In respect of the legal scope of patents, the active ingredient "as such" is suitable, i.e. also derivatives, salts and esters are comprised as long as they do not present substantially different characteristics. Due to the express wording in Art. 1 (c) SPCR, also *process patents* and *use patents* are generally admissible subject matters of a basic patent. The latter is especially important for the prevalent *Second-Medical-Use patents*.

In reverse conclusion, formulation patents and medical device patents were widely considered to not be suitable basic patents. Nevertheless, the German Patent Court (*Bundespatentgericht*, "**BPatG**") recently rendered a decision[1] which granted an SPC for a product protected by a basic formulation patent. In that specific case, a formulation of six established and well-known active ingredients with adjuvants to a new mixed vaccine product was the subject of the judgement. The court reasoned that the SPCR is meant to support any research activities in the pharmaceutical sector, also for formulation patents which are a subclass of product patents.

1. BPatG, decision of 23 January 2018, file no. 14 W (pat) 10/16 – *Hexavalenter Impfstoff*.

This judgement was not challenged and presents an extension of SPC protection at least in Germany. However, it remains to be seen if the ECJ will object to this opinion in one of the upcoming preliminary rulings currently pending and concerning the interpretation of Art. 3 (a) SPCR[2].

Scope of the basic patent claims

Another notable aspect in the context of Art. 3 (a) SPCR is that the (combination of) active ingredients have to be specified in the wording of the claims. This rule is a cornerstone of the SPC granting process since the infamous "*Medeva*" landmark decision by the ECJ[3]. Before "*Medeva*", national courts applied a standard that was similar to patent infringements, thus allowing any product for SPC consideration if it would be an infringement of the basic patent.

The ECJ judgement in "*Eli Lilly*"[4] confirmed that rather narrow standard. However, it also added that a structural formula is not necessary, but also a functional formula might be sufficient if "*the claims relate, implicitly but necessarily and specifically, to the active ingredient*". This, of course, allows the interpretation of the patent claims in concordance with Art. 69 EPC for European patents and their national patent law counterparts which might be regarded as a step back to former standards.

Just weeks ago, the ECJ confirmed this direction in its ruling of the case "*Teva v. Gilead*"[5] concerning the AIDS-medicament Truvada. According to this new milestone judgement, a product composed of several active ingredients with a combined effect must not expressly be mentioned in the claims of the basic patent, but the claims must "*relate necessarily and specifically to that combination*". A person skilled in the art must be able to identify the combination in the invention covered by the patent and all combined active ingredients must be specifically identifiable. Again, this is not feasible without patent law specific interpretation of patents, somewhat leading back to the "patent infringement standard".

In essence, the ECJ leaves the decision of the scope of protection of the basic patents with the patent courts but did not yet clarify if the doctrine of equivalents is applicable. What complicates the situation even more is that the doctrine of equivalents differs in the main European jurisdictions. Upcoming preliminary rulings of the ECJ might shed light on the questionable applicability of equivalents.

Scope of protection of an SPC

According to Art. 4 SPCR, the SPC is not a prolonged patent term but an extended term of protection of the specific product. Therefore, a patent that protects more than one product must be extended by more than one SPC. If an SPC is granted, the product is protected against unauthorized use in the same form as it was protected under the basic patent. Therefore, not only is the identical use protected but also, if applicable in the country, equivalent use.

2. Such as the pending cases no. C-650/17 and C-114/18.
3. ECJ, decision of 24 November 2011, case no. C-322/10 – *Medeva*.
4. ECJ, decision of 12 December 2013, case no. C-493/12 – *Eli Lilly*.
5. ECJ, decision of 25 July 2018, case no. C-121/17 – *Teva v. Gilead*.

Calculation of the term of an SPC

The term of an SPC is always calculated accurately to a day. The SPC can provide a patent term extension of up to five years (Art. 13 (2) SPCR), but will not necessarily reach the term of five years. The purpose of the SPC is extending the patent term for the time delay before legally marketing a product, which arises out of the period between filing the patent application and the first EU marketing authorization. This period has to be reduced by five years to calculate the exact term of the SPC (Art. 13 (1) SPCR). The formula is:

(application date until first EU marketing authorization = x years and y days) – 5 years = SPC term

For example, given the hypothetical case where a product based on the patent application of Patent 1 filed on 1 January 2014 (see above) would have received first authorization on 1 January 2024, the applicable period would be ten years and, subtracting five years, lead to a five-year (maximum term) SPC with a term until 1 January 2039.

Otherwise, if the first market authorization is granted earlier than ten years after application date of the patent, the SPC term will be less than five years. In the case of an authorization just five years after patent application or even earlier, no SPC extension would be granted at all.

There might also be an SPC with a term of zero or even a negative term as established by the ECJ in the case "*Merck v. DPMA*"[6]. Applying for such zero or negative term SPC could make sense if the patent owner requests for a Paediatric Extension governed by Regulation (EC) No 1901/2006 which might provide for additional six months of protection adding up to the SPC term.

Attempts to circumvent the "one product, one SPC"-rule

As described above, the provision in Art. 3 (c) SPCR foresees that any product should only be awarded further market exclusivity by an SPC once[7]. Conversely, this does not mean that one patent can only lead to one SPC. Rather a wide basic patent protecting several active ingredients or combinations thereof is suitable to protect several products and, therefore, several SPCs. For illustration purposes: if the basic patent protects the active ingredient A as well as the combination of A with the pre-existing active ingredient B and there are the two products A and AB authorized on the market, then the patent owner might be granted SPCs for A and AB. Or as the ECJ rendered in its decision "*Georgetown*"[8]: the patent owner is not excluded from being granted an SPC for each of the single active ingredients W, X, Y or Z after obtaining an SPC for the combination of WXYZ.

6. ECJ, decision of 8 December 2011, case no. C-125/10 – *Merck v. DPMA*.
7. This means once per patent owner. If there are more than one patent owners, any owner might be awarded an SPC for its products once in order to avoid a "greyhound racing" between the owners which would practically only be depending on the coincidence of duration of the patent office proceeding.
8. ECJ, decision of 12 December 2013, case no. C-484/12 – *Georgetown University v. Octrooicentrum Nederland (NL Octrooicentrum).*

However, in practice, patents do not protect a large number of products. Hence, patent owners of "narrow" patents are interested in modifying existing products, especially combination products and try to extend the term of protection for the core of the product. This could be, for example, adding another existing active ingredient D to the one protected by the basic patent C, but without the basic patent protecting this combination CD[9]. Then the relevant question is if the addition of D to C leads to a new product in the sense of the SPC.

On several occasions, the ECJ had the opportunity to rule on the interpretation of Art. 3 (c) SPCR. In its judgment "*Actavis v. Sanofi*"[10], the ECJ ruled that, after being granted an SPC for the active ingredient irbesartan ("**I**"), the patent owner should not obtain a second SPC for the combination of I and hydrochlorothyiazide ("**H**") because the combination does not have any new therapeutic effect and therefore does not qualify as a new product.

In the decision "*Actavis v. Boehringer*"[11], the patent owner was granted an SPC for the active ingredient telmisartan ("**T**"). After the grant of this SPC, the owner added a claim to the basic patent for the combination of T and H. On this basis, the owner applied for a second SPC covering TH. Again, the ECJ rejected the second SPC because the sole subject matter of the patented invention was T. In this decision, the ECJ brought together the aspect of innovation with the interpretation of products which resulted in harsh critics by patent law commentators.

Conclusion

Although the ECJ delivered some meaningful decisions on the SPCR, the law of the Supplementary Protection Certificate is still developing to some extent. In any case, advising on the matter becomes more predictable with every judgement by the ECJ or national courts. As the SPC is of such high economic value, we will keep you updated as new landmark judgement are rendered. For companies in the healthcare sector, a profound strategy for their patent and product portfolio is mandatory to maximize market exclusivity and profits.

9. E.g. because it is not inventive and would therefore not be admissible as a patent.
10. ECJ, decision of 12 December 2013, case no. C-443/12 – *Actavis v. Sanofi*.
11. ECJ, decision of 12 March 2015, case no. C-577/13 – *Actavis v. Boehringer.*

BARCELONA: ERODING SUPPLEMENTARY PROTECTION CERTIFICATES? THE CONTROVERSIAL "MANUFACTURING EXCEPTION FOR EXPORT PURPOSES" PROPOSED BY THE COMMISSION OF THE EUROPEAN UNION

On May 28, 2018, the Commission of the European Union ("**EU**") published the "Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 469/2009 on the supplementary protection certificate for medicinal products", which aims to introduce a "Manufacturing Exception for Export Purposes" in EU law ("**Manufacturing Exception**"). The Commission, giving in to the interests of the European lobby of manufacturers of generic and biosimilar medicines, has proposed this controversial exception whose benefits for the whole of the European pharmaceutical industry are highly debatable.

This proposal finds its place in a wider initiative carried out in the EU to adjust some aspects of the current patent and supplementary protection certificate ("**SPC**") legal framework, including the possible creation of a unitary SPC with effect in all the EU Member States and the harmonization of the scope of the so-called Bolar patent exception. This recent proposal, however, exclusively targets the introduction of the Manufacturing Exception and leaves the implementation of other measures for the future. The reason to prioritize this specific aspect now (the EU institutions look forward to introducing and implementing this exception in 2019) may be explained by the will to urgently pave the way for the EU-based generic and biosimilar medicines manufacturers in view of the upcoming "patent cliff", as many patents protecting important biological medicines will expire in 2020.

Scope and objectives of the Manufacturing Exception

The proposed Manufacturing Exception implements a restriction on the rights conferred by an SPC, allowing the manufacturing of products protected by an SPC (either the active ingredients and/or final medicinal products), in the territory of a Member State during the term of an SPC, for the exclusive purpose of exporting them to non-EU countries where the relevant patents and SPC already expired (or were never granted). The envisaged exception also comprises all the related necessary acts for the manufacturing or for the export itself, like the supply of active ingredients to the manufacturer or the temporary stockpiling of the finished products intended for exportation. It is important to clarify that the Manufacturing Exception would **not** limit the rights derived from the basic patent, but only those derived from the SPC.

Key Issues

- The proposed Manufacturing Exception implements a new restriction to the rights conferred by an SPC (not to the rights conferred by a patent).
- Under the new exception, the manufacturing of products protected by an SPC, in the territory of a Member State during the term of an SPC, for the exclusive purpose of exporting them to non-EU countries would not constitute an SPC infringement act.
- The proposal envisages a series of safeguards aimed at creating transparency and preventing products manufactured under the exception from being diverted onto the markets of the EU Member States.
- The Manufacturing Exception will not apply to an SPC granted before its implementation but will affect pending applications.
- The compatibility of the Manufacturing Exception and Article 30 of the TRIPS Agreement is far from being crystal clear.

The Explanatory Memorandum ("**Memorandum**") accompanying the proposal justifies the introduction of the Manufacturing Exception referring to "*certain unintended consequences resulting from the SPC regime*" implemented three decades ago. First, it refers to the supposedly competitive disadvantage position that would be encountered by EU-based generic and biosimilar drug manufacturers compared to those based outside the EU, in countries where the legal concept of an SPC does not exist. According to the Memorandum, the former would be losing "export markets", which would be falling into the hands of companies based in the territory of other business partners of the EU.

The Memorandum also explains that the objective of the reform is not only to facilitate the access of European manufacturers to "export markets" but also their swift access to the EU market the following day ("**day-1**") after the SPC expires. According to the Memorandum, access to the EU market on "day-1" would be easier and faster for EU-based businesses if they had previously set up the costly manufacturing lines for products intended for exportation.

To try to minimise the detrimental impact of the Manufacturing Exception on the SPC holders, the proposal is accompanied by a set of "safeguards" that aim to prevent products manufactured for export from ending up being marketed in the EU. These safeguards include (i) the obligation to notify relevant information to the competent authorities, at least 28 days ahead of the intended manufacturing date; this information, which will be published, includes who will make use of this exception, when and where the manufacturing is planned to start, what products will be manufactured and which are the intended export markets; (ii) due diligence requirements, pursuant to which manufacturers will have to take appropriate measures to ensure that third parties engaged in the supply chain do not divert products manufactured under the exception onto the EU, and (iii) the obligation to affix a "for export"-type logo in the outer packaging of the products. According to the Memorandum, the combined effect of these safeguards should create transparency and prevent products that would infringe existing intellectual property rights from entering the markets of the EU Member States.

To preserve the acquired rights and legitimate expectations of the holders of an already granted SPC, the proposal envisages that the Manufacturing Exception will only apply to an SPC granted on or after the first day of the third month that follows the month in which the amending Regulation is published in the Official Journal. In other words, with regard to an already granted SPC, the manufacturing of products for exclusive export purposes in the EU would still constitute an SPC infringement act. However, the exception would apply to pending applications not yet granted.

A controversial exception

The implementation of the Manufacturing Exception is far from being a healthy exercise of consensus between all the players in the pharmaceutical field. Leaving aside the logical and irreconcilable interests of the R&D-based industry, on one hand, and the generic and biosimilar EU producers, on the other, there are a lot of legal question marks surrounding the proposal.

For instance, some voices have raised sound and serious concerns questioning the compatibility of the proposal and Article 30 of the TRIPS Agreement ("**TRIPS**"). This article, entitled "Exceptions to rights conferred" [by patents], states that "*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*"

Although the Memorandum timidly contends that the Manufacturing Exception does not conflict with TRIPS, the doctrine laid down by the WTO Dispute Settlement Body interpreting, among others, Articles 28 and 30 of TRIPS suggests otherwise and allows us to predict that the proposed Manufacturing Exception, if finally implemented, might end up navigating stormy waters.

DÜSSELDORF:
OVERVIEW OF THE PROMISING MARKET OF MEDICAL CANNABIS IN GERMANY

In 2017, the regulatory requirements to prescribe medical cannabis in Germany have significantly been extended. Since the treatment costs will generally be covered by the patient's health insurance, the market for medical cannabis shows extraordinary growth potential.

Key Issues

- In Germany, the costs for the use of medical cannabis is generally covered by health insurances.
- The market of medical cannabis has significant growth potential.
- Since March 2017 more than 44,000 units of cannabis blossoms were handed out to patients.

Introduction

In July 2018, Veritas Pharma Inc. ("**Veritas**") signed an IP sharing agreement with Sativa Investments PLC ("**Sativa**"), UK's **first medical cannabis investment fund**. Sativa's strategy is to invest in well-placed cannabis companies. Veritas is an emerging pharmaceutical and IP development company, whose affiliate Cannevert Therapeutics Ltd. focuses on advancing medical cannabis science. Veritas aims to develop the most effective cannabis strains specified on the sectors of pain, nausea and epilepsy.

This development gives rise to the need to bring your attention to the statutory provisions of the use of medical cannabis in Germany and the future potential of this sector.

Regulatory Provisions

The regulatory requirements to prescribe medical cannabis in Germany have significantly been extended by the Act to Amend Narcotic Drugs Provisions and Other Related Provisions ("**Amendment**") which came into force on 10 March 2017. This amendment to the Narcotic Drugs Act (*Betäubungsmittelgesetz, "***BtMG**") **allows doctors to prescribe cannabis** to seriously ill patients even if other treatment options are available. Additionally, the Amendment allows a **state-controlled cultivation** of cannabis for medical purposes in Germany. In order to control this cultivation, the Federal Institute for Drugs and Medical Devices has even set up a cannabis agency. Since the legislator relies only on state controlled cultivation, not necessarily on a German, it is recognized that cannabis, which was manufactured under state-controlled cultivation in the Netherlands, may also be sorted to Germany. This may also be applicable to other non-German state-controlled cultivations.

Health Insurance Coverage

The Amendment also fundamentally changed the statutory provisions of the coverage of costs of the medical cannabis. Under the former regulations, the costs for medical cannabis treatments were not covered by the health insurance. However, according to the Amendment and the related change of the Social Security Code V (*Fünftes Buch des Sozialgesetzbuch, "***SGB V**"), the **treatment costs will generally be covered** by the patient's health insurance, and a refusal will only be possible in duly justified exceptional cases. Therefore, the number of patients ordering prescribed medical cannabis will constantly grow within the next years.

Before the Amendment came into force, medical cannabis was only available to seriously ill patients with a special permit granted by the Federal Institute for Drugs and Medical Devices. By March 2017, there were only around 1,000 patients in possession of this special permit. In contrast, in the second quarter of 2017, more than 4,600 prescriptions of cannabis were handed in by patients and 10,000 units were dispensed to them. Already in the third quarter of 2017, about 12,500 prescriptions were handed in combined with a dispensation of 18,800 units. In total, 44,000 units of cannabis blossoms were handed out to patients since March 2017.

Growth Potential

When in 2016, only 170 kg of cannabis were imported to Germany, it is expected that about 2,000 kg will be harvested from the state-controlled cultivations in 2020.

One year after the legalization of medical cannabis in Germany, the **demand is still increasing**. More than 16,000 applications for the coverage of costs were received by the statutory health insurances, which granted about 60 percent of the applications. The actual number of patients is even higher due to private prescriptions.

Combined with the diverse use of medical cannabis for **numerous methods of treating diseases or disorders**, including cancer, pain and epilepsy, this shows the extraordinary growth potential of medical cannabis.

PARIS: SUFFICIENCY OF DISCLOSURE AS A GROUND OF PATENT NULLITY IN FRENCH AND EUROPEAN CASE LAW

On 23 March 2018, the *Tribunal de Grande Instance* (First Instance Court) of Paris ("**TGI**") rendered an interesting decision regarding sufficiency of disclosure as a patent validity requirement[1].

In the case at hand, Bayer Pharma ("**Bayer**") had initiated a nullity action with respect to a French patent on a composition of contrast agent owned by the French company Guerbet. The revocation request was based on several grounds, including insufficiency of disclosure, Bayer claiming that there was a contradiction in the patent claim which refers to both a free compound (the lanthanide) and the same compound entirely complexed.

The TGI rejected the claim of insufficiency of disclosure, ruling in particular that "*it can be inferred from common general knowledge that it is impossible to find free lanthanide if the complexation lanthanide is to be total, resulting in that [the skilled person] reading the patent in a manner which will give effect to this patent which provides various steps for making the dissolution process, measuring and adjusting, will understand that the total complexation of lanthanide can be performed at a later stage and that this circumstance does not result in an impossibility to reproduce the claim, which involves to implement the claim as a whole, without focusing on one of its steps without taking the other ones into account*".

This ruling follows the common approach of the European Patent Office ("**EPO**") pursuant to which the skilled man is a "*man willing to understand, and not a man desirous of misunderstanding*", who should try "*building up rather than tearing down, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent*"[2], even when the terms of the claim are not clear or are contradictory.

It is recalled that, pursuant to article 138 of the European Patent Convention ("**EPC**") and article L.613-25 of the French intellectual property code ("**IPC**"), a patent can be revoked[3] if it "*does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*".

Key Issues

- The insufficiency of disclosure is a ground of nullity of a patent, contrary to the lack of clarity of the patent claim, which is not a ground of nullity *per se*.
- In order to constitute a basis for a revocation of a patent, the lack of clarity has to amount to insufficiency of disclosure and therefore must affect the patent as a whole, not just the claims, so that the skilled person is prevented from implementing the invention.
- In other words, to avoid the nullity of the patent, the claims need to give the skilled man enough information in order to implement the invention without undue burden, using the disclosure as a whole and his common general knowledge.

1. TGI Paris, 3ème chambre, 3ème section, *Bayer Pharma Akiengesellschaft v. Guerbet*, 23 March 2018, No. 15/12348.
2. Board of Appeal of the European Patent Office, 6 March 2001, T190/99, *YKK Corporation v. Opti Patent – Forschungs- und Fabrikations- AG*.
3. Insufficiency of disclosure is also a ground for opposition before the EPO.

On the contrary, lack of clarity – based on article 84 EPC and article L. 612-6 IPC which state that "*the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description*" – is not a ground of nullity[4] of the patent *per se*, although it can lead to objections from the patent office.

EPO case law is constant on the fact that, where a claim contains an unclear parameter and where, consequently, the skilled person would not know whether he was working within or outside of the scope of the claim, this, by itself, is not a reason to deny sufficiency of disclosure. What is decisive for establishing insufficiency of disclosure is whether this parameter is so unclear that the skilled person is not able, on the basis of the disclosure as a whole and using his common general knowledge, to identify, without undue burden, the technical measures necessary to solve the problem underlying the application at issue.[5]

In other words, lack of clarity, in order to amount to insufficiency of disclosure, must affect the patent as a whole, not just the claims, so that the skilled person is prevented from implementing the invention.

Following this trend, the TGI had already ruled that, for the patent to be revoked on the grounds of insufficiency of disclosure, the claimant has to evidence the impossibility for the skilled person to reproduce the invention using his common general knowledge of theory and practice.[6]

Therefore, although insufficiency of disclosure is clearly a strategic ground when it comes to trying to obtain the revocation of a patent, it looks that revoking a patent whose claims are unclear on the ground of insufficiency of disclosure is ultimately not an easy exercise.

4. Or opposition before the EPO.
5. Board of Appeal of the European Patent Office, 20 December 2011, T593/09, *Toyo Kohan Co., Ltd v. Tata Steel Ijmuiden BV*; Board of Appeal of the European Patent Office, 13 May 2014, decision T754/13, *Universidad de Sevilla*.
6. TGI Paris, 3ème chambre, 3ème section, 23 June 2017, *AstraZeneca AB. v Ethypharm*, n°11/11460.

PARIS:
FRENCH STATUTE OF LIMITATION IN PATENT NULLITY ACTIONS

Last year, we were debating in this Newsletter[1] the applicability to patent nullity actions of article 2224 of the French civil code on the statute of limitations. This article, which was introduced in French law in 2008, provides that "*personal or real actions are time-barred five years from the day when the owner of a right knew or should have known the facts making the action possible*".

Despite an important controversy amongst legal practitioners and doctrine, the *Tribunal de Grande Instance de Paris* (the Paris First Instance Court, which has exclusive jurisdiction to hear patent cases in France) has consistently ruled that the five-year limitation period of article 2224 CC applies to patent nullity actions. This resulted in that statute of limitation suddenly becoming one of the main arguments in defence raised in patent nullity actions, whereas it had never been raised in the past; the former applicable limitation period was 30 years. The debate was all the more vigorous because France was one of the very few, if not the only, European country where such a statute of limitation applied to nullity actions.

The applicability of the five-year limitation period being clearly settled in the jurisprudence, the debate mostly focused on the starting point of the limitation period and the determination of the moment "*when the owner of a right knew or should have known the facts making the action possible*". French judges adopted in most of the cases an *in concreto* approach[2], however, resulting in a wide range of potential starting dates of the limitation period, such as, for instance, the publication of the patent[3], the expiration of the opposition deadline before the European Patent Office[4], or the date when the application for a marketing authorization could be filed[5]. Those discrepancies in fact reflected the difficulty of determining the date when the claimant acquired standing to sue.

Fortunately, the French legislator recently, through a Decree-Law of 9 May 2018 relative to the European patent with unitary effect and the Unified Patent Court, decided to solve this issue by adding to the French Intellectual Property Code a new article L. 615-8-1 stating that there shall be no statutory barring of patent nullity action.

Key Issues

- In France, statutes of limitation in IP rights nullity actions is a recurrent topic since a 2008 reform which set up the general limitation period in ordinary civil law procedure to five years.
- The French legislator recently decided to put an end to this issue by introducing a new article in the French Intellectual Property Code stating that patent nullity actions cannot be time-barred.
- However, the entry into force of this new text is on hold until the Unified Patent Court Agreement enters into force. In addition, the five-year statute of limitation will still apply to nullity actions relative to IP rights other than patents.

1. 16th Edition of the IP Newsletter – December 2017.
2. TGI Paris, 3ème chambre, 1ère section, 5 October 2017, n°17/01156, *LuK Gmbh & Co KG v. Valeo Embrayages*.
3. CA Paris, Pôle 5 chambre 2, 22 September 2017, n°14/25130, *Mr. and Mrs. Halgand & SAS Matériaux Equipements Plastiques v. SAS Raccords et Plastiques Nicoll*.
4. TGI Paris, 3ème chambre 1ère section, 26 January 2018, n°16/01225, *Ethypharm v. Merck*.
5. TGI Paris, 3ème chambre, 1ère section, 30 November 2017, n°16/14466, *Mylan v. Merck*.

This new text is very good news for the market actors. Yet, three points obscure the picture:

First, this text does not solve the problem of statute of limitation with respect to others' intellectual property rights such as trademarks. Indeed, the *Cour de Cassation* (the French Supreme Court) ruled one year ago that the five-year limitation period of article 2224 CC applies to trademark nullity actions[6]. It is also important to note that the text does not address the question of the supplementary protection certificate for medicinal products[7], even if it will probably follow the patent's statute of limitation regime, as its protection is modelled on the basic patent.[8]

Second, the text will enter into force only once the Unified Patent Court Agreement enters into force. The Brexit context has importantly slowed down the process. Now that the UK has ratified the Unified Patent Court Agreement on 26 April 2018, all eyes are turned towards Germany, whose ratification is needed for the Unified Patent Court Agreement to take effect.

Last, although the new text will have no effect on the limitation periods that would have already expired at the time it enters into force, it is likely that judicial disputes on limitation periods will continue, at least for a while, since the question of whether or not the limitation period would have expired at the time of entry into force of the new text will be a tricky one.

6. Cass. Com. 8 June 2017, n°15/21357, *Cheval Blanc*.
7. TGI, 3ème chambre, 1ère section, 30 November 2017, n°16/14446.
8. Article 5 of the Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

WARSAW:
SUPREME COURT PROVIDES ANSWERS TO QUESTIONS ON THE NATURE OF COPYRIGHT ENFORCEMENT IN POLAND

Under Article 79 section 1 point 3b) ("**Provision**") of the Polish Copyright Act ("**Copyright Act**"), an author whose rights have been infringed has a right to demand a remedy on the basis of the general principles of damages under the Polish Civil Code or by payment of a sum of money corresponding to twice, or, in the event of a culpable infringement, three times, the amount of the appropriate fee that would have been payable at the time it was sought if the copyright holder had given permission for the work to be used. However, on 23 June 2015 the Polish Constitutional Tribunal declared the triple licence fee unconstitutional as it found such protection of copyright inconsistent with Article 32 (equal treatment before the law) and Article 64 (equality of protection for property ownership) of the Polish Constitution. Thus, the question of the double licence fee and calculation of damages remained unanswered until recently.

Key Issues

- Copyright protection must be in line with the constitutional provision ensuring equality of protection for property ownership.
- The obligation to pay a fine for infringement should not lead to a disproportion between the size of the loss incurred and the compensation due.

Case

The Polish Filmmakers Association (*Stowarzyszenie Filmowców Polskich*) ("**SFP**") sued a cable network provider, Oławska Telewizja Kablowa ("**OTK**") as OTK continued to make use of audio-visual works managed by SFP after the licence agreement with SFP had been terminated. The Supreme Court was required to examine the case for a third time (each party filed appeals against the judgments of lower courts), after a preliminary ruling in the case was issued by the Court of Justice of the European Union ("**CJEU**" and "**Ruling**", respectively).

Analysis

The Supreme Court declared that the double licence fee introduces a disproportionate sanction, which may lead to violation of the principle of social justice and equal protection of property rights, both of which are guaranteed by the Polish Constitution.

In the justification of the judgment, the Supreme Court referred to EU directive 2004/48/EC ("**Directive**") and to the Ruling, in which the CJEU reasoned that in exceptional cases payment for a loss calculated on the basis of twice the amount of the hypothetical royalty will significantly exceed the loss actually suffered, thus such an approach may potentially constitute an abuse of rights, which is prohibited under Article 3 point (2) of the Directive. The Supreme Court stated that SFP vs. OTK case is

an example of an exceptional case where compensation for damage, calculated on the basis of twice the hypothetical licence fee, clearly and significantly goes beyond the actual damage suffered.

The Supreme Court stated that the double licence fee is a special form of compensation, which does not require a demonstration of basic premises determining the claim for damages, as required by the general principles for damages laid down in the Polish Civil Code. The Supreme Court argued that such compensation is a textbook example of a civil penalty, well-known in the common law system, but inadmissible under the concept of damages in Poland.

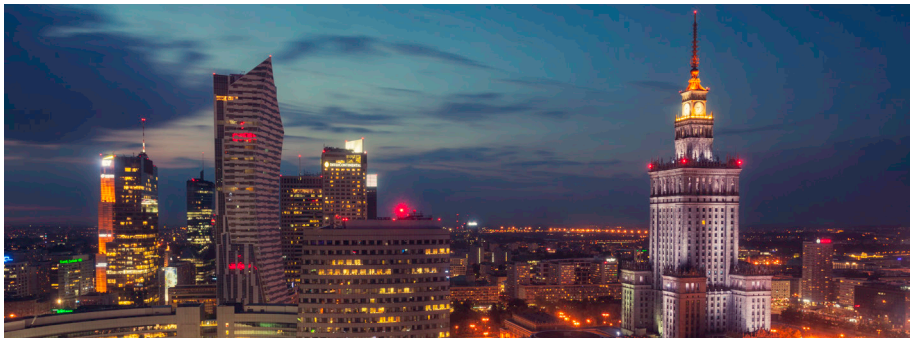
Having regard to all the circumstances described above, the Supreme Court concluded that the double licence fee results in a lack of respect for the principle of equal protection for property ownership. At the same time, the Supreme Court emphasized that the necessity of equal treatment of everyone by the public authorities, and consequently also by the laws they set, is assured by the Constitution, as its provisions prohibit discrimination in the protection of property rights for any reason.

Implications

The judgment of the Supreme Court is the next step on the road to changes in the perception of copyright protection in Poland. As previously the triple licence fee was declared unconstitutional by the Polish Constitutional Tribunal, the Supreme Court followed its conclusions and made a pro-constitutional interpretation of the controversial Provision. Moreover, the Provision is questionable not only on the foundations of constitutional law, but also on the principles of the civil law, which is based on compensation and not on punitive damages.

Conclusion

The judgment of the Supreme Court proves that a new line of jurisprudence is being created, in which the courts look at the protection of copyrights differently and abandon the arguments that were raised at the time the Provision was adopted. Nevertheless, as the judgment of 10 November 2017 is still quite new, it is difficult to predict whether the approach set out in it will ultimately be regarded as dominant in copyright infringement cases in Poland.



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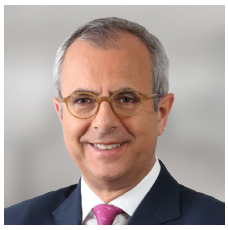

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