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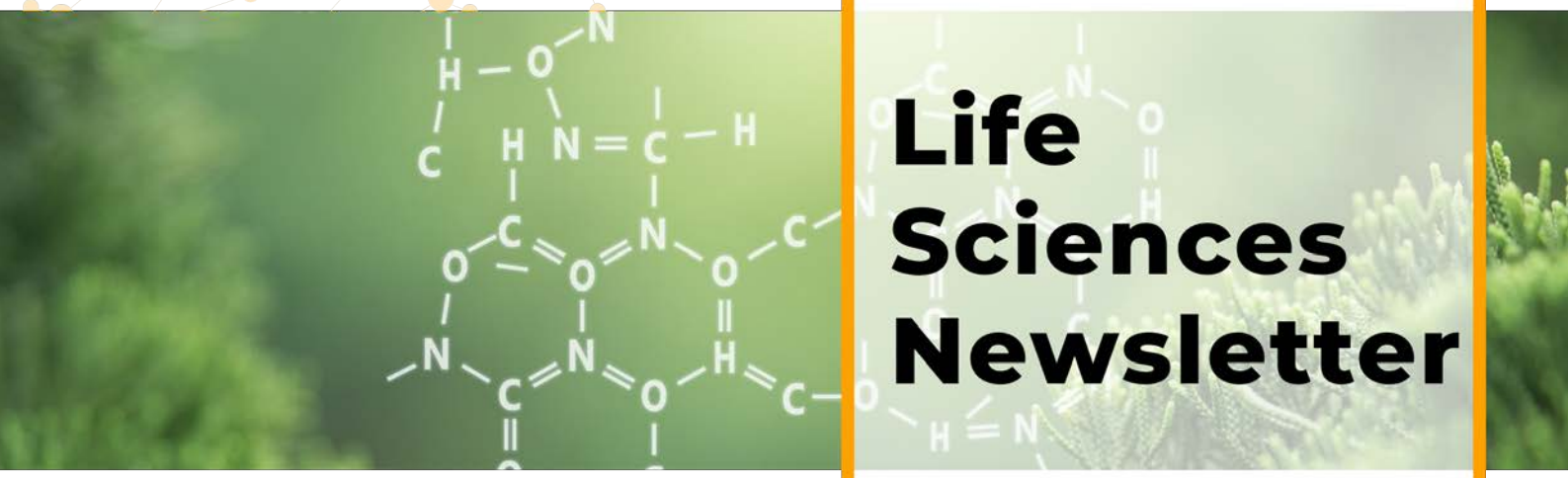

Life Sciences Newsletter

SUMMER / AUTUMN 2020

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Welcome

Welcome to the Summer Edition of the HMC-IP Life Sciences Newsletter covering the many recent legal updates from the past few months.

HMC-IP are pleased to continue to be listed in MIP IP Stars and IAM Patent 1000 this year. We are also delighted to be listed in the Financial Times Europe's leading patent law firms for 2020 and to be part of a prestigious grouping of 160 European IP firms selected on the basis of recommendations by clients and peers.

Whilst, like many other companies worldwide, we continue to #wfh, we are pleased that the HMC-IP team and IT systems have adapted well to continuing to provide a seamless service to our clients around the world. We hope that all our clients and colleagues around the world are safe and well and wish all continued good health.

Unitary Patent Court update – UK confirms withdrawal – where to next?

NEWS IN BRIEF

On 20 July 2020, the UK made its final preparation to withdraw from the Unified Patent Court project: https://www.unified-patent-court.org/news/uk-withdrawal-upca

THE BACKGROUND

A formal withdrawal notification of ratification has been deposited with the Council Secretariat. In addition, there has been the following parliamentary written statement in the UK Parliament in the House of Commons by Amanda Solloway, Parliamentary Under Secretary of State, Minister for Science, Research and Innovation:

"UNIFIED PATENT COURT
I am tabling this statement for the benefit of Honourable and Right Honourable Members to bring to their attention the UK's withdrawal from the Unified Patent Court system.

Today, by means of a Note Verbale, the United Kingdom of Great Britain and Northern Ireland has withdrawn its ratification of the Agreement on a Unified Patent Court and the Protocol on Privileges and Immunities of the Unified Patent Court (dated 23 April 2018) in respect of the United Kingdom of Great Britain and Northern Ireland and the Isle of Man, and its consent to be bound by the Protocol to the Agreement on a Unified Patent Court on provisional application (dated on 6 July 2017) (collectively "the Agreements").

In view of the United Kingdom's withdrawal from the European Union, the United Kingdom no longer wishes to be a party to the Unified Patent Court system. Participating in a court that applies EU law and is bound by the CJEU would be inconsistent with the Government's aims of becoming an independent self-governing nation.

The Agreements have not yet entered into force. However, in order to ensure clarity regarding the United Kingdom's status in respect of the Agreements and to facilitate their orderly entry into force for other States without the participation of the United Kingdom, the United Kingdom has chosen to withdraw its ratification of the Agreements at this time. The United Kingdom considers that its withdrawals shall take effect immediately and that it will be for the remaining participating states to decide the future of the Unified Patent Court system".

WHAT NEXT?

So whilst this announcement is not a surprise, the way forward for the UPC is not entirely clear. London is a crucial part of the agreement as a location for one of the Central Division Courts (Article 7(2) UPC Agreement) and the UK was one of the top 3 countries (UK, FR, DE) required to ratify the agreement so it can come into effect.

Interestingly, as the agreement stands Ireland and the UK were the only 2 common law countries in the UPC. Now Ireland will be the only common law country and English will still be the main language of the UPC system.

On a more practical note for applicants, the loss of the UK as part of the UPC does make the system less attractive to users who require patent protection in the UK. Will the UPC still be of interest to applicants?

To further complicate matters, the ratification of the UPC agreement in Germany had been delayed by a constitutional issue but is now set to proceed.

Accordingly, we now await the UPC Preparatory Committee announcement concerning the impact of the UK withdrawal and outlining if there is a way forward for the much talked about UPC.

Contact the authors, Marie Walsh or Anna Hally or your usual HMC-IP attorney for further advice.

EPO Perspective – Fighting Coronavirus Resource from the EPO

NEWS IN BRIEF

A new research resource from the EPO - the EPO's fighting coronavirus resource provides an overview of the patent landscapes of various relevant technology areas and provides search statements for users of espacenet.

THE DETAILS

We note with interest that the European Patent Office has recently published a set of patent search statements prepared in the Espacenet patent search system to assist users and researchers in identifying relevant prior art documents in the technical fields relating to treating the coronavirus at the following resource: Fighting coronavirus.

It has been widely report that largescale investments have been made in developing technologies and innovations to assist in the response to the coronavirus including in the fields of vaccines, therapies, and also in the field of diagnostics. While there is normally a delay of 18 months (from the priority date) before publication of new patent application, the search statements constitute a useful research tool for providing an overview of the prior art. It will be most interesting to review developments in these fields over the next 18 months.

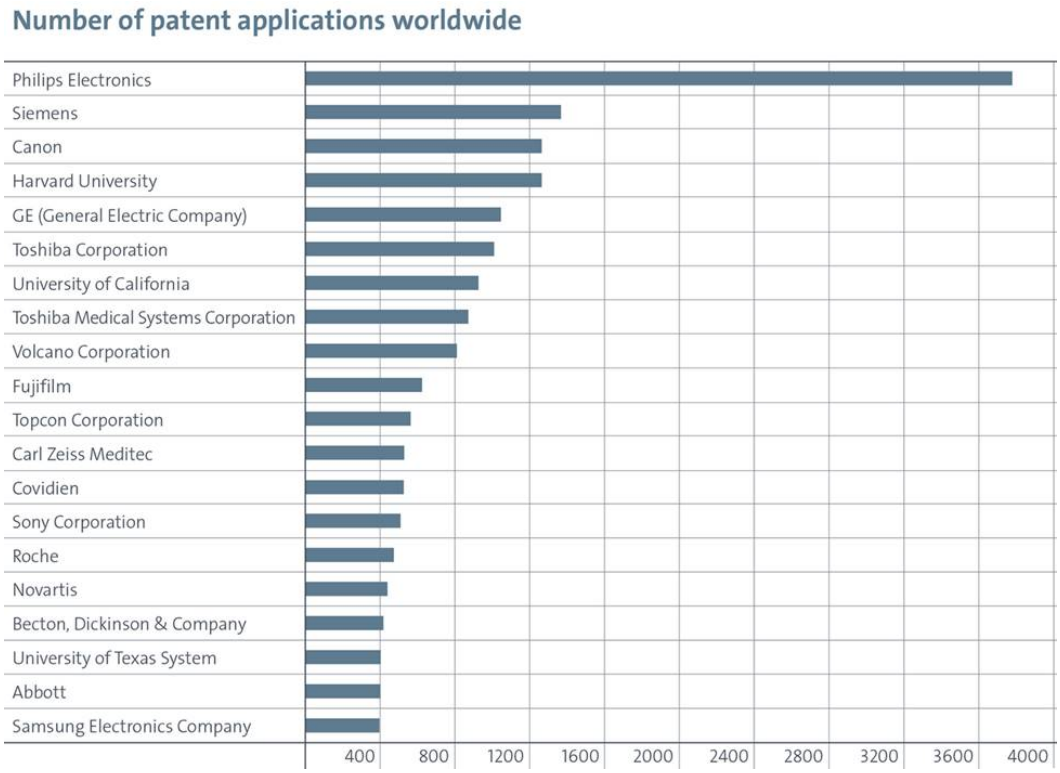
The European Patent Office has provided copies of the search statements in the Espacenet patent search system for retrieving patent documents in the following broad categories:

Vaccines
Overview of candidate therapies for COVID-19
Candidate antiviral and symptomatic therapeutics
Nucleic acids and antibodies to fight coronavirus
Diagnostics – Protein and nucleic acid assays
Diagnostics – Analytical protocols

In the first section, vaccines, the search options include for example, all vaccines against coronaviruses provides a search statement which will return an overview of vaccines specifically directed against coronaviruses or coronaviruses proteins. The limitation to vaccines is achieved by the class A61K39/215 (vaccine against coronavirus) or C12N2770/20034 (coronavirus component as a vaccine) which as of today returns 500+ results.

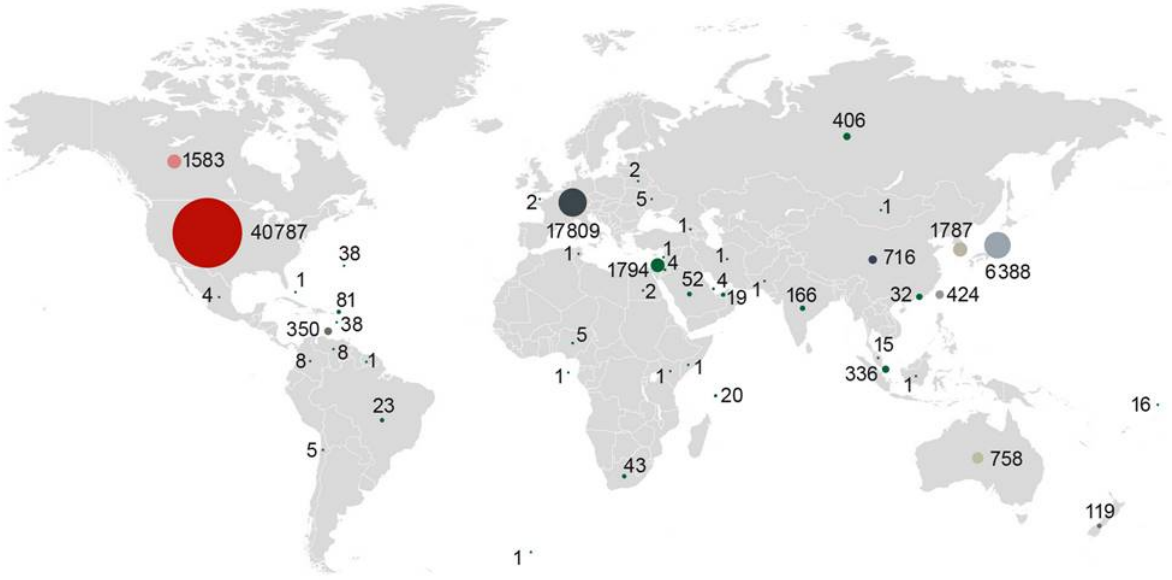
In addition, to providing search statements we note that the Fighting coronavirus resource from the European Patent Office include analysis of the current Patent Landscapes of technology in the above listed categories.

With reference to **Diagnostics – Analytical protocols** analytics are provided including Number of applications worldwide by applicant and Patent filings worldwide:



Source: https://www.epo.org/news-events/in-focus/fighting-coronavirus/diagnostics2-top-applicants-large.png

PATENT FILINGS WORLDWIDE -

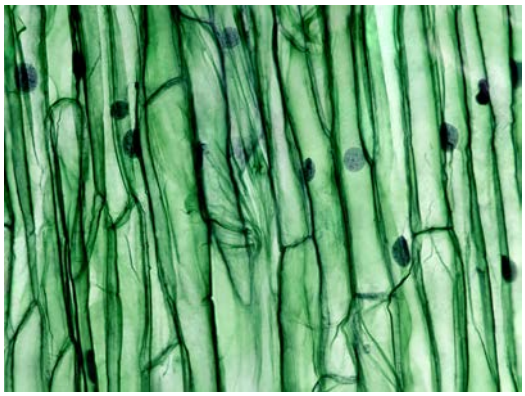


Source: https://www.epo.org/news-events/in-focus/fighting-coronavirus/diagnostics2-world-map-large.jpg

The search statements are provided based on key words and classifications that cover devices for the diagnosis of coronavirus infection or for monitoring the symptoms associated with the infection in patients. The search statements also include computer implemented technologies that support the practitioner in the diagnosis of the infection including as follows:

- Processes to obtain or perform image processing on X-ray computer tomography of the lung or the respiratory system
- Processes to recognise the presence of a virus in a patient from medical imaging (e.g. lung imaging)
- Processes to recognise the presence of a virus in a patient from microscopic images

EPO Perspective – Plant Patenting in Europe – Enlarged Board of Appeal (EBA) Decision G 3/10



NEWS IN BRIEF

On 14 May 2020, the EBA issued their decision in G3/10, ending the lengthy 'Pepper' case saga, and concluding that plants and animals exclusively obtained by essentially biological processes are **no longer patentable**.

THE BACKGROUND

The list of exceptions to patentability under Art. 53(b) EPC includes *"plant or animal varieties or essentially biological processes for the production of plants or animals"*. However, at the time of drafting the EPC did not address whether this exclusion extended to products (i.e. plants and animals) exclusively produced by essentially biological processes. This led to the 'Pepper' and 'Tomato' cases.

After some recent EC intervention and a stay placed on EPO proceedings on plant related cases, on 1 July 2017, the EPO Administrative Council (AC) changed the wording of Rule 28(2) EPC to prohibit the patenting of *'plants or animals exclusively obtained by means of an essentially biological process'*.

EPO case T1063/18 (Syngenta – the 'Pepper' case) concerned the appeal by the applicant against the decision of the examining division to refuse European patent application no. 12 756 468.0 (publication no. EP 2 753 168) for the sole reason that the claimed subject-matter falls within the exception to patentability according to Article 53(b) and new Rule 28(2) EPC. At the oral proceedings, which took place on 5 December 2018, Technical Board of Appeal 3304, in an enlarged composition consisting of three technically and two legally qualified members, held that Rule 28(2) EPC (see OJ 2017, A56) is in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in decisions G 2/12 and G 2/13. The Board referred to Article 164(2) EPC, according to which the provisions of the Convention prevail in case of conflict with the Implementing Regulations, and decided to set the decision under appeal aside and to remit the case to the examining division for further prosecution.

This case led to the EBA Referral from the President on T1063/18. As it was a referral to from the President of the EPO, the Applicant was not party to the proceedings and no oral proceedings were held. This case gathered great publicity from both sides and 41 amicus curiae briefs were filed.

The two questions asked to the EBA:
(1) the scope of the Administrative Council's power to adopt/amend Rules that give a different interpretation of the EPC compared to earlier EBA decisions; and
(2) the proper interpretation of Article 53(b) following the adoption of Rule 28(2).

In its opinion, the seven-member EBA re-phrased and combined the two questions, as it found them "too general and unspecific." Instead, it reframed the questions and asked whether the exception in Article 53(b) could

> *"have a negative effect on the allowability of product claims or product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature define an essentially biological process."*

THE DECISION

The EBA held that neither a grammatical, systematic or teleological reading of Article 53(b) was satisfactory. In adopting this **dynamic interpretation**, the Enlarged Board **abandoned its earlier interpretation of Article 53(b) EPC in decisions G 2/12 and G 2/13**.

The EBA said it cannot now ignore the decision to introduce paragraph 2 into Rule 28 when interpreting Article 53(b). The EBA endorsed the conclusions in G 2/12 but noted that Rule 28(2) meant that "*the legal and factual situation underlying decision G 2/12 has substantially changed*".

It held that, after the introduction of new **Rule 28(2) EPC**, Article 53(b) EPC was to be interpreted to exclude from patentability plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process.

In order to ensure legal certainty and to protect the legitimate interests of patent proprietors and applicants, the Enlarged Board ruled that the new interpretation of Article 53(b) EPC given in G 3/19 had **no retroactive effect** on European patents containing such claims which were granted before **1 July 2017**, or on pending European patent applications seeking protection for such claims which were filed before that date.

WHAT NEXT?

The EPO appear to now have ended this lengthy saga. However, it is interesting to note that *'the Enlarged Board found that **a particular interpretation which has been given to a legal provision can never be taken as carved in stone**, because the meaning of the provision may change or evolve over time. **This meant that decisions G 2/12 and G 2/13 did not settle the meaning of Article 53(b) EPC once and for all**.'* Only time will tell if these comments open the door to the AC make further 'clarifications' of the EPC.

Contact the author Anna Hally or your usual HMC-IP attorney for further advice.

EPO - Question Of Double Patenting To Be Considered By The Enlarged Board Of Appeal As G4/19

In the case **T 318/14**, the Board of Appeal decided at oral proceedings in February 2019 to refer questions concerning double patenting to the Enlarged Board of Appeal. The written decision in the case T 318/14 issued on 20 December 2019 and discusses the background and issues in detail. The case relates to an application filed by Société des Produits Nestlé S.A. having claims directed to a pharmaceutical composition. While a European Patent had already been granted on the basis of the priority founding application (having the priority date of May 11 2009 as filing date) the applicant filed a second application for the same invention having a filing date of May 7 2010. As the filing date and not the priority date is the relevant date for calculating the 20-year term of the patent, the later filed second application would provide an additional year of patent protection for the invention. If the Enlarged Board of Appeal considers that the issue of double patenting is a matter for National Law, this will result in a change of practice at the EPO in so far as the matter would not be considered in examination but rather by the National Patent Offices after grant and validation. In practice, double patenting may already be considered by the National Patent Offices of the EPC member states. For example, in Ireland, if it appears that a National Patent and a European Patent have been granted for the same invention, and having the same priority date and applicant, the Controller may revoke the patent granted under national provisions.

The leading Enlarged Board of Appeal decisions relating double patenting are G1/05 and G1/06 in which issues relating to double patenting in the context of the filing of a divisional application were considered. In these cases, the Enlarged Board accepted the *principle of the prohibition on double patenting.* The principle of the prohibition of double patenting is based on the idea that the applicant has no legitimate interest in proceedings that give rise to the **grant** of a second patent in respect of the same subject-matter for which he already holds a patent. There is therefore nothing objectionable in the established EPO practice that amendments to divisional applications are objected to and refused, when the same subject-matter is claimed in the amended divisional application as in a pending parent application or a granted parent patent. It was concluded that this principle could not be applied with a view to preventing the **filing** of identical applications, because that would infringe the prevailing principle that an assessment of the EPC requirements is made on the basis of the final version of the application put forward. (**G 1/05** and **G 1/06)**.

In the appeal case **T 318/14** the applicant appealed the decision to refuse European Patent Application EP10718590. The questions considered by the Broad of Appeal related to double patenting arising from internal priority NOT from the filing of a divisional application. The application at issue claims priority from an earlier European Patent Application which had already been granted and has identical scope. The examining division in refusing the application *found that claim 1 of the sole claim request on file was directed to subject-matter which was "100% identical" to the subject-matter claimed in European patent No2251021 the priority document of the present application. This was held to be contrary to the principle of the prohibition on double patenting referred to in decisions G1/05 and G1/06.* However, the appeal from the decision of the examining division to refuse the application is motivated on the basis that a longer term of protection would be available with the later filing, in view of the fact that the filing date and not the priority date was the relevant date for calculating the 20-year term of the patent.

Decisions **G1/05** and **G1/06** were made in the context of divisional applications and there has been divergence in opinion on the issues of double patenting in past decisions. In **T 1423/07** the Board of Appeal held that double patenting was **not prohibited** for European applications claiming a European priority because of the applicant's clear legitimate interest in the longer term of protection. However, in **T 2461/10**, the Board of Appeal noted that double patenting could arise in three scenarios: (i) two applications filed by the same applicant on the same day; (ii) parent and divisional application; and (iii) a European priority application and a subsequent European application claiming this priority. The Board of Appeal in that case was of the opinion from the *travaux préparatoires* to the EPC 1973 that prohibition of double patenting applied to all three scenarios. It also highlighted that **G 1/05** and **G 1/06** had referred to a **legitimate** interest. With reference to the *travaux préparatoires* the Board expressed doubt that the interest identified in **T 1423/07** could be considered legitimate. However, in that case the question was left open as the claimed subject matter was not identical with that of the granted priority application.

In the case T 318/14, the Board of Appeal has referred the following questions to the Enlarged Board of Appeal:

1. Can a European patent application be refused under Article 97(2) EPC if it claims the same subject-matter as a European patent which was granted to the same applicant and does not form part of the state of the art pursuant to Article 54(2) and (3) EPC?

2.1 If the answer to the first question is yes, what are the conditions for such a refusal, and are different conditions to be applied depending on whether the European patent application under examination was filed

a) on the same date as, or
b) as a European divisional application (Article 76(1) EPC) in respect of, or
c) claiming the priority (Article 88 EPC) in respect of a European patent application on the basis of which a European patent was granted to the same applicant?

2.2 In particular, in the last of these cases, does an applicant have a legitimate interest in the grant of a patent on the (subsequent) European patent application in view of the fact that the filing date and not the priority date is the relevant date for calculating the term of the European patent under Article 63(1) EPC?

The referred questions consider the issue of internal priority for which the applicant had argued that the there is a legitimate interest in a longer term of protection resulting from the later filing date of the application claiming priority. In addition, the questions also cover parent and divisional applications (considered in G 1/05 and G 1/06), and parallel applications filed by the same applicant on the same date.

It is noted that where a referral to the Enlarged Board of Appeal is pending and the outcome of examination or opposition proceedings depends entirely on the answer to the questions referred to the Enlarged Board of Appeal, **the proceedings may be stayed by the examining or opposition division on its own initiative or on request of a party or the parties**.

Contact the author, Catherine Hanratty or your usual HMC-IP attorney for further advice.

European Perspective – SPC Legal Update – CJEU Decision C-673/18 (Santen)

NEWS IN BRIEF

On July 9th 2020, in Santen, C-673/18, the Court of Justice of the European Union (CJEU) ruled that a Marketing Authorisation (MA) for a new therapeutic application of a medicine that was previously authorised for another application, can NOT be used as the basis for a supplementary protection

certificate (SPC) for that medicine. This decision will disappoint many companies in the pharmaceutical industry and already, we are seeing Office Actions issued from the Intellectual Property Office of Ireland (IPOI) in cases that had been stayed pending the Santen decision.

THE BACKGROUND

In Europe, SPCs are governed by the SPC EU Regulation (EC 469/2009). One of the requirements for grant of an SPC is set out in Article 3 (d) of the EU Regulation, which requires:

d) The authorisation referred to in point b) (i.e. the Marketing Authorisation covering the product) is the first authorisation to place the product on the market as a medicinal product.

For this purpose, the "Product" is interpreted as being an active agent such as a drug compound. A strict interpretation of Art 3(d) would permit an SPC to be granted only the first time a specific active ingredient was marketed, whether that was used for human medicine or in animals. This would reward the development of new active ingredients but not new uses of known active ingredients.

A relatively strict interpretation of the SPC regulation was the usual approach by the national patent offices of European Countries including the UKIPO, French patent office and German patent office until 2012 when the "Neurim" referral to the CJEU (C-130/11) changed the SPC legal landscape significantly. Thus, before the Neurim decision in 2012, the wording of Article 3(d) was interpreted as preventing any SPC for a medicinal product based on a new MA for a product previously authorised for another therapeutic use. However, in the CJEU decision in the Neurim case in 2012 (C-130/11), the CJEU, allowed an SPC based on a second medical use patent and an MA which fell within the scope of that patent, despite the existence of an earlier MA for a veterinary use of the same product.

Since the Neurim decision in 2012, there has been huge uncertainty in Europe amongst SPC practitioners over whether the decision in Neurim could be applied more widely to allow SPCs for new therapeutic uses of previously authorised products.

The Neurim decision was, of course, considered in the present case. The applicant, Santen, filed an SPC for the drug, cyclosporin, based on a second medical use patent and an MA for its use to treat keratitis. This SPC was rejected by INPI (the French patent office) on the grounds of not meeting the requirements of Article 3(d), because a prior MA had been granted for the same drug. Santen appealed the decision. The French court referred the matter to the CJEU.

Now, in the Santen decision issued on July 9th, 2020, the CJEU departed from the Neurim decision and held that the scope of the basic patent is irrelevant in determining whether the requirements of Article 3(d) are met. In fact, the Court considered that doing so would undermine the objectives of the entire SPC Regulation, and would lead to divergent decisions from national patent offices.

Thus, the CJEU decided that an MA for a new therapeutic application of a product cannot be regarded as the first MA for that product for the purposes of Article 3(d) if the product has already received an MA for a different therapeutic application.

OPINION

The European court's decision will result in an end to the possibility of obtaining SPCs at the national patent offices of European countries, for new therapeutic uses for pharmaceutical products that have

already been granted a marketing authorisation. In my opinion, this is bad news for patentees who are carrying out research into new medical uses for known pharmaceutical compounds as it means that there will be no possibility of extension of patent term in Europe for such new medical uses. Many applications for SPCs had already been "Stayed" while awaiting this decision and in my view, these applications are now likely to be refused unless the particular circumstances of the subject matter of the SPC application can be differentiated from the Santen case.

Contact the author, Marie Walsh or your usual HMC-IP attorney for further advice.

European Perspective – SPC Legal Update – CJEU Decision C-650/17 (Royalty Pharma)

NEWS IN BRIEF

In April 2020, the CJEU issued their decision in Royalty Pharma (C-650/17) which addressed the interpretation of Article 3(a) of the SPC Regulation, which requires that the product of an SPC must be "*protected by a basic patent'.*

THE BACKGROUND

This CJEU decision, was based on a referral from the German Court and related to Sitagliptin (JANUVIA®) used in treating diabetes and centred around the interpretation of Art. 3(a) of SPC Regulation which provides that the first condition of an SPC is that the product (i.e. the active ingredient or combination of active ingredients) must be "***protected by a basic patent in force***".

Previous CJEU case law (Teva C-121/17), relating to combination products, had established in 2018 that to be 'protected', a product must do more than simply infringe the patent claims, the requirement is that the combination of active ingredients must 'necessarily fall under the invention' covered by the patent and that there must be ***some degree of specificity is required by the language of the claims and of the disclosure in the specification***.

THE DECISION & COMMENTARY

In this decision, the CJEU was asked to address the scenario where an active ingredient is neither expressly mentioned in the claims nor described as an embodiment in the description. Specifically, the SPC was for sitagliptin which was encompassed in the claims as part of a functional definition (DPP-IV inhibitors for lowering blood glucose levels) but it was not specifically individualised as it was developed post-filing.

This CJEU judgment confirmed that active ingredients that are covered by a functional definition in the claims but that were nevertheless developed only *after* the filing date of the basic patent as a result of an independent inventive step, are NOT 'protected' by that basic patent.

This judgment once again restricts applicants' ability to obtain SPC protection, particularly when the basic patent represents early-stage research or platform technology. However, this is a constantly evolving aspect of SPC law so expect to see more CJEU referrals and decisions being issued as the interpretation of Article 3(a) continues to evolve.

Contact the author, Anna Hally or your usual HMC-IP attorney for further advice.

News in Brief – Irish Perspective

Irish SPC Court decision are not frequent and end 2019/start 2020, two decisions issued from the Irish High Court regarding Supplementary Protection Certificates.

Gilead v Teva - This case related to the Irish SPC for Truvada, the combination product tenofovir disoproxil and emtricitabine used in treating HIV. Teva had challenged the validity of the SPC under Article 3(a) on the grounds that the basic patent did not mention the name or structure of emtricitabine and therefore did not protect the combination product. This decision, which revoked the Irish SPC for Truvada, is in line with the decision of many other European National Courts including Belgium, Finland, France, Germany, Italy, Portugal, Spain and the United Kingdom.

Merck Sharp & Dohme (MSD) v Clonmel Healthcare - MSD had obtained an SPC for *Inegy* which expired in April 2019. On the basis the *Inegy* SPC was invalid, Clonmel Healthcare launched a generic *Inegy* product the day after the *ezetimibe* SPC expired in April 2018. This case related to an infringement action brough by MSD relating to Inegy (a combination product comprising ezetimibe and simvastatin) used for lowering cholesterol.

In this decision, the Court applied the previously approved Teva test (C-121/17) and concluded that the combination therapy was not the innovation of the underlying patent according to Article 3(a) of the SPC Regulation. Accordingly, the High Court issued a Declaration that the SPC was invalid and should be revoked. This Irish decision is in line with decision of other European National Courts.

These decisions confirm that Irish Courts are in line with other European national court SPC related decisions, at least when interpreting Article 3(a) for combination products.

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