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Happy New Year

We wish you health, happiness, joy and opportunities during the coming year.

Recent update to the EPO Guidelines for examination at the EPO of Computer Implemented Inventions (CII)

The manner in which patent applications (or oppositions to patents) are examined by examining Division (and indeed, also at the opposition Division) of the EPO is governed by the Guidelines for Examination. While the Guidelines are updated annually, the most recent update in November 2018 was particularly extensive in the area of computer implemented inventions (CII). In particular, the update introduced a section on artificial intelligence (AI) and machine learning. Provisions relating specifically to CII are largely contained in the Guidelines Section G.II.3, with sub-section G.II.3.6 explaining that to avoid being excluded from patentability under EPC Article 52, a CII must produce a "further technical effect" when run on a computer, that is, something going beyond the "normal" physical interactions between the program and the computer on which it is run.

Questions which can be used to determine if a CII produces a further technical effect include:

- Does the computer program control the functioning or operation of the computer; or
- Does the design of the computer program rely on specific technical considerations of the internal functioning of the computer?

Examples of such CII comprise technical applications which serve a specific technical purpose, for example: distributing load in a computer; cryptographic computation with masking operations to protect the computation against power analysis; or use of neural networks in heart monitoring apparatus for identifying irregular heartbeats; or specific technical implementations comprising methods designed based on technical considerations relating to the internal functioning of the

computer, for example: where the method is specifically adapted to exploit the hardware on which it is implemented; or where the method is designed based on technical considerations relating to the internal functioning of the computer.

An index is now provided within the Guidelines providing pointers to aspects of the Guidelines relating specifically to CII as well as to both positive and negative examples of patentable CII. Many of these examples within the Guidelines in turn refer to EPO Board of Appeal decisions which can provide useful templates against which to compare a given case both for eligibility and inventiveness. For example: security of game machines or networked games (**T1644/06**); resolving technical constraints, e.g. bandwidth, field-of-view (**T928/03**); and technical efficiency and effectiveness of implementation (**T1543/06**).

It is also worth noting that once a claim for an invention is found not to be excluded from patentability under EPC Article 52, it still needs to be examined for novelty and inventiveness under EPC Articles 54 & 56, typically using the EPO problem-solution approach.

As such, we strongly recommend that specific advice be sought for any particular invention you have in mind before deciding on how to approach protecting such inventions in Europe.

For more information, please contact Marie Walsh or Amber Guo at china@hmc-ip.com

Oppositions at the EPO – Case Law update

Key take-way: The recent update in the EPO Guidelines relating to Oppositions filed against granted patents at the EPO Opposition Division suggests that opponents in EPO Opposition proceedings will be restricted in the number of attacks which they can make in Oppositions by using different prior art documents as the starting point for "closest prior art" for inventive step attacks.

Parties who file an opposition against a granted European Patent at the EPO will frequently present a series of attacks on the validity of the patent, starting from different prior art documents, and arguing that the starting document is the “closest prior art”, even if each document is very different from a previously argued "closest prior art" document.

However, the updated Guidelines for Examination at the EPO which are in force since November 1st, 2018 have been amended to reflect case law that may restrict this practice in EPO Oppositions. The relevant text of the Guidelines now reads:
“In some cases, there are several equally valid starting points for the assessment of inventive step, e.g. if the skilled person has a choice of several workable solutions, i.e. solutions starting from different documents, which might lead to the invention. If a patent is to be granted, it may be necessary to apply the problem-solution approach to each of these starting points in turn, i.e. in respect of all these workable solutions.

However, applying the problem-solution approach from different starting points, e.g. from different prior-art documents, is only required if it has been convincingly shown that these documents are equally valid springboards. In particular in opposition proceedings the structure of the problem-solution approach is not that of a forum where the opponent can freely develop as many inventive step attacks as he wishes in the hope that one of said attacks has the chance of succeeding (**T 320/15**, Reasons 1.1.2).”

In the event of refusal or revocation, it is sufficient to show, on the basis of one relevant prior art document that the claimed subject-matter lacks an inventive step: there is no need to discuss which document is “closest” to the invention; the only relevant question is whether the document used is a feasible starting point for assessing inventive step…[see EPO Guidelines G-VII, 5.1]”

The updated EPO Guidelines do not prevent an opponent from using several starting points or from applying the problem-solution approach to each of those starting points. However, before being allowed to do so, the opponent should now expect to have to "convincingly show" that any other document is an "equally valid springboard" before being allowed to develop the inventive step argument for that document; patentees should find that EPO opposition divisions are more likely to allow arguments that the opponent should be limited to just one or a small number of "best" attacks and even then, that opponents will have to justify having more than one starting point for lack of inventive step attacks.

The case law behind this update to the Guidelines

The reason for the change in the Guidelines is found in Decision T320/15, in which the Board of Appeal considered if the opponent's right to be heard was infringed because only one inventive step attack had been assessed during the Oral Proceedings and the opponent was not permitted to develop several lines of attack.

Patentability of Plants at the EPO – Case Law update

In December 2018, the EPO issued a **Communication** about a new EPO Board of Appeal Decision (T1063/18) concerning the patentability of plants. This follows on from our 2017 update on the change to Rule 28(2) EPC which prohibited the patenting of plant products obtained by essentially biological processes.

The EPO Board of Appeal in T1063/18 held that the controversial 2017 change to Rule 28(2) EPC was in conflict with Article 53(b) EPC as interpreted by the Enlarged Board of Appeal in the recent Broccoli/Tomato decision (G 2/12 and G2/13).

This is a very interesting development (and turnaround) from the EPO Board of Appeal on the patentability of plant products obtained by essentially biological processes and, in practice, plant products obtained by essentially biological processes may (once again) be patentable at the EPO. However, how the EPO will now deal with this conflict is unclear. In the meantime, the application at the center of this decision (**EP12756468**), has now been sent back to the Examining Division for further examination.

Sequence Listing Requirements at the EPO – a practical update

Under Rule 30 EPC if, for example, a PCT application for European Regional Phase entry discloses unbranched sequences of four or more amino acids or unbranched sequences of ten or more nucleotides, the EPO must be provided with an electronic version (.txt) of the sequence listing according to WIPO Standard ST.25; and a statement that the sequence listing does not add subject-matter beyond that of the application as filed. The EPO's free BiSSAP® software or PatentIn® software is recommended to generate the sequence listing.

If the EPO decides that a WIPO Standard ST.25 compliant sequence listing is not available at the time of entering the European Regional Phase, the applicant will be invited to furnish a compliant sequence listing and pay a late furnishing EPO official fee within a period of two months. Additionally, the failure to provide the EPO with the required sequence listing may result in the potential refusal of the application.

Furthermore, although the EPO has confirmed that prior art sequences which have been identified by their database accession number and either the version number or database release number do not need to be included in the sequence listing, we would strongly advise including the full sequence data

in the application. This will avoid any doubt over the specific sequence information and permit the recitation of the specific nucleotide or amino acid sequences in the claims whilst complying with the strict European added subject-matter requirements.

Additionally, for any divisional patent application, at present, an applicant cannot rely on the sequence listing filed in relation to the parent application; it is very important that applicants must file a sequence listing together with the other documents that comprise the divisional application. However, this requirement may be abolished by the EPO in the future and we will keep you updated on any changes.

In order to ensure the sequence listing requirements are met on European Regional Phase entry to avoid the requirement to pay a late furnishing fee, when instructing us to enter the European Regional Phase it is preferable to provide the following information:

i) provide a sequence listing in text format (.txt) in accordance with WIPO Standard ST.25;
ii) confirm that all sequences of four or more amino acids or of ten or more nucleotides are included in the sequence listing; and
iii) confirm that the sequence listing does not add subject-matter beyond that of the application as originally filed.

Updates on Supplementary Protection Certificates

SPCs & medical devices

The European Court of Justice (CJEU) recently issued decision **Case C-527/17** provides legal certainty on what type of marketing authorisation for a medical device/drug combination meets the requirements of the SPC regulation (EU Regulation 469/2009).

In this decision, the CJEU held that SPC protection in Europe does not extend to medical device/drug combinations which are regulated as a medical device under the Medical Devices Directive. Whilst this is undoubtedly negative for medical device innovators relying on the Medical Devices Directive, this outcome is not entirely unexpected as the SPC Regulation does not explicitly refer to the Medical Devices Directive as a valid authorisation under the SPC Regulation. Thus, moving forward the regulatory regime which a medical device/drug combination undergoes will be crucial in determining eligibility for SPC protection.

SPCs & second medical indications

The Advocate General of the CJEU recently delivered his non-binding opinion in **Case C-443/17** (Abraxis Bioscience).

The Abraxis case concerns Abraxane®, a product for the treatment of certain breast, pancreatic and lung cancers consisting of paclitaxel formulated as albumin bound nanoparticles, “nab-paclitaxel”. The UKIPO rejected an SPC application made by Abraxis for a combination of active substances containing the active ingredient paclitaxel in the form of nanoparticles bound to albumin which, Abraxis call “Abraxane®”, because the active ingredient in Abraxane® is paclitaxel, and paclitaxel had been the subject of an earlier Marketing Authorisation (MA). Therefore, the MA for Abraxane did not constitute the first MA for the “product” (Article 1(b) SPC Regulation 469/2009 - “product means the active ingredient or combination of active ingredients of a medicinal product”).

Abraxis appealed the decision to the UK High Court, who referred the following question to the CJEU: *"Is Article 3(d) of the SPC Regulation to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in Article 3(b) is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?"*

The Advocate General has advised the CJEU to rule as follows:
Article 3(d) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products precludes the grant of such a certificate where the marketing authorisation relied upon in support of the application for a supplementary protection certificate under Article 3(b) of that regulation is not the first marketing authorisation for the active ingredient or combination of active ingredients at issue as a medicinal product. This is so even in a situation, such as that at issue in the main proceedings, where the marketing authorisation relied upon is the first to cover the formulation protected by the basic patent relied upon in support of the application for a supplementary protection certificate under Article 3(a) of that regulation.

The Advocate General's opinion is not binding on the CJEU and the CJEU may opt to take a different approach in its decision. If the CJEU follows the Advocate-General's advice, the decision would provide national patent offices with much clearer guidance in these specific situations. We await the CJEU's final judgment in this case.

Brexit Update- Strategies for EU Trade Marks and EU Designs

With only weeks to go to the UK's scheduled date to exit the EU, which is set to take place on 29th March 2019, it is important for EU trade mark and EU design rights owners to ensure they are up to date on developments and Hanna Moore +Curley is ready to advise and ensure that our clients have a strategy for all possible scenarios. The UK Parliament recently voted to reject the draft UK/EU Withdrawal Agreement, and this leaves open a number of possible outcomes from the political process including that Brexit could be delayed; or possibly, may not happen if there is a second Referendum; or that there may be a "no deal" Brexit (so-called "hard Brexit").

No matter what the outcome of the political process, we focus on strategies for our clients. The UK Government has indicated that it is committed to the following to protect EU IP rights in the UK after Brexit on March 29th:

For owners of existing registered EUTM and RCD rights:

The UK government has confirmed that the rights in all existing registered EU trade marks and registered EU designs will continue to be protected in the UK, and to be enforceable in the UK, by granting an equivalent registered trade mark or registered design in the UK; and that this process would involve "minimal administrative burden" for rights owners. The trade mark or design rights issued by UKIPO will be treated the same as if the rights had been applied for and registered under UK law. This means that there will be "equivalent" UK registered trade marks and designs which will exist in parallel to the registered EU trade marks and designs respectively.

These “equivalent” UK trade marks and designs registrations:

- *will be subject to payment of renewal fees to the UK Intellectual Property Office (UKIPO);*
- *can form the basis for proceedings before the UK Courts and the UKIPO’s Tribunal; and*
- *can be assigned and licensed independently from the corresponding EU rights.*

For Applicants whose EUTM or RCD is pending at the date of Brexit:

After Brexit, business, organisations and individuals having EU trade mark and EU design applications which are pending at the date of Brexit will be able to refile their applications with the UK Intellectual Property Office (UKIPO) under the same terms for a UK equivalent right, using the UK application process for registering trade marks and designs in the UK.

For Applicants seeking EU and UK Rights after the date of Brexit:

After Brexit, separate applications will be required for the UK and EU territories.

Hanna Moore + Curley has offices in the UK and in the EU; and our trade mark and design attorneys are qualified to represent our clients before both the UKIPO and EUIPO and thus we are ideally placed to represent clients both in the EU and UK, regardless of the outcome of Brexit. Our focus is on protecting our clients’ IP rights and having strategies for our client to achieve this goal.

Invitation to Meet our Team during the Year of the Pig:

We will be attending the following international events and would be honoured to meet you:

25 April 2019 – Boston, USA
Marie Walsh will be attending the **Life Sciences Patent Network Conference**

3-6 June 2019 – Philadelphia, USA
Anna Hally will be attending the **BIO International Convention**

15- 18 September – London, UK
Marie Walsh will be attending the **AIPPI World Congress**

October 2019 – Shanghai, China - 4th China Pharma IP Summit

We would love to meet you, please let us know if you are attending any of the above events. Please contact Marie Walsh or Yan Guo (Amber) at china@hmc-ip.com