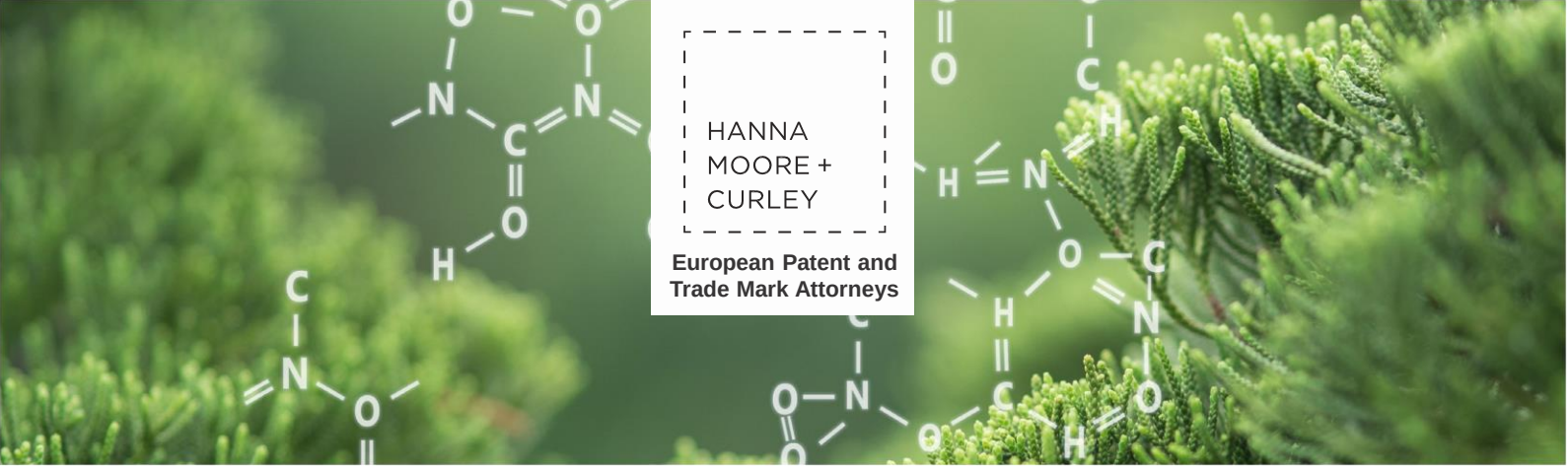

HANNA MOORE + CURLEY

European Patent and Trade Mark Attorneys

Life Sciences NEWSLETTER

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Patentability of Plants at the EPO – the saga continues

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 centre of this decision (**EP12756468**), has now been remitted to the Examining Division for further prosecution.

Oppositions and practice at the EPO – closest prior art or is it?

Key take-way: A recent change in the EPO Guidelines 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 new 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 (**T320/15**, 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 was considered and the opponent was not permitted to develop several lines of attack.

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 (AG) 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 AG 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 AG'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.

Meet the HMC Team – Upcoming International Events

25 APRIL 2019 – BOSTON – Marie Walsh will be attending the **Life Sciences Patent Network Conference**
3-6 JUNE 2019 – PHILADELPHIA – Anna Hally will be attending the **BIO International Convention**

We would love to meet up, please let us know if you are attending.

Further advice?

For any further specific questions, please contact the authors

ANNA HALLY
European Patent + Design Attorney

Chartered Patent Attorney
Irish Patent Agent

Direct: +353 1 618 1916
Email: ahally@hmc-ip.com

MARIE WALSH
European Patent + TradeMark Attorney

Chartered Patent Attorney
Irish Patent Agent

Direct: +353 1 618 1917
Email: mwalsh@hmc-ip.com

SINEAD LUCY
European Patent + TradeMark Attorney
Chartered Patent Attorney
Irish Patent Agent

Direct: +353 1 618 1911
Email: slucy@hmc-ip.com

For any further specific questions, please contact any one of our European Patent and Trade Mark Attorney team at Hanna Moore + Curley. This guidance document provides general information only and does not constitute legal advice.