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Life Sciences **NEWSLETTER**

SPRING 2018 Issue:

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- > Plant Patents – changes to EPC Rules
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Invalid Priority before the EPO – be wary!

A recent EPO Opposition Decision revoked the CRISPR European Patent **2,771,468**. According to **the Broad Institute**, this decision is unrelated to the substantive merits of the CRISPR patent and concerns the current interpretation of rules that dictate what happens when the names of inventors differ across international applications.

The Facts

PCT application PCT/ US13 / 74819, from which EP 2,771,468 derives, was filed on 12 December 2013 and claims priority from 12 US provisional applications (P1-P12), each with different inventor-applicants. EP 2,771,468 now stands in the name of 3 applicants, the Broad Institute, MIT and Harvard College.

After very detailed submissions by the patentee and the 9 opponents, the Preliminary Opinion of the EPO Opposition Board was that, based on the evidence on file, priority was not validly claimed from P1, P2, P5 and P11 as a successive chain of title from inventor to applicant was not established. At the EPO, the succession in title must have taken place before the filing of the second application, and for reasons of legal certainty, a retroactive effect is excluded. This is in contrast with the situation in the US.

The EPO was also of the opinion that the priority of at least claim 1 was validly claimed from P12 filed on 17 June 2013 (compared to a priority date of 12 December 2013 from P1). This allowed the opponents to cite various intervening documents (published before the valid priority claim of 17 June 2013) against the novelty of the claims. The hearing took place on 16-17 January 2018 and we await the publication of the full EPO written decision.

Take home advice

This outcome highlights the differences between US and EPO practice in their approach to priority entitlement and the problems patentees can encounter when a successive chain of title from inventor to applicant cannot be established. Although, the Broad Institute has now filed a Notice of Appeal and have indicated that they will continue to argue that EPO law is inconsistent with international treaties, it will be several years before a final outcome.

In the meantime, *we strongly caution applicants to err on the side of caution and ensure there is clear chain of title from each inventor to each successive applicant put in place prior to filing a PCT or European application.* This is particularly important where the initial application is a US provisional application and, as in this case, there are a number of different priority applications. Problems with priority entitlement usually only come to light during post-grant proceedings, however, getting the priority claim right at the time of filing will ensure that intervening disclosures cannot be cited. Furthermore, if getting an assignment executed before the filing of the PCT or European patent application is not possible, we would recommend ensuring the PCT or European patent application is filed in the same names as the priority application and assigned later.

Disclaimer Practice at the EPO – clarity on the horizon!

The Enlarged Board of Appeal at the EPO issued a new Decision G1/16 on 18 December 2017. This decision provides clarity to applicants on the EPO approach to allow-ability of claim amendments using both ‘disclosed’ and ‘undisclosed’ disclaimers. ‘Un- disclosed disclaimers’ are disclaimers which do not have strict support in an application as filed as required by the EPO and which aim to carve out from the scope of a claim subject-matter from an earlier disclosure which the applicant could not have known at the time of filing (e.g. intervening prior art or an accidental anticipation) or unpatentable subject matter.

The EBA has confirmed that the test for ‘undisclosed’ disclaimers is set out exclusively in previous EBA Decision G1/03. Importantly, the disclaimer must not remove more subject-matter than necessary to restore the novelty of a claim or to disclaim unpatentable subject-matter. In accordance with G1/03, the introduction of a disclaimer of this type is not permitted to provide a technical contribution to claimed invention.

Specifically, such an ‘undisclosed’ disclaimer may not be taken into account when considering inventive step or sufficiency.

The EBA also confirmed that for ‘disclosed’ disclaimers the proper test to fulfil is the ‘gold standard’ test set out in previous EBA Decision G2/10. This ‘gold standard’ test sets out that where a ‘disclosed’ disclaimer is used in a claim, the remaining subject-matter must be derivable from the application as filed in order to comply with Article 123(2) EPC.



Plant Patents – changes to EPC Rules regarding ‘essentially biological processes’

It is established case law at the EPO, that transgenic plants which are novel and inventive are eligible for patent protection, provided that they are not directed to a particular plant variety. Furthermore, biotechnological processes used to make plants are also eligible for patent protection. In recent years, the EPO Enlarged Board of Appeal (EBA) considered the patentability of plants and, in particular, essentially biological processes for their production. In 2015, it was held that the products of essentially biological processes, such as plant or seeds, could be patented. However, this ruling was controversial in Europe and there were some conflicting views around this decision.

On 1 July 2017, the European Patent Office, amended the rules in relation to the patentability of products, such as plants or seeds, obtained from conventional breeding processes:

‘(2) Under Article 53(b), European patents shall NOT be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.’ (new Rule 28(2) EPC).

This rule change by the EPO aims to harmonise the law in Europe and prohibit the patenting of products obtained from essentially biological processes, such as plants or seeds derived from conventional plant breeding processes. Further details can be found [here](#).

UKIPO / EPO Fee Changes – taking effect in April 2018

The EPO and UKIPO have announced fee changes which will enter into force on 1 April 2018 and 6 April 2018 respectively. Further details on how these changes may impact you can be found in the [News Section](#) of our website.

Meet the HMC Life Sciences Team – upcoming events

26th April 2018 – Boston

Marie Walsh will be attending the [Life Sciences Patent Network Conference](#)

4 – 7th June 2018 – Boston

Anna Hally will be attending the [BIO International Convention](#)

We would be delighted to meet with you, please contact [Marie](#) or [Anna](#) to let us know if you are attending.

Our Life Sciences Team

For any further specific questions, please contact any one of our Life Sciences team at Hanna Moore + Curley.



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