

## **Much needed clarification on allowability of amendments under section 102(1) post Raising the Bar**

The Federal Court of Australia recently overturned a decision by the Commissioner of Patents whilst clarifying the test for determining whether an amendment to a complete specification is allowable (*Commonwealth Scientific and Industrial Research Organisation v BASF Plant Science GmbH* [2020] FCA 328).

In doing so, the Federal Court concluded that the approach taken under section 102(1) of the *Patents Act 1990* (Cth) (the Act) as amended by the *Intellectual Property Laws Amendment Act 2012* (Cth) (the Raising the Bar Act) aligns with the UK approach.

### **Amendments that add matter**

Amendments that add matter to a patent application as filed are prohibited under UK law as well as under the European Patent Convention (EPC). The UK authorities adopt a somewhat strict approach when assessing whether an amendment has basis in the application as filed, only permitting amendments which are “clearly and unambiguously” derivable from the application as filed. Any amendments that are not derivable from the application as filed are found to “add matter”. The required disclosure may be express or implied, but on any view must be clearly and unambiguously so. Matter added by way of an intermediate generalisation - where a feature(s) disclosed in one context is introduced into the specification stripped of that context – is not permitted.

### **Background**

BASF Plant Science GmbH (BASF) filed AU2013273704, a divisional application of AU2007304229, on 19 December 2013 entitled “Process for the production of polyunsaturated fatty acids in transgenic organisms” (the application as filed). The application describes polynucleotide sequences isolated from *Ostreococcus lucimarinus* which encode polypeptides having fatty acid desaturase or elongase activity. Of relevance is the polypeptide sequence shown in SEQ ID NO:14 which encodes an *O. lucimarinus*  $\Delta$ 6-desaturase.

The application as filed defined the invention as follows:

*“**The invention**, the subject of the present application, is directed to the following:*

- *a CoA-dependent delta-6 desaturase having the substrate specificity of the delta-6 desaturase shown in SEQ ID NO:14 (**feature A**), and*

- ***the above** CoA-dependent delta-6 desaturase which has a preference for conversion of alpha linolenic acid compared to linoleic acid (**feature B**).*" (at page 6, line 31 to page 7, line 2, emphasis added).

This passage is referred to by the parties and the Court as the 'bridging paragraph', following the object statement, and spanning the background description and more detailed description of the invention.

The bridging paragraph was removed by amendment during prosecution and replaced with a description that defines the invention as:

- *a process for the production of a substance of general formula I that relies on cultivation of a host cell or a transgenic non-human organism comprising "an isolated polynucleotide comprising a nucleic acid sequence coding for a CoA-dependent delta-6 desaturase having at least 75% identity to a nucleotide sequence which codes for a polypeptide as shown in SEQ ID NO: 14" (**feature C**); and*
- *corresponding use of the isolated polynucleotide (or vector, host cell, or transgenic non-human organism comprising said nucleic acid sequence) for the production of an oil, lipid or fatty acid composition.*

This description corresponds to accepted process claim 1 and use claim 5 (the consistory clause).

Amendments post acceptance (the amendments) sought to insert new dependent claims 2 and 7.

The amendments sought to claim a CoA-dependent  $\Delta 6$  desaturase:

- a) *having at least 75% identity to a nucleotide sequence which codes for a polypeptide as shown in SEQ ID NO: 14 (**feature C**) (claims 1 and 5, now claim 6); and*
- b) *that preferentially converts alpha linolenic acid compared to linoleic acid (**feature B**) (new claims 2 and 7, when read with claims 1 and 6).*

The amendments also sought to introduce the following description after the consistory clause:

*"According to an embodiment of the abovementioned process and use, the CoA-dependent desaturase preferentially converts alpha-linolenic acid compared to linoleic acid."*

This appeal is from the decision of the Commissioner of Patents allowing the amendments following opposition to allowance of the amendments by the Patent Office by the Commonwealth Scientific and Industrial Research Organisation (CSIRO).

CSIRO alleged that the amendments constitute an inadmissible intermediate generalisation of the originally disclosed information and thereby introduce matter that extends beyond that disclosed in the specification as filed and are impermissible under section 102(1) of the Act as it now stands.

### **The Appeal**

CSIRO contended that (based on the bridging paragraph) the application as filed disclosed a CoA-dependent  $\Delta$ 6-desaturase having the substrate specificity of SEQ ID NO:14 (feature A) and a conversion preference for alpha linolenic acid (feature B), and that the amendments sought by BASF take feature B which is only disclosed in the context of feature A and introduce it into the specification and the claims deprived of that context.

Specifically, the amendments introduce a CoA-dependent  $\Delta$ 6-desaturase that has 75% identity to SEQ ID NO:14 (feature C), which includes a CoA-dependent  $\Delta$ 6-desaturase that does not have the substrate specificity of SEQ ID NO:14 (feature A) but has a conversion preference for alpha linolenic acid (feature B). In other words, the amendments introduce a CoA-dependent  $\Delta$ 6-desaturase having feature C combined with feature B without also requiring feature A.

BASF's primary argument in response was that there is broad disclosure in the specification as filed of a polynucleotide coding for a  $\Delta$ 6 desaturase having the amino acid sequence shown in SEQ ID NO:14 and of variants having a degree of sequence homology (feature C). This description is referred to as 'the page 8 paragraph'.

BASF further argued that the bridging paragraph has a broader construction than that contended for by CSIRO and should not be read as limiting the scope of the disclosure of the  $\Delta$ 6 desaturases that follows. BASF said that the bridging paragraph discloses that the SEQ ID NO:14 polypeptide preferentially converts alpha linolenic acid compared to linoleic acid.

### **The law - Section 102(1)**

The Commissioner must not allow an amendment that is not allowable under section 102 of the Act.

Prior to Raising the Bar, section 102(1) provided that:

*“An amendment of a complete specification is not allowable if, as a result of the amendment, the specification would claim matter not in substance disclosed in the specification as filed.”.*

This provision was given a broad construction in favour of amendment. The requirement of “in substance disclosed” was analogous to the test for internal fair basis, requiring a “real and reasonably clear disclosure” in the specification as filed of the proposed amendment.

Section 102(1) in its present form provides that:

*“An amendment of a complete specification is not allowable if, as a result of the amendment, the specification would claim or disclose matter that extends beyond that disclosed in the following documents taken together:*

- (a) the complete specification as filed;*
- (b) other prescribed documents (if any).”.*

The trial judge applied the UK legal concepts of “added matter” and “intermediate generalisations” to the construction of the present form of section 102(1) which closely corresponds with the language of section 76(2) of the Patents Act 1977 (UK), confirming that the comparison between what is disclosed, both explicitly and implicitly in the specification as filed to that of the specification as amended is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed. Further, a patent applicant cannot extract features disclosed in one context and introduce them into a specification as an amendment stripped of that context.

## **Conclusion**

The trial judge considered that “the polynucleotides described in the page 8 paragraph [of the specification as filed] are examples of polynucleotides coding for the invention described in the bridging paragraph (at [109]), the page 8 paragraph referring to polynucleotides “according to the invention”.

The trial judge also considered that the specification as filed only disclosed a  $\Delta 6$ -desaturase which has the ALA conversion preference in the context of the  $\Delta 6$ -desaturase also having “the substrate specificity” feature of the  $\Delta 6$ -desaturase shown in SEQ ID NO: 14. The trial judge reasoned that the bridging paragraph due to use of the conjunctive “and” at the end of the first bullet point and reference to “the above” at the start of the second bullet point defines the alpha linolenic acid preference (feature B) “by reference to, and combined with, the previously mentioned feature of the required substrate specificity” (feature A) (at [321]).

As such, whether the amendments added matter (by way of introducing an intermediate generalisation) depended on what is meant by “substrate specificity” of the  $\Delta 6$ -desaturase shown in SEQ ID NO: 14. That is, whether the % identity definition of the CoA-dependent  $\Delta 6$ -desaturase (feature C) equates with a CoA-dependent  $\Delta 6$ -desaturase having the substrate specificity of the  $\Delta 6$ -desaturase shown in SEQ ID NO:14.

Based on the evidence, the trial judge considered that the “substrate specificity” of the  $\Delta 6$ -desaturase shown in SEQ ID NO: 14 refers to the ability of the desaturase to recognise and bind to particular fatty acid substrates (at [262] to [264, [277]); and that polynucleotides encoding polypeptides having at least 75% identity to SEQ ID NO:14 may not have the substrate specificity of the CoA-dependent  $\Delta 6$ -desaturase shown in SEQ ID NO: 14 (at [306]).

The trial judge therefore concluded (at [324]) that:

*“BASF impermissibly seeks to strip the conversion preference (feature B) from the context in which it is disclosed in the bridging paragraph, by attempting to describe it as a property of SEQ ID NO: 14 and therefore combine feature B with the required sequence homology (feature C). But feature C is not coterminous with the required substrate specificity (feature A).”*

Accordingly, the trial judge considered that new claims 2 and 7 claim a CoA-dependent  $\Delta 6$ -desaturase that was not disclosed in the specification as filed and as such, add matter.

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