# ES – BRUDY TECHNOLOGY, S.L. v. LABORATORIOS THÈA, S.A. & ESTEVE PHARMACEUTICALS, S.A., Commercial Court no. 4 of Barcelona, 7 March 2022

This first-instance decision issued by Barcelona Commercial Court no. 4 deals with a case of direct infringement of second medical use "Swiss-type" claims. Furthermore, it address the applicability of Prosecution History Estoppel in determining the scope of patent protection.

The plaintiff, BRUDY TECHNOLOGY, S.L. (BRUDY), filed infringement proceedings against LABORATORIOS THÈA, S.A. (THÈA) and ESTEVE PHARMACEUTICALS, S.A. (ESTEVE) before the Barcelona Commercial Courts based on patent EP1962825 (EP 825), validated in Spain as ES2384701 "*Use of DHA for treating a pathology associated with cellular oxidative damage*".

In the context of the proceedings, the technical features of claim 1 were divided as follows:

Feature (a).- *Use of docosahexaenoic acid,*
- *which is specifically incorporated into at least one position of a glycerol via an ester bound,*

Feature (b).- *for manufacturing a pharmaceutical composition,*

Feature (c).- *characterized in that said docosahexaenoic acid*
- *is in a percentage by weight between 40 and 100% in relation to the total fatty acids; or*
- *is incorporated into the sn-2 position,*

Feature (d).- *for treating a pathology associated with cellular oxidative damage,*
*wherein said pathology associated with cellular oxidative damage is*
- *a neurodegenerative pathology,*
- *an ocular pathology,*
- *an ischaemic pathology,*
- *or atherosclerosis.*

The patent's independent claim 13 was identical to claim 1, the only difference being that in feature (b) the docosahexaenoic acid ("DHA") was not used *"for manufacturing a pharmaceutical composition"* but "*for manufacturing a nutraceutical*".

The plaintiff BRUDY alleged that THÈA and ESTEVE's products sold under the name HYABAK CAPS® and OFTAN MACULA OMEGA® directly infringed independent claims 1 and 13. Both claims 1 and 13 of EP 825 were "Swiss-type" second medical use patent claims, which are considered, as

stated by the Court, to be “purpose-limited process claims”, i.e., they grant protection only for the product as directly obtained from the claimed manufacturing method.

To assess the patent scope of protection of claims 1 and 13 of EP 825, the Barcelona Court referred to the EPO Board of Appeals Decision T 138/02 (see paragraph 2.5), according to which the structure of "Swiss-type" claims contains the following three essential elements:

- “the use of a compound or composition”: use of DHA as protected by feature (a) of claims 1 and 13;
- “for the manufacture of a medicament”: for manufacturing a pharmaceutical composition or a nutraceutical according to feature (b) of claims 1 and 13, respectively;
- “for a therapy”: for the purposes of being used for treating a pathology, in particular a neurodegenerative pathology, an ocular pathology, an ischaemic pathology, or atherosclerosis, as protected by feature (d) of claims 1 and 13.

The use of DHA (feature a) in the allegedly-infringing products was not disputed by THÈA and ESTEVE. However, the defendants argued that HYABAK CAPS® and OFTAN MACULA OMEGA® did not infringe the patent, as they did not meet the other technical features of the patent, and in particular features (b) and (d) of claims 1 and 13.

Firstly, as regards feature (b), THÈA and ESTEVE alleged that HYABAK CAPS® and OFTAN MACULA OMEGA® were food supplements which as such could not fall within the scope of protection of feature (b) of claims 1 and 13 protecting pharmaceutical compositions and nutraceuticals, respectively.

**Infringement of feature (b)**

- Claim 1: “***for manufacturing a pharmaceutical composition***”

The plaintiff BRUDY argued that the term "pharmaceutical composition" had to be understood in a broad sense, not limited to the form of presentation, formulation or dosage of a medicament, but referring to any substance with a pharmacological action intended to prevent, cure, or alleviate a disease or its symptoms, which would include the THÈA and ESTEVE products HYABAK CAPS® and OFTAN MACULA OMEGA®.

However, the Court rejected this argument based on the consideration that a “pharmaceutical composition” within the meaning of “Swiss-type” claim 1 had to necessarily refer to the manufacture of a medicament.

To that end, the Court cited Decision G5/83 in which the EPO Enlarged Board of Appeal held that claims on second and further medical uses of a known substance were allowable provided that the claims were "*directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application"*.

As noted by the Barcelona Court, in this Decision G5/83 and subsequent case law of the EPO Board of Appeal, the Board reasoned that by directing the claim to the manufacture of a medicament, Swiss-type claims were said to avoid the EPC prohibition on patenting medical treatment methods. The Board adopted the so-called "Swiss-type" claim format ("*Use of a compound X for the manufacture of a medicament for treating disease Y*") in this way. As a consequence, in the Court's view, food supplements (which are not medicaments) could not possibly fall within the scope of protection of feature (b) of EP 825.

Furthermore, in reaching this conclusion that food supplements did not fall within the scope of protection of feature (b), the Barcelona Court referred to the patent prosecution history of EP 825.

The Court stated that reference to the patent's prosecution file during infringement proceedings (application of the so-called doctrine of the "Prosecution History Estoppel") should be the exception and not the rule. However, in the present case, resorting to the prosecution file was justified following the guidelines given by Lord Neuberger in the *Actavis* case, Judgment of 12 July 2017 of the UK Supreme Court (paragraph 88): *"reference to the file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored; The first type of circumstance is, I hope, self-explanatory; the second would be exemplified by a case where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes".*

On the assumption that the conditions established by Lord Neuberger were met, the Barcelona Court considered it appropriate to review the prosecution history of EP 825 for the interpretation of the patent claims.

In the present case, prosecution before the EPO showed that the patentee BRUDY had attempted to patent food supplements for use in various pathologies. However, the EPO rejected these claims protecting food supplements during the examination phase. In other words, protection for food supplements was specifically rejected by the EPO during prosecution, upon BRUDY's request. This led the Court to conclude that "*as long as claim 1 refers to pharmaceutical compositions, it refers to medicines; it does not include food supplements. The plaintiff cannot extend the scope of protection of its claim to what the EPO had already denied*".

- Claim 13: ***"for manufacturing a nutraceutical"***

As regards claim 13, in order to ascertain whether food supplements could be covered by this claim protecting nutraceuticals, the Court once again turned to the patent's prosecution file.

During opposition proceedings, BRUDY argued –for the purposes of defending claim 13 against an objection to added subject-matter as filed by an opponent– that the term "nutraceutical" could be found in the patent application as originally filed. According to BRUDY, claim 13 resulted from the combination of the original claim 31 claiming the "*use of the active ingredient for manufacturing a pharmaceutical composition carried out in the food industry*" and the second medical use claim 1 (claiming the use of the active ingredient for manufacturing a pharmaceutical composition, as seen above), on which claim 31 was dependent. Furthermore, in this communication before the EPO, BRUDY specifically stated that a "nutraceutical" was "*a pharmaceutical in nutrition"*.

By following this approach, the EPO granted claim 13 on the understanding that: "*The original application referred to a substance or composition for a specified medical use. Original claim 31 referred to this substance or composition being used in the food industry and page 27, line 23 refers to "enriching food products". This is a basis for a "nutraceutical" in accordance with Article 123(2) EPC*".

In light of the above, the Barcelona Court concluded that the term "nutraceutical" within the meaning of claim 13 had to be considered a substance or composition for a medical use (that is, a medicament). In the Court's words: "*claim 13, when referring to nutraceuticals, is referring to a DHA-based enriched food product that is used in the food industry for a specific medical use, in short, a DHA-based medicine".* Therefore, food supplements could not fall within the scope of protection of claim 13.

- Food Supplements v. Medicines

Having declared that food supplements could not be protected by Swiss-type claims 1 and 13, the Court went on to analyse whether HYABAK CAPS® and OFTAN MACULA OMEGA® were food supplements (as alleged by the defendants) or medicines (as alleged by the plaintiff BRUDY).

To this end, after analyzing the relevant Spanish regulations applying to food supplements (Spanish Royal Decree 1487/2009, of 26 September on Food Supplements) and medicines (Law 29/2006, of July 26 on Guarantees And Rational Use Of Medicines And Medical Devices), the Court considered that: "*food supplements cannot be conferred the ability to prevent or treat disease, which do not have a significant impact on the body through a pharmacological, immunological or metabolic action, that is, they cannot be considered medicines. The line between medicines and food supplements is vague, therefore it is the administrations' duty to analyse product by product to determine their legal category"*. That is, it was the Court's task to determine on a case-by-case basis whether under Spanish Law the

HYABAK CAPS® and OFTAN MACULA OMEGA® products fell under the category of medicaments (Law 29/2006, of July 26) or food supplements (Royal Decree 1487/2009, of 26 September).

To that end, the Court assessed *inter alia* the following evidence as submitted by the parties:

- Information sheets.- The products were identified as "food supplements" in their technical data sheets including the ingredients, nutritional information and dosage regimen. However, as stated by the Court, these sheets did not meet the requirements as established by Spanish Law 29/2006, of July 26, for the marketing of medicines.

- Packaging.- The term "food supplement" also appeared in various places in HYABAK CAPS® and OFTAN MACULA OMEGA®'s packaging.

- Medicines Registry.- HYABAK CAPS® and OFTAN MACULA OMEGA® could not be found in the registry of authorized medicines by the Spanish Medicines and Health Products Agency (AEMPS).

- Information for health professionals.- The information provided to ophthalmologists and other health professionals did not indicate that the products were being marketed or offered as medicines or for the treatment of any pathology covered by the patent. Additionally, as stated by the Court, health professionals would know on their own how to differentiate a medicine from a food supplement.

- Information for consumers.- No indication on the use of the products for the treatment of any particular disease was included in the product information.

In view of the above, the Court concluded that HYABAK CAPS® and OFTAN MACULA OMEGA® could only qualify as food supplements but not medicines, thus falling outside the scope of protection of "Swiss-type" claims 1 and 13 of BRUDY's patent EP 825.

**Infringement of feature (d)**

Concerning feature (d) ("*for treating a pathology associated with cellular oxidative damage, wherein said pathology associated with cellular oxidative damage is a neurodegenerative pathology, an ocular pathology, an ischaemic pathology, or atherosclerosis*") the plaintiff BRUDY argued that the scope of protection of this feature should not be limited to specifically treating diseases, but also to preventing such diseases. However, the Court did not agree with BRUDY's approach.

Firstly, the Court pointed out that the patent specification of EP 825 did not contain a single reference to the prevention of diseases. On the contrary, paragraph [0082] of the Patent description implied a pre-existing disease to be treated: *"[0082] Therefore, in another embodiment as disclosed herein, said pharmaceutical composition is administered to a patient who is already receiving a treatment against a pathology associated with oxidative damage*."

Secondly, the Court recalled that, according to the EPO case law (T 454/08 and T 2251/14 were cited), second medical use "Swiss-type" claims were allowable precisely because the use of a known substance is aimed at treating a specific pathology, such that up until that moment, the ability of that substance for treating that specific pathology was not known. The Court found that the treatment of a pathology was thus the very nature of "Swiss-type" claims.

Finally, the Court turned again to the patent's prosecution file. The EPO Opposition Division, in its decision confirming the granting of the patent, stated that as regards the novelty of the invention: "*D1 teaches the use of a 1050 TG for "supplementing ocular health". The Opposition Division believes that the treatment of "ocular pathologies" is novel over a disclosure of "supplement for ocular health*". *"Supplementing" health implies that the user is already healthy and not suffering from a pathology"*. That is, according to the EPO, the treatment of an existing disease –and not "supplementing" a person's health, one free from pathology– was one of the reasons for justifying the granting of the patent.

For all these reasons, the Court concluded that the scope of protection of claims 1 and 13 could not be broadened as claimed by BRUDY to preventing a disease or supplementing a health status, but only to treating an existing disease. According to the Court, BRUDY's patent could only protect the use of DHA for treating (but not preventing) "*a neurodegenerative pathology, an ocular pathology, an ischaemic pathology, or atherosclerosis*", those pathologies being "*associated with cellular oxidative damage*". Since HYABAK CAPS® and OFTAN MACULA OMEGA® were food supplements and not medicines, they could not possibly be used for treating any of those diseases, thus falling outside the scope of protection of the patent's feature (d).

## Conclusion

This decision is particularly relevant for two main reasons: first, it analyses a case of infringement of "Swiss-type" claims, which are usually rare in Spain. As stated by the Barcelona Court itself in paragraph 7.5 of the decision: "*In Spain, unlike other fellow countries, there is little case-law dealing with this type of claim*…".

Secondly, it applies the doctrine of the prosecution history estoppel for the purposes of ascertaining the patent scope of protection which led, in the present decision, to a more limited scope of protection than that claimed by the plaintiff.

This decision may therefore constitute a warning call for patentees to look more closely at the prosecution history before bringing infringement proceedings before Spanish Courts, in order to analyse whether a limited interpretation of patent claims may be applied because of “estoppels” resulting from the patent’s prosecution file.

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