



Valeria Croce

Partner, Italian and European Patent Attorney, Professional Representative in Community Design matters before the EUIPO.

Valeria has extensive experience drafting and prosecuting European, International and Italian patent applications relating to chemical, pharmaceutical and biotechnological inventions. She has been involved in opposition procedures before the European Patent Office and has acquired substantial experience filing and prosecuting Italian and Community Design applications.

[read more on
www.jacobacci.com](http://www.jacobacci.com)

20 December 2017 – *IAM Weekly E-mail*

File wrapper estoppel trumps infringement under doctrine of equivalents

The Court of Milan recently held that the text of a European patent application and the applicant's actions during the prosecution history of the application which sought to limit a claim to a compound's specific salt form precluded a finding of infringement – including under the doctrine of equivalents – by other salt forms.

Facts

Fresenius Kabi Oncology Plc and Fresenius Kabi Italia Srl applied for interlocutory measures before the Court of Milan and requested a declaration that their medicinal product pemetrexed Fresenius Kabi (PFK), a diacid pemetrexed with ditromethamine, did not infringe the Italian designation of EU Patent 1313508, which had been granted to Eli Lilly and Company.

Claim 1 of the patent was granted (in the Swiss-type format allowed at that time) for the use of pemetrexed disodium in the manufacture of a medicament in a combination therapy for inhibiting tumour growth in mammals. The medicament was sold by Eli Lilly as pemetrexed Alimta (PA).

Both PFK and PA were sold in powder form and had to be reconstituted in a solution in order to prepare an injection formulation for use. However, the instructions for use of PFK stated that a glucose solution should be used in such preparation. Use of glucose prevents the formation of sodium salts.

Background

Fresenius argued that the wording of Claim 1 was limited during examination to the disodium salt form, noting that the patent was completely silent with respect to diacid pemetrexed with ditromethamine, which was used in its PFK product.

Eli Lilly maintained that the problem solved by its invention was the reduction of the toxicity of the active principle pemetrexed. Eli Lilly conceded that Claim 1 was limited to disodium salt, but asserted that a person skilled in the art would have understood that other salts could be used as well. Further, Eli Lilly argued that the limitation of the claim to disodium salt was necessary to meet certain European Patent Convention patent requirements relating to:

- description sufficiency;
- clarity; and
- added subject-matter prohibition.

Eli Lilly also asserted that:

- PFK and PA were equivalent because they performed the same activity and had the same low toxicity;
- a skilled person could have easily substituted the disodium salt for the diacid pemetrexed form with ditromethamine; and
- Fresenius's product infringed the patent indirectly because it exploited an essential element of Eli Lilly's invention – specifically the pemetrexed anions, which were formed when the powder solubilises and which were responsible for the product's therapeutic effects.

Fresenius's primary position in the action was based on an argument consistent with the theory of file history (or prosecution history) estoppel used primarily in the United States. Fresenius highlighted that during prosecution Eli Lilly had limited the scope of protection of the patent specifically to disodium salt and was therefore prevented from claiming infringement beyond that limitation, even under the doctrine of equivalents.

Eli Lilly asked the court to evaluate infringement by equivalents which, under Article 52(3)bis of the Industrial Property Code, requires that "to determine the scope of the protection granted by the patent, every element that is equivalent to an element indicated in the claims must be considered".

Courts in Italy have used a couple of approaches in applying Article 52(3)bis. Some courts have applied the aptly named 'triple test', which evaluates the function, way and result when comparing a claim element to a feature of an accused product. However, in 2004 the Court of Cassation used the so-called German 'obviousness approach'. Under the obviousness approach, infringement under the doctrine of equivalents can be found where it would be obvious to a person skilled in the art that the same result as that achieved by means of a claim element can be achieved by means of an equivalent element. A 2013 Court of Cassation decision expressed this somewhat differently, explaining that infringement can exist when the inventive core of the protected idea is reproduced.

Court of Milan Decision

Because of the complexity of the case, the Court of Milan requested the assistance of a neutral technical expert.

Literal infringement

The court held that the wording of the claims clearly stated that the patent was limited exclusively to the disodium salt of pemetrexed. This was further supported by a specific passage of the patent specification, which referred to the disodium salt of pemetrexed as the anti-folate drug of the invention sold by Eli Lilly as Alimta. Since PFK did not contain disodium salt, the court concluded that there could be no literal infringement.

Indirect infringement

Indirect infringement was also excluded. The court determined that:

- the claimed active principle was not the pemetrexed anion (as argued by Eli Lilly), but the disodium salt form; and
- the preparation of PFK called for a glucose solution that prevents the formation of sodium salts.

Further, the court found no evidence to suggest that a person skilled in the art would depart from the manufacturer's instructions to use a glucose solution for reconstitution.

Infringement under doctrine of equivalents

During the technical investigation, the court-appointed expert examined the merits of the claim of infringement by equivalents. Applying the obviousness approach, the expert concluded that PFK's diacid pemetrexed in association with tromethamine could not be considered an obvious alternative to the disodium salt of pemetrexed in the PA product because of (among other things) clear statements in the patent description against using other salt forms of pemetrexed. Accordingly, the expert concluded that there had been no infringement by equivalents.

However, the court found that it was unnecessary to enter into the merits of the issue, as the patent file history excluded infringement entirely. The court concluded that the applicant was bound by the description statements and the Claim 1 amendments during prosecution, which unambiguously referred only to the disodium salt, regardless of the reasons behind those statements and amendments.

The court noted that in order to protect the legitimate expectations of third parties, the applicant should not be permitted to widen the scope of protection to include other compounds that it had voluntarily excluded from the claims.

Comment

This decision shows that a theory consistent with file wrapper estoppel can have a place in Italian patent litigation. Unambiguous statements in a patent application which specifically characterise an invention, along with arguments and amendments during patent prosecution, can be considered important factors in limiting the reach of direct infringement – and specifically the doctrine of equivalents – in Italy.

For further information please contact:

Valeria Croce
Jacobacci & Partners
www.jacobacci.com
Email: vcroce@jacobacci.com
Tel: +39 21 772 271