

Court of justice decides on what constitutes a first marketing authorisation for plant protection products

Background

Bayer Cropscience AG sells the herbicide Husar, containing iodosulfuron. A Supplementary Protection Certificate (SPC) was granted for iodosulfuron. The SPC was based on a provisional marketing authorization.

Lovells sought annulment of the SPC at the German Federal Patent Court. Lovells argued that only a definitive marketing authorization could be used as the first marketing authorization in Europe on which to base an SPC.

The German Federal Patent Court referred the case to the Court of Justice, the highest Court in Europe.

The Advocate General to the court provided his opinion, finding that that a provisional marketing authorization is not the first marketing authorization in Europe for grant of an SPC.

The decision

The Court of Justice disagreed with its Advocate General. The Court looked at the overall scheme and objectives of the system of which the SPC regulation is part. It concluded that the system is to ensure adequate protection for innovation in plant protection, while guaranteeing the proper functioning of the internal market. The Court found that this supported its interpretation that a provisional marketing authorization can constitute the first marketing authorization in Europe.

Conclusion

This is only the second judgment of the Court of Justice on SPCs for plant protection products.

This judgment will be welcome news for SPC holders in Europe, most of which have an SPC based on provisional marketing. If the judgment had gone the other way, this would have led to serious economic consequences for the plant protection industry.

The wider relevance of this judgment to SPCs for medicinal products is limited, because the regulation on SPCs for those products is different. This is largely due to considerable differences between the regulatory systems for medicinal products and plant protection products. The medicinal products regulatory system has no equivalent to the provisional marketing authorization for a plant protection product.