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Generics (UK) Limited v Synaptech Inc.

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In October 2009, we reported the UK Court of Appeal's referral to the European Court of Justice (as it was then known) regarding the meaning of the term '*the first authorisation to place the product on the market*' referred to in Article 13(1) of Council Regulation (EEC) 1768/92 (the "Regulation") concerning the creation of a supplementary protection certificate ('SPC') for medicinal products. In particular, the referral concerned the question of whether the first authorisation has to be issued in accordance with Council Directive 65/65/EEC (which has now been replaced by Directive 2001/83/EC (as amended)).

The reference was made during proceedings between Generics (UK) Limited ('Generics') and Synaptech Inc. ('Synaptech') concerning the SPC granted for the alkaloid 'galantamine or acid addition salts thereof'.

Galantamine has been known since the 1950s and used for the treatment of certain neuromuscular conditions. In 1963 a marketing authorisation was issued to Waldheim in Austria for galantamine to be used for the treatment of the viral infectious disease poliomyelitis under the trade mark Nivalin®. The drug had already been on the market in Germany in the 1960s, also under the Nivalin® mark. Under German legislation, galantamine could remain on the German market as a product "deemed to be authorised".

In January 1987, Synaptech filed a patent application at the EPO, claiming the use of galantamine for the treatment of Alzheimer's disease. In 1999, Janssen-Cilag (which had taken over distribution of Nivalin® in Austria) filed an application in Sweden for a marketing authorisation for the use of galantamine to treat Alzheimer's disease under the trade name Reminyl®. In accordance with Directive 65/65, Reminyl® was authorised in March 2000.

The German authorisation and the Austrian marketing authorisation issued in 1963 from which Nivalin® had benefited were withdrawn in the second half of 2000 and in 2001 respectively.

In December 2000, Synaptech applied to the UK Patent Office (now known as the UKIPO) for an SPC for galantamine, listing the Swedish marketing authorisation as the first authorisation to place the product on the market as a medicinal product in the Community. Based on that authorisation, the UK Patent Office granted Synaptech an SPC with a maximum term of five years, expiring in January 2012. Generics brought a claim in the UK High Court, arguing that the SPC's date of expiry had not been calculated correctly by the UK Patent Office(**FN*), which had relied on the Swedish marketing authorisation. The claim was rejected and Generics brought an appeal before the Court of Appeal. The Court of Appeal had doubts as to the interpretation of 'first authorisation

to place the product on the market in the Community', referred to in Article 13(1) of the Regulation, so it decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

(1) For the purposes of Article 13(1) of the Regulation, is the "first authorisation to place the product on the market in the Community" the first authorisation to place the product on the market in the Community which was issued in accordance with [Directive 65/65] (now replaced with Directive 2001/83/EC) or will any authorisation that enables the product to be placed on the market in the Community or [EEA] suffice?

(2) If, for the purposes of Article 13(1) of the Regulation, an "authorisation to place the product on the market in the Community" must have been issued in accordance with [Directive 65/65] (now replaced with Directive 2001/83/EC), is an authorisation that was granted in 1963 in Austria in accordance with the national legislation in force at that time (which did not comply with the requirements of [Directive 65/65]) and that was never amended to comply with [that directive] and was ultimately withdrawn in 2001, to be treated as an authorisation granted in accordance with [that directive] for that purpose?'

In other words, which was the first authorisation to place galantamine on the market in the Community in order to determine the duration of the SPC? Of course, the answer to those two questions would be relevant only if galantamine was within the scope of the Regulation (as defined by Article 2) and could, thus, be the subject of an SPC.

In its reasoning, the Court of Justice referred to its judgment in Case C 195/09 *Synthon*, i.e. that Article 2 of the Regulation must be interpreted as meaning that a product which had been placed on the market in the Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Directive 65/65, and, in particular, without undergoing safety and efficacy testing, was not within the scope of the Regulation and could not therefore be the subject of an SPC.

In the present case, it followed that galantamine was outside the scope of the Regulation, and therefore it could not be the subject of an SPC. Thus, Article 13 of the Regulation referred to by the UK court, did not apply and so there was no need to interpret those provisions.

Conclusion

The Court of Justice has held that a product which has been placed on the market in the Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Directive 65/65, and, in particular, without undergoing safety and efficacy testing, is not within the scope of the Regulation (as defined in Article), and may not be the subject of an SPC.

**FN Synaptech's SPC No. SPC/GB00/033 expired on 15 January 2012. Generics argued that the SPC ought to have expired (at the latest) on 31 December 2008 (calculated from the date that Austria joined the EEA on 1 January 1994).*

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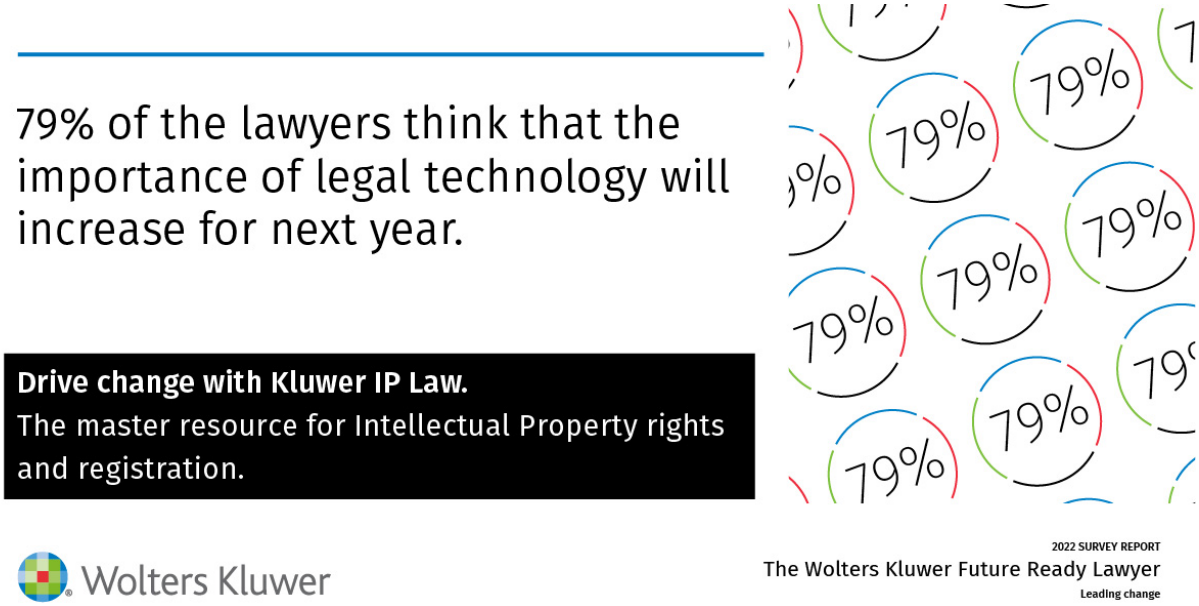

This entry was posted on Tuesday, September 6th, 2011 at 4:48 pm and is filed under European Union, SPC, United Kingdom
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